



**PART ONE**

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## ACRONYMS AND ABBREVIATIONS

ADNS	Animal Disease Notification System
AFSSA	Agence Française de Sécurité Sanitaire des Aliments
AHS	African Horse Sickness
AI	Avian Influenza
ASF	African Swine Fever
BT	Bluetongue
CA	Competent Authority
CAHP	Community Animal Health Policy
CRC	Community Reference Centre
CRL	Community Reference Laboratory
CSF	Classical Swine Fever
CVO	Chief Veterinary Officer
DG SANCO	Directorate General Health and Consumers
DIVA	Differentiating infected from vaccinated animals
EC	European Commission
EHN	Epizootic Hematopoietic Necrosis
EMVD	European Veterinary Diagnostics Manufacturers
EU	European Union
EUS	Epizootic Ulcerative Syndrome
EQA	External Quality Assessment (also known as ring trial or proficiency test)
FVO	Food and Veterinary Office
GMP	Good Manufacturing Practice
HPAI	Highly Pathogenic Avian Influenza
IAH	Institute for Animal Health
IATA	International Air Transport Association
IFAH	International Federation for Animal Health
IHN	Infectious Hematopoietic Necrosis
INIA	Instituto Nacional de Investigación y Tecnología Agraria y Alimentaria
ISA	Infectious Salmon Anaemia
ISSG	Inter-Service Steering Group
LPAI	Low pathogenic avian influenza
MS	Member State
ND	Newcastle Disease
NVI	National Veterinary Institute
NRL	National Reference Laboratories
OIE	World Organisation for Animal Health
PCR	Polymerase chain reaction
PT	Proficiency Test (or ring trial, or EQA)
SOP	Standard Operating Procedures
SVD	Swine Vesicular Disease
SWOT	Strengths, Weaknesses, Opportunities, Threats
TSE	Transmissible Spongiform Encephalopathy
VHS	Viral Haemorrhagic Septicaemia
VLA	Veterinary Laboratories Agency
WP	Working Programme

## **KEY MESSAGES**

1. The 12 Community Reference Laboratories (CRLs) covered by this evaluation have, over the last 15 years, significantly contributed to harmonised diagnosis and control of the relevant animal diseases in the European Union.
2. The duties and tasks performed by the 12 CRLs, as defined in the EU legal basis, are assessed to have been met and are considered good value for money.
3. Over the past 15 years, CRLs have increased in number while the EU has expanded. During this period CRLs have assembled a growing volume of valuable archives, including documents, training materials and manuals, and collections of reference strains of isolates, sera and reagents. In addition there is a large body of data on the results of proficiency tests and a series of reports of annual meetings. This material should be stored in such a way that full and practical access is guaranteed for the future.
4. The working programmes of the last 15 years were mainly qualitative descriptions of activities to be undertaken. The CRLs have interpreted these according to their individual capabilities and responsibilities, resulting in differences in the activities performed by each CRL. As an example, some CRLs provide weeks of systematic training every year, others only provide training on demand. A more precise and quantitative description of activities to be undertaken by CRLs would improve the accountability and comparability between CRLs.
5. The complexity of relations in the expanding network between CRLs, National Reference Laboratories (NRLs), the European Commission and the Competent Authorities (CAs) in EU Member States requires high quality professional management and coordination. It is recommended that a CRL Coordination Centre at the Commission is set up.
6. The Commission CRL Coordination Centre should be responsible for developing guidelines on best practices and training, managing stakeholder relations and relations with industry, providing guidelines for publication rights and commercial rights for submission of strains, harmonising training, reporting and communication of CRLs, developing and maintaining a dedicated website with open and secured sections, and organising regular meetings of CRLs to improve the performance of the network as a whole.
7. The majority of CRLs are virtual laboratories embedded in larger institutional organisations. To avoid conflict of interest or distortion of competition in the development and commercialisation of diagnostics or vaccines, it is recommended that CRLs are staffed with personnel who only work on public tasks in a public laboratory. Any commercial developments or activities should be undertaken in a separate commercial laboratory.
8. For training activities for Third Countries, financial input from the DG SANCO Better Training for Safer Food (BTSF) programme or from other DGs such as the Technical Assistance Information Exchange Instrument (TAIEX) from the Directorate General for Enlargement should be investigated and communicated to the CRLs to expand financial resources.
9. Options to combine certain CRLs are recommended. In particular, the following CRLs could be combined: the CRLs for Avian Influenza (AI) and Newcastle Disease (ND); the CRLs for Foot-and-Mouth Disease (FMD) and Swine Vesicular Disease (SVD); the CRLs for Rabies (serology) and the CRL for Rabies (diagnosis).



10. Options to designate new CRLs are recommended. In particular, the following CRLs could be considered: a CRL for West Nile Virus (one sub-option to examine further would be integrating this within the existing CRL for horse diseases) and a CRL for Bee and Bumble bee diseases. Also, a Community Reference Centre (CRC) (the designation CRL is not appropriate for organisations that are not a laboratory) for harmonisation of Identification & Registration of animals could be considered.

## EXECUTIVE SUMMARY

### Background and scope of the evaluation

The new Animal Health Strategy for the European Union for 2007-2013<sup>1</sup> identified the need for a comprehensive evaluation of Community Reference Laboratories (CRLs) in the field of animal health and live animals<sup>2</sup>. The aim of the evaluation has been to assess the current performance of the CRLs and investigate options for the future operation of the system, taking into account the changing circumstances and future needs of the Community Animal Health Policy (CAHP).

The new strategy recognises that there have been fundamental changes in the field of animal health control and in the general circumstances in which animal health policy is applied since the CAHP was first developed several decades ago. EU enlargement and increased international trade have resulted in greater animal health risks. This requires more focus on prevention and early detection. There has been progress in diagnostic techniques and a more flexible EU approach towards vaccination, along with the development of “DIVA” (differentiating infected from vaccinated animals) vaccines. Thus, there is a need to re-evaluate priorities based on risk assessment and scientific advice. Also, emerging and re-emerging diseases may result in the need to expand the network of CRLs. This will require even more efficient control and management of the network’s operations and budget.

The evaluation covered 12 CRLs within the animal health and zootechnics sector<sup>3</sup>: avian influenza, Newcastle disease, bluetongue, classical swine fever, African swine fever, swine vesicular disease, African horse sickness, rabies, fish diseases, mollusc diseases, zootechnics and transmissible spongiform encephalopathies (TSEs).

The evaluation had three main tasks:

- Evaluation of the individual CRLs: this covered the fulfilment of the duties and tasks of each CRL as established in the legislation and in the work programmes and included an analysis of the resources (human, financial facilities, etc) for carrying out these tasks.
- Evaluation of the current EU system of CRLs: this covered the concept and operation of the structure of CRLs as a whole.
- Options for improvement: this involved the identification of possible problems, challenges and areas for improvement, and the development of options for the future to improve the current system in case it is considered necessary.

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<sup>1</sup> New Animal Health Strategy for the European Union (2007-2013) where “Prevention is better than cure”, COM (2007) 539 Final

<sup>2</sup> VetEffecT Consulting and Recruiting in association with Agra CEAS Consulting (the Evaluator) was contracted by the European Commission to carry out the ‘Evaluation of Community Reference Laboratories in the field of animal health and live animals’.

<sup>3</sup> The CRLs for foot and mouth disease and brucellosis were appointed more recently and were therefore not included in the evaluation.

## Evaluation of the performance of individual CRLs

A rating system was used to assess whether each of the 12 CRLs meets the requirements for its role and duties as laid down by the legal base. Evaluation visits were made to each CRL and 16 aspects of performance were rated under four main functions. The evaluation visits were corroborated by questionnaire surveys of Member State Chief Veterinary Officers (CVOs) and of National Reference Laboratories (NRLs).

An overview of the ratings for the main functions of the CRLs is presented in the table below:

### Overview of individual CRL evaluations

CRL	Overall Rating	Rating for Main Functions		
	Fulfilment of duties and tasks Networking	Diagnosis & assistance Quality Issues		Training
AI	+++	+++	+++	+++
ND	++	++	++	++
BT	+++	+++	+++	++
AHS	+	++	+	++
SVD	++	++	++	++
ASF	++	++	+++	++
Rabies (serology)	++	+++	++	++
Mollusc diseases	++	++	+++	++
Zootechnics	++	++	++	++
Fish diseases	++	++	++	++
CSF	+++	+++	+++	++
TSEs	+++	++	++	+++

#### Rating codes:

Outstanding (provides excellence or added value)

Satisfactory (meets EU requirements)

Underperforming (some shortcomings identified that require improvement)

The evaluation identified certain issues to be addressed at some individual CRLs. However, there was no regular pattern of failings across the CRLs and no evidence of systemic failure. All CRLs were largely found to be fulfilling their contractual obligations.

Some reservations were identified in the case of the CRL for African horse sickness (AHS), for which the CVO survey confirmed the expert analysis that the CRL had been underperforming for a number of years. However, this was not due to professional inadequacy or insufficient technical skills, which were found to be on a par with the staff of the other CRLs. The evaluators concluded that these problems have now been largely overcome and there is reason to expect improved performance of the CRL for AHS in the near future. It is therefore important in this case to monitor closely performance in the next 1-2 years and for the CRL to demonstrate that this has been improved.

The CRL for Newcastle disease was awarded lower ratings than the CRL for avian influenza, which is in the same institute and utilises most of the same staff. The reason for the difference in performance may be that, as a disease, AI has become a higher priority in recent years and has drawn attention away from Newcastle disease to some extent.

The results of the evaluation indicate that harmonised diagnosis has been significantly improved for most diseases under this evaluation since the CRLs became operational. The positive findings of the expert reports from the CRL field missions are supported by the results of the CVO and the NRL surveys.

The CRL for Rabies (serology) has a particular position in the CRL network, as it is not involved in responses to diseases outbreaks. Its role is to appraise laboratories in Member States and third countries willing to perform the serological titration on domestic carnivores vaccinated against rabies.

The CRL for Zootechnics (Interbull) is a special case as it has different objectives to the animal health and public health CRLs. The CRL has been successful in its objective to harmonise testing methods and assessment of breeding quality of bovine animals. This harmonisation has facilitated the trade in semen at EU and global levels. Interbull now faces a major challenge to keep pace with developments in genomics. There is a risk that its role may be taken over by commercial multinational companies, but it is considered essential that a non-commercial body remains to provide unbiased breeding evaluations.

### **Evaluation of the current system of CRLs**

The evaluation shows that the CRLs in general have made a significant contribution to improving animal health and food safety and the implementation of EU requirements.

In most cases diagnostic activity is the main priority for CRLs and utilises the most resources. All CRLs have supplied diagnostic tools to other laboratories, but to different extents depending on the demand and availability of the diagnostic tools. Producing reagents is costly and time consuming and guidelines on what should be supplied free of charge would help to harmonise this activity amongst CRLs. Furthermore, harmonised guidelines on shipment of diagnostic tools and biosecurity requirements for receiving laboratories would also be useful.

CRLs provide assistance for diagnosis in case of an outbreak to other laboratories on demand. Due in part to this assistance, many NRLs have greatly improved their skills and this has reduced the demand for the CRLs to assist with diagnosis. Assistance with diagnosis is now mostly confined to new EU MS, and CRLs are mainly focused on confirmation of diagnosis.

Most CRLs benefit from being embedded in centres of excellence and are thus able to add value by incorporating scientific advances in their activities. This added value is highlighted in the ratings in the individual CRL assessments.

There is considerable variety in the scope and volume of training provided by individual CRLs. Each CRL has developed its own training programmes and there does not appear to be common training practices. Exchange of information between CRLs for the organisation and provision of training and training materials, coordinated by the Commission, would help to harmonise this activity among CRLs. The drafting of annual work plans tends to be a routine procedure without much variation from year to year, and this has resulted in gaps in the pro-active identification of real needs (e.g. for training).

Eight of the laboratories hosting the CRLs are accredited and have at least satisfactory quality standards in place, although in some cases not all the tests are accredited. The other four are working towards accreditation and/or improvement of quality standards. Increasingly, CRLs are gaining accreditation for the execution of proficiency testing programmes, which is considered an extra quality criterion and performance indicator.

All CRLs have suitably qualified staff. However there is a need to ensure appropriate succession procedures are in place to maintain a high level of expertise.

Most CRLs have developed informal networks for cooperation with NRLs and the scientific community, and these links have strengthened over time. However full transparency and information sharing has not been reached in all cases and some scientific and academic rivalries continue. Whilst the collegial collaboration generally fosters the free exchange of information, it can make it more difficult to address areas of underperformance of NRLs. Increasing authority to CRLs is not favoured, because this would jeopardize the collegial relationship. In this situation, the Commission could assist the CRL in addressing shortcomings of NRLs to the Competent Authority of the Member State concerned. Informal networking links may be less effective with the increasing number of Member States and may be augmented by a centrally coordinated network of NRLs and national contacts.

There is a lack of communication between CRLs; the evaluation has found that they do not yet operate as a system and fail to benefit from inter-CRL collaboration and sharing of best practices.

The appropriateness, effectiveness and efficiency of the EU financial rules and procedures were examined with the conclusion that the rules are closely adhered to and generally accepted. Nonetheless, three issues in particular were highlighted where further improvements could be made:

- The need for further flexibility, over and above that currently allowed by Regulation 1754/2006, particularly to deal with unforeseen or emergency situations;
- The need for some simplification, in terms in particular of the necessity and added value of the multiannual framework agreements.
- The need to train CRL staff on administrative and financial procedures to be followed and on the availability of EU funds from other sources.

According to data submitted by the CRLs from their own accounts, the actual contribution of Community funding to CRL operational expenditure can range from 24% (African swine fever) to 90% (Fish diseases)<sup>4</sup>. In most cases national governments contribute the balance, with the exception for the CRL for Zootechnics, where member fees are the greatest source of income. In most cases the CRLs receive additional research funding from DG Research. The principle of co-financing is

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<sup>4</sup> These percentages should be treated with caution when comparing between CRLs as the calculation method for estimating CRL operational expenditure can differ between CRLs.

not questioned as it underlies the legal basis of the Community assistance. However, a heavy dependence on national funding could raise concerns of sustainability and has been identified as a potential threat for the future operation of the CRLs.

## Options for the future

Changes at both global and EU level including increased global trade, climate change and technological advances, are likely to bring new challenges to the EU and the system of CRLs. Improvement of the current system can be considered to address these challenges.

Deregulation is not considered as the current system of designating a CRL within a national institute is cost-effective and provides essential support to Member States, which is crucial to the adoption of timely and effective control measures.

A number of options for the future have been developed to address the shortcomings and future challenges. Different combinations of options would be possible. The options are:

### 1. Maintain and improve the current CRLs

- Modify the scope of existing CRLs, including modifying tasks and duties, outsourcing, and exploring synergies with other EU financial assistance;
- Reinforce the network of CRLs to provide coordination and make it work more effectively as a whole;
- Improve EU financial rules and procedures including harmonised procedures, multiannual framework agreements, use of performance indicators, improvements in financial monitoring and efficiency.

### 2. Modify the individual CRLs and the system of CRLs

- Designate new CRLs, in particular a:
  - o CRL for West Nile Virus (one possibility being to integrate this within the existing CRL for horse diseases);
  - o CRL for Bee and Bumble bee diseases;
  - o Community Reference Centre (CRC) for harmonisation of identification & registration of animals could be considered (the designation CRL is not appropriate for organisations that are not a laboratory).

A list of potential indicators is proposed and discussed for the selection of future CRLs.

- Combine certain CRLs, in particular:
  - o Avian Influenza (AI) and Newcastle disease (ND);
  - o Foot and mouth disease (FMD) and Swine vesicular disease (SVD);
  - o Rabies (serology) and Rabies (diagnosis).

## MAIN REPORT

### 1. Introduction

VetEffecT Consulting and Recruiting in association with Agra CEAS Consulting (the Evaluator) has been contracted by the European Commission to carry out an 'Evaluation of Community Reference Laboratories in the field of animal health and live animals'<sup>5</sup>. The evaluation was launched in January 2009 (kick-off meeting on 27 January) and activities have been completed in September 2009. VetEffecT have covered, in particular, the technical and scientific aspects of the individual CRLs under evaluation (e.g. diagnostic capacity, training, networking, quality); Agra CEAS have designed the evaluation methodology and have carried out the economic/policy analysis for the performance of the overall system of CRLs (including financial aspects).

This Final Report provides the conclusions of the evaluator for each of the evaluation questions in the Terms of Reference together with recommendations reached on the basis of the conclusions for future improvements. It was presented and discussed with the Steering Group (SG) on 12 October 2009 and incorporates the comments received from the SG.

The Final Report is structured as follows:

#### PART ONE

##### **Key Messages**

One page summary of the key messages of the evaluation

##### **Executive Summary**

Synthesis of main analyses and conclusions, added value of the proposals including cost/benefits.

##### **Main Report**

Presentation in full of the results of the analysis, conclusions and recommendations

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<sup>5</sup> The contract was awarded by the European Commission, Directorate General Health and Consumers (DG SANCO) following Open Invitation SANCO/2008/D1.

## 1.1. Background

The new Animal Health Strategy for the European Union for 2007-2013<sup>6</sup> identified the need for a comprehensive evaluation of Community Reference Laboratories (CRLs) in the field of animal health and live animals, to assess the performance of the CRLs and propose options for the future operation of the system, in particular in view of the changing circumstances in which these operate and future needs.

The network of CRLs dealing with major animal diseases has been set up progressively over time since the late 1970s. Their functions have been specified individually in a number of Community legal acts. The CRLs may receive financial aid from the Community for fulfilling their duties and functions in relation to the EU policy objectives. Regulation (EC) No 882/2004 lays down a series of general requirements for CRLs for animal health (which are covered by this evaluation) as well as for food (including veterinary public health) and feed safety. The functions and duties of the CRLs are detailed in the various Commission Directives designating the CRLs (full list in the Technical Annexes). Additional responsibilities and tasks for CRLs may be laid down by comitology.

The external evaluation of the Community Animal Health Policy (CAHP) for 1995-2004, which was led by Agra CEAS Consulting, concluded from surveys of authorities and stakeholders that the capacity of the EU CRLs, co-ordinated and financed by DG SANCO, is adequate and that the established network of CRLs and national reference laboratories (NRLs) appears to be fairly or very effective. The overall conclusion of the CAHP evaluation with regard to CRLs was: *“The creation of the CRLs and their co-operation with national laboratories avoids duplication of work, generates costs savings, contributes to the development of common approaches and improves the quality of the diagnosis at EU level.”*

The new Animal Health Strategy recognises that there have been fundamental changes in the field of animal health control and in the general circumstances in which animal health policy is applied since the policy was first developed several decades ago. EU enlargement and increased international trade have resulted in greater animal health risks. There is more focus on prevention and early detection. There has been progress in diagnostic techniques and a more flexible EU approach towards vaccination, along with the development of “DIVA” (differentiating infected from vaccinated animals) vaccines. Thus, there is a need to re-evaluate priorities based on risk assessment and scientific advice. Also, emerging and re-emerging diseases may result in the need to expand the network of CRLs. This will require even more efficient control and management of the network’s operations and budget.

Within the framework of the new Strategy there is a need for more in-depth evaluation of the work and performance of the CRLs. This is necessary to ensure that the network of CRLs is best able to meet EU objectives for animal health in the most efficient manner now and in the future.

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<sup>6</sup> New Animal Health Strategy for the European Union (2007-2013) where “Prevention is better than cure”, COM (2007) 539 Final, Brussels



## 1.2. Objectives

The objectives of this evaluation are two-fold:

The **first objective** is to assess the functioning, performance and fulfilment of the obligations and duties of the CRLs in the field of animal health and live animals, as established in EU legislation and work programmes in the last 15 years. In this context, the evaluation has considered aspects related to relevance, effectiveness, efficiency, utility and sustainability of each of the CRLs in the field of animal health and live animals, and of the CRLs structure in the animal health field as a whole. This included assessing the added value provided by the CRLs and considering whether their performance can be enhanced.

In terms of efficiency issues, the evaluation has assessed the efficiency of the use of financial aid from the Community to CRLs for eligible costs, in particular during the last 15 years. The evaluation has also analysed their respective financial capacities and their dependence on financial aid from the Community for operating costs with a view to assess whether the scale of inputs from the community funds can be justified on the basis of outputs and performance.

The main goal of this evaluation was to evaluate the concept and performance of the CRLs in the context of the Community objectives which the CRLs have been set up to fulfil in the EU legislation. It was not to undertake a technical quality or financial audit of the CRLs, as such. In this context, the classical tools of evaluation criteria and indicators have been applied, as commonly used in EU policy evaluations. Inevitably, issues relating to the current quality standards and technical aptitude of the CRLs have been touched upon, as inextricably linked with the question of the final performance of the CRLs, but these were not the main focus of this evaluation.

Thus, the main emphasis of the evaluation visit was on indicators that address the duties and obligations of the CRLs in the context of the EU legal basis. For example, efficiency issues were assessed in the context of the financial contributions that CRLs receive from the Community, and only to the extent this is relevant in terms of their overall financial efficiency. More generally, information and evidence related to the CRL's financial and technical/quality standing has been taken into account; to the extent this was relevant and readily available in quality and financial reports of the last few years.

The **second specific objective** is forward looking. Based on the conclusions of the analysis of past performance, the evaluation points out potential shortcomings, challenges and areas for improvement and propose options to enhance the current structure and functioning of the CRLs, both individually and as a whole. This forward looking element has taken into account the strategic goals and the action plan established in the new Animal Health Strategy. The options considered include "do-nothing" and deregulation.

The objectives of this evaluation are represented in **Figure 1**.

The CRLs covered by this evaluation are:

- CRL Avian Influenza, VLA, New Haw, Surrey, UK
- CRL Newcastle Disease, VLA, New Haw, UK
- CRL Bluetongue IAH, Pirbright, Surrey, UK
- CRL Classical Swine Fever, Tiho, Hannover, Germany
- CRL African Swine Fever, INIA, Valdeolmos, Madrid, Spain
- CRL Swine Vesicular Disease, IAH, Pirbright, Surrey, UK

CRL African Horse Sickness, LSPA, Algete, Madrid, Spain

CRL Rabies (serology), AFSSA, Nancy, France

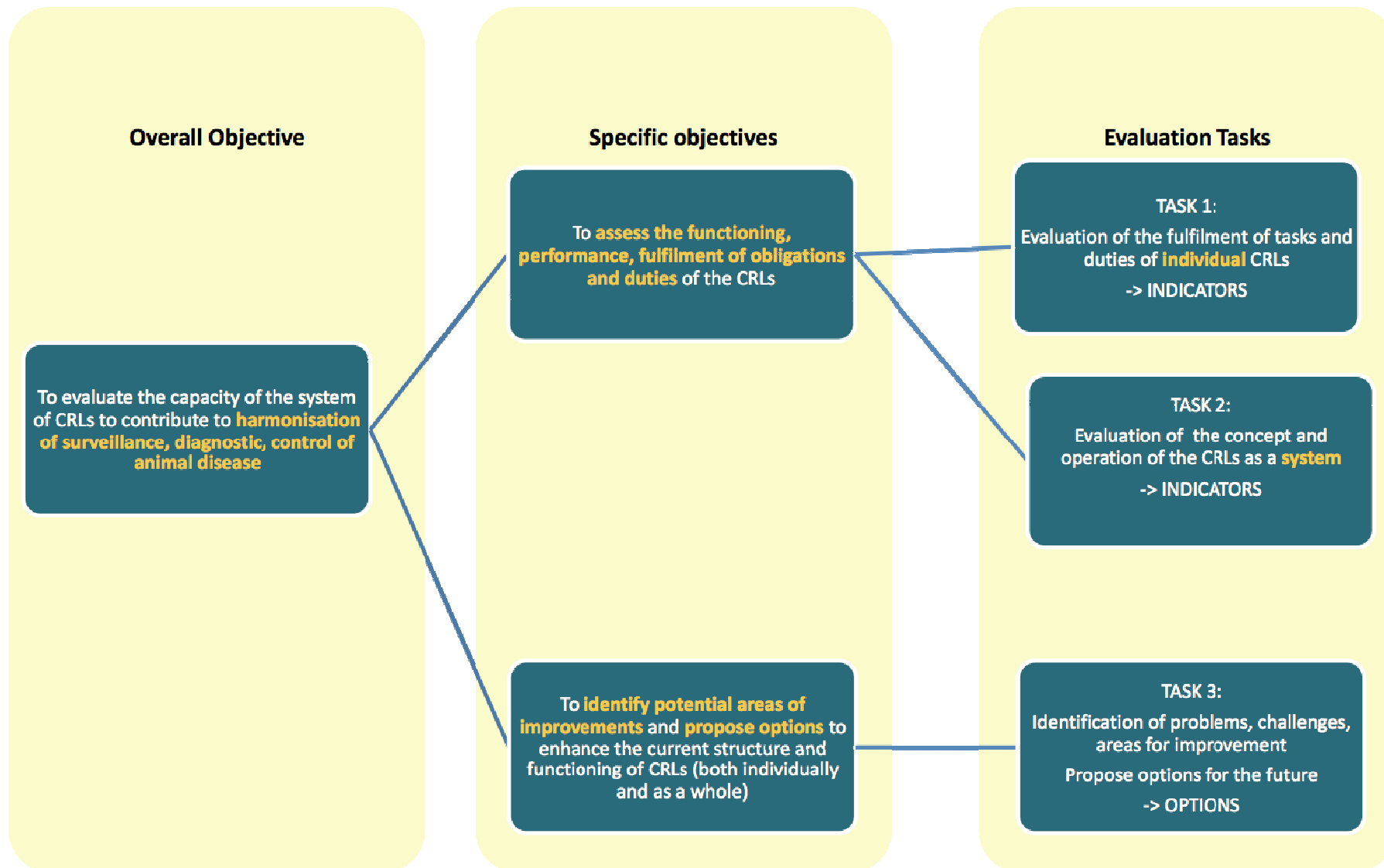
CRL Fish diseases, NVI, Arhus, Denmark

CRL Mollusc diseases, Ifremer, La Tremblade, France

CRL Zootechnics, Interbull, Uppsala, Sweden

CRL Transmissible Spongiform Encephalopathies , VLA, New Haw, Surrey UK

Figure 1 Objectives of the evaluation



### 1.3. Methodology

The study has been based on the following main methodological tools as outlined in the Inception Report:

1. **Desk research.** This involved the collection, identification and review of basic available literature and other material, including the legislation and other official documents covered by this study, CRL work programmes and reports. These provided essential information for carrying out the interviews, survey and CRL field visits that form the main body of the methodology followed here.
2. **Stakeholder/expert interviews.** This involved a first round of detailed interviews with a selected number of key relevant stakeholders and experts at EU and national level and with private organisations and international bodies. The purpose of this round was to perform a first data collection, identify and confirm the list of relevant stakeholders for the survey and CRL field visits, and establish the range of issues that are important for the design of the survey questionnaire and the preparation of CRL field visits.
3. **Development of indicators.** The structuring phase of the evaluation has involved the development of the intervention logic and of indicators to assess the performance of the CRLs in terms of the various parameters covered by this evaluation (appropriateness, relevance, added value, effectiveness, efficiency).
4. **CRL field visits** in the selected 12 CRLs. A second round of detailed interviews was conducted in the context of the field visits. The field visits focussed on the 12 CRLs under review, and were conducted in the six Member States where the CRLs are located. The interviews were based on a semi-structured interview guide.
5. **Surveys** of Member State (MS) National Reference Laboratories (NRLs) and Chief Veterinary Officers (CVOs). This is a comprehensive survey of all EU-27 MS, based on structured questionnaires, including forced multiple-choice (closed-format) and free-text (open-format) fields. One generic survey was addressed to the NRLs of each MS (the CRL for Zootechnics received a specially tailored survey). A second survey was addressed to CVOs.

In addition, we have undertaken a number of team **brainstorming sessions** at critical points of the study's development to support the data collection and analysis. Such critical points included the refinement of the methodology, design of the survey questionnaire and semi-structured interview guides to be used for the expert interviews and CRL case studies, and the development and analysis of options for improvement.

#### 1.3.1. Desk research

The following key relevant documents and material have been reviewed:

- Background legislation and other official documents covered by this study. A non-exhaustive list of the main background legislation at EU level is provided below. The

purpose has been to understand in detail the roles and tasks of the CRLs (Technical Annexes: List of CRLs and legal basis).

- The various documents of the reporting cycle between CRLs and the Commission. As detailed in Regulation (EC) No 1754/2006, the following documents are prepared during this process<sup>7</sup>:
  - Before 1 September of a given year (n), a CRL should set out the activities planned for the next year, including an estimated budget. This is done in the form of the **Working Programme and budget (WP)**. Subsequently the CRL and the Commission enter into a specific agreement, including financial aspects.
  - In the year following the activities (n+2) and before March 31, the CRL must submit a **Technical Report** (Annual Reports) and a **Financial Report** to the Commission
  - Within 2 months after a workshop, the Technical and Financial reports must be sent to the Commission.

In addition, all CRLs submit interim reports. Consequently, from each CRL for every year three reports should be available: Working Programme (WP) (including or separate with the finances); Interim Report (including or separate with the finances); and, Annual Report (including or separate with the finances). A first set of such documents was provided by DG SANCO. The process of collecting these documents has proven rather complex, especially from the early years of the 15 year period. The CRLs have provided extensive documentation, including WPs, Technical and Financial Reports since their designation as a CRL or for the last 8 years, as well as Standard Operating Procedures, Quality System information, Organograms etc. In some cases, interim reports were not available. A full list of the documents provided by each CRL is included in the Technical Annexes.

- Other background literature and material assembled at the national or international level included information from disease outbreaks from the OIE database. This also includes information on the CRLs and NRLs from the EU Food and Veterinary Office (FVO) reports on the control and eradication of various diseases, to the extent these are relevant (e.g. TSEs, rabies).

### **1.3.2. Interviews with key experts and stakeholders**

The interview process has involved discussion with the following experts and stakeholders:

- **Desk officers and experts at Commission level**, in particular the relevant units in DG SANCO, including the desk officers responsible for the CRLs, the evaluation cell, the financial cell (veterinary control programmes), and the operational units. The purpose of these interviews was to: gain a deeper understanding of the objectives and expectations from the evaluation, relating both to each individual CRL and the network as a whole; collect information, background and views on the CRLs; and, consult on the development of the indicators and the design of the survey and of CRL field visits. In addition, relevant Units on research related aspects were interviewed in DG Research.

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<sup>7</sup> The rules and procedures for the allocation of Community aid to the CRLs are described in more details in section 4.8.1.

- **Industry stakeholders and OIE.** The following stakeholders were interviewed:
  - IFAH-Europe: International Federation for Animal Health – Europe, representing the European animal health industry;
  - EMVD (formerly AEFRV): European Veterinary Diagnostics Manufacturers;
  - OIE: World Organisation for Animal Health.

### 1.3.3. Development of indicators

An evaluation matrix was developed, based on the legal duties of each CRL as arising from the relevant legislation. In this matrix, each CRL task has been analysed in order to identify measurable indicators for the areas of work attributed to the CRLs. The matrix was completed with the inclusion of some aspects (and the related indicators), not explicitly referred to in the legislation but deemed essential for the functioning of the CRL, which emerged when the intervention logic was developed. The matrix was presented and discussed with the Steering Group of the evaluation during the inception phase; this internal working document was revised and updated in the course of the evaluation as new evidence came to light.

The majority of the indicators are horizontal and applicable to all CRLs, although some are specific for each CRL, to allow for differences in the context of the disease or the characteristics of the CRL<sup>8</sup>, as depicted in the legal basis that is specific to each CRL.

The indicators formed the basis for the development of the questionnaires which were submitted to the CRLs prior to the CRL field visits, and of the questionnaires for the surveys conducted among the NRLs and the CVOs. The performance of the CRLs in the reference period as presented in this study is evaluated taking into account these indicators. A selected set of these indicators could be used to monitor the work of the CRLs in future, as further discussed in section 5.

### 1.3.4. CRL field visits

Field visits were made to all the 12 CRLs covered by this evaluation. The evaluation teams were comprised of at least two experts: a veterinary expert and an evaluation expert. An exception was the CRL for Rabies (serology), which was visited by one expert. The visits commenced in April and the programme was completed in the first week of July, except for the CRL for Rabies, which was visited at the beginning of September. The visit schedule is shown in the following table:

**Table 1 Schedule of the visits to the CRLs**

Visit date	CRL
27-28/04/2009	Avian Influenza, Pirbright, Surrey, UK
27-28/04/2009	Newcastle Disease, Pirbright, Surrey, UK
27-28/04/2009	TSEs, Pirbright, Surrey, UK
20/05/2009	Classical Swine Fever, Hannover, Germany
25/05/2009	Mollusc Diseases, La Tremblade, France
10-12/06/2009	African Swine Fever, Madrid, Spain

<sup>8</sup> CRLs for Rabies and Zootechnics.

10-12/06/2009	African Horse Sickness, Madrid, Spain
23/06/2009	Fish Diseases, Arhus, Denmark
29/06/2009	Zootechnics, Uppsala, Sweden
1/07/2009	Bluetongue, Pirbright, Surrey, UK
1/07/2009	Swine Vesicular Disease, Pirbright, Surrey, UK
03/09/09	Rabies (serology), Nancy, France

The CRL field visits involved a detailed investigation (but not a technical or financial audit) of the CRLs' work and activities. Interviews with the key staff involved in carrying out the CRL duties were conducted based on a semi-structured interview guide, which was developed after the interviews held during inception and submitted for comments and approval to the relevant DG SANCO officer. Prior to the visit<sup>9</sup>, a questionnaire was sent to the Director of the CRL. A master questionnaire was developed for the ten CRLs for animal diseases; two specific questionnaires were developed for the CRL for Rabies and Zootechnics.

The full visit reports and the questionnaires returned by the Directors of the CRLs are included in **Part Two** of the Final Report.

### 1.3.5. Survey of CVOs and NRLs

Although this was not originally foreseen in the Terms of Reference, the opportunity to launch a 'satisfaction' survey of NRLs and CVOs in all MS of the EU-27 was identified during the Inception Phase. The purpose of this survey was to collect views on the coordination and collaboration between the MS and the CRLs, and to establish the extent to which MS appreciate the usefulness and value of the current set up of CRLs. The survey also attempted to identify any shortcomings in the system and seek suggestions for improvement.

The added value of carrying out this survey was twofold. First, it allowed the evaluation to cover all EU MS, including those that do not currently have a CRL and were therefore not visited. Second, it yielded useful and significant data for a more graphical representation of various potential indicators of the level of collaboration between the CRLs and MS (which is a key role of the CRLs).

The survey adds to the robustness of the methodology followed in this evaluation, in that the two sets of results (CVO survey and NRL survey results) together with the CRL field visits by the experts of the evaluation team provide three independent sources for analysing the performance of individual CRLs and the system of CRLs as a whole.

The survey was based on two structured questionnaires: one aimed at NRLs, the other at CVOs. The NRLs survey focuses on the specific diseases (or genetic evaluation) of the NRL. The CVO survey covers all CRLs and also asks more general questions about the system for CRLs. Both questionnaires were based around the five broad areas of investigation identified in the intervention logic: A: Diagnosis; B: Training; C: Networking; D: Financial issues; E: Quality issues. The questionnaires included closed-format and open-format fields. The closed-format fields are in the

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<sup>9</sup> One month before the visit.

form of a scoring range (e.g. on a scale of 1 to 5) from which summary graphs could be prepared. The two questionnaires, together with the methodology are included in the Technical Annexes. The results of the surveys are included in section 3.

The questionnaires were developed and validated in close consultation with Commission experts and the Steering Group. The questionnaires were then distributed with a covering letter explaining the purpose of the survey in the context of the evaluation.

The survey was addressed to the competent authorities of each MS. This included the CVO and NRLs for the relevant diseases (or genetic evaluation) covered by the project. The NRL survey was carried out independently of the CVO survey.

The NRL survey was extensive, taking into account a possible 312 responses from 12 NRLS in each of the 27 MS. The NRLs in the Member State that has the respective CRL were not included as these are likely to be part of the same laboratory.

Of the CVOs, 17 out of 27 or 63% responded to the survey.

Of the NRLs, 137 replies were received from 312 NRLs: a response rate of 44%.

Regarding the response by CRL, between 10 and 19 replies were received in respect of nine of the CRLs, with three receiving less than 10 replies (Molluscs-7, Zootechnics-7 and Rabies serology-5). It is appreciated that there will be less interest in some CRLs from MS that are at low risk of the diseases in question.

Regarding the response rate by Member State, the mean number of responses per MS was 5.1, with a range from 0 to 10.

## **2. Description of the system of CRLs**

### **2.1. Intervention logic**

The objectives of the establishment of CRLs are laid down in Regulation (EC) No 882/2004. In the context of official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules, the rationale for the designation of CRLs lies in the necessity of a reliable and harmonized diagnostic service at MS level to ensure that controls are carried out in the most effective and efficient manner. In particular, the work of the CRLs and NRLs is aimed at ensuring a “high quality and uniformity of analytical results”.

Harmonised diagnosis is crucial, in this context, for several reasons:

- When results are discussed by interested parties there is common acceptance of their reliability, especially in terms of sensitivity and specificity, and scientific significance;
- Laboratories can participate in proficiency tests and generate additional data for refining and developing tests, which are of benefit to all participants and with the ultimate aim of scientific validation;
- Standardised reagents can be developed and shared.



The Regulation also indicates the activities through which such harmonization may be reached, notably:

- the application of validated analytical methods;
- ensuring that reference materials are available;
- the organisation of comparative testing (also called 'ring trials, or proficiency testing programmes', or external quality assurance - EQA), and;
- the training of staff from laboratories.

The specific Directives designating the CRLs further detail their tasks and duties (as discussed in section 2.2), which may differ according to the specific diseases. This takes place within the main type of activities, as highlighted above, which are implemented in the frame of the specific functions of the CRL.

Based on the above objectives, tasks and duties, **Figure 2** presents the intervention logic of the Community financial assistance in this field, as established by the work undertaken during the structuring phase of the evaluation.

It is noted that the ultimate objective of the work of the CRLs is to liaise and cooperate with the NRLs in order to guarantee appropriate disease diagnosis and the application of necessary control and eradication measures (as will be discussed further in section 4.1.2). In order to achieve this objective, the CRLs should perform various activities, which all work in common towards the harmonization of diagnostic techniques.

The work of the CRLs, and the effectiveness of their interaction with the NRLs, is important both in peacetime and in the case of emergencies (i.e. in the case of an outbreak). In the first case, the role of the CRLs is mainly to coordinate diagnosis. This is carried out through specific activities, such as the organisation of proficiency tests, the production and supply of reference reagents (→ *Diagnosis coordination*). In case of emergencies, the priority for the CRLs is to confirm the diagnosis of NRLs at MS level, in the most quick and accurate way, and to provide assistance to the MS in the form of missions or scientific advice to deal with the emergency (→ *Diagnosis assistance*). As a follow up of Proficiency Tests, or in the framework of new development in diagnostic methods, the CRL also provides (or facilitates) training through the organization of workshops, *ad-hoc* training sessions or through the diffusion of SOPs (→ *Training*)<sup>10</sup>.

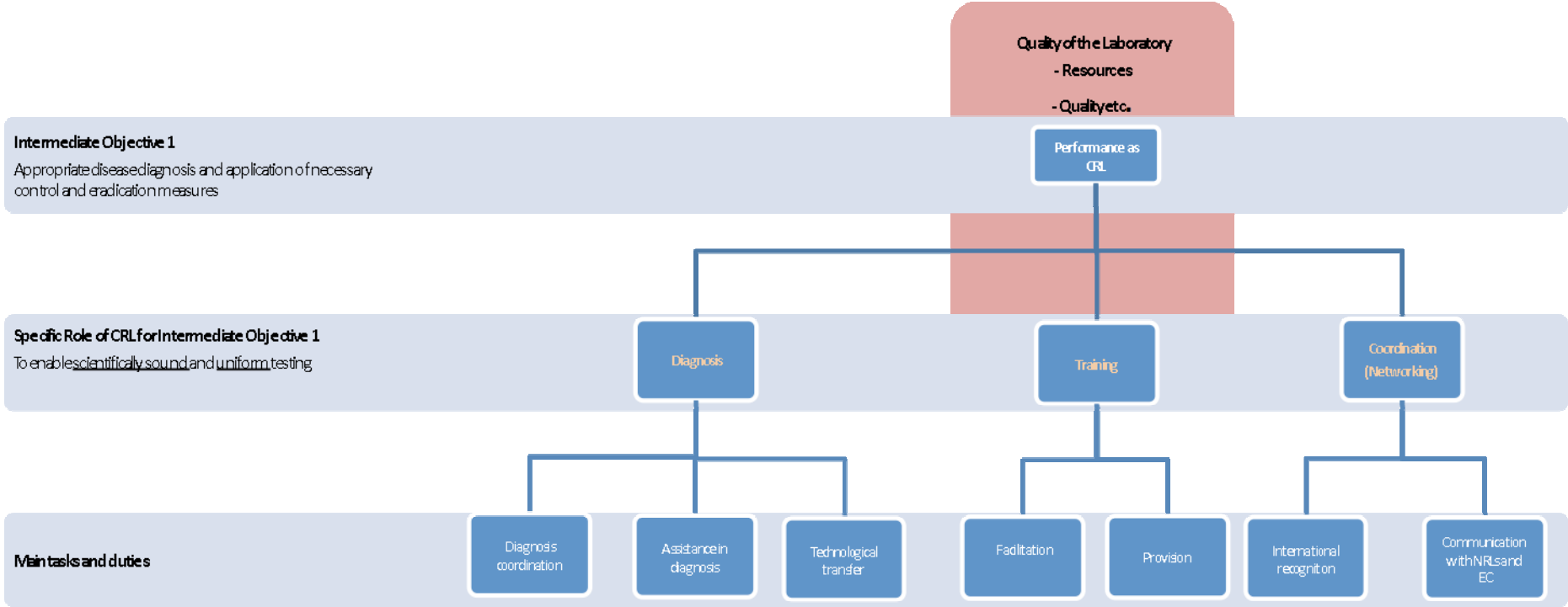
The reference laboratories, at both the Community and national levels, are intended to work as a network. The robustness of the network is based on the development of reciprocal *trust*, which guarantees that cooperation is in place and ensures effective collaboration and sharing of information (→ *Coordination/Networking*). Therefore, an important element of the CRL networking is communication with the other interested parties (NRLs in the first place, but also the European Commission). Another important element is participation in international activities and groups, which relates to the ability of the CRL to keep abreast of new developments, as well as their ability to influence international standards.

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<sup>10</sup> The elements described here as actions related to the various areas have to be intended as examples, since other indicators and specific duties fall within these functions. These will be fully analysed in the related sections of this Report.

The performance of the CRLs should therefore be evaluated with regard to these activities and the degree of achievement in these areas. This formed the basis of the evaluation methodology, i.e. according to the legislation, all the duties of the different CRLs were analysed and attributed to these areas, indicators were developed and on this basis the questionnaires were refined, as described in the methodology section. This allowed the evaluator to gain insights on the different aspects of the work of a CRL.

**Figure 2 Intervention logic**



## 2.2. Tasks and duties of the CRLs

The main functions and duties of the CRLs are defined in the legal basis, and can be briefly summarised as follows:

- (a) Harmonising and coordinating MS methods for disease diagnosis;
- (b) Assisting actively in the diagnosis of disease outbreaks in MS;
- (c) Facilitating expert training in laboratory diagnosis (with a view to the harmonisation of diagnostic techniques throughout the Community);
- (d) Collaborating with competent laboratories in third countries on methods of disease diagnosis;
- (e) Conducting training courses (for staff from EU NRLs and experts from third countries);

These functions and duties are commonly defined for all CRLs in Regulation 882/2004, but currently apply to varying degrees among CRLs, as evident by the CRL designating legal basis and WPs.

Table 2 provides an overview of the various functions and duties applying in each CRL. Also, the CRLs have issues of particular relevance depending on the animal disease. For this reason, in addition to a general common approach for all CRLs, an individual tailoring of the data collection and analysis was followed in the evaluation of each CRL.

**Table 2 Functions and duties of individual CRLs**

	(a) Coordinating MS disease diagnosis	(d) Assisting actively in diagnosis	(c) Facilitating training	(d) Collaborating on methods of disease diagnosis with TCs	(e) Conducting training	other
<b>Avian Influenza</b>	<input type="checkbox"/> (detailed)	<input type="checkbox"/> (detailed)	<input type="checkbox"/>	specific objectives f & g on international cooperation		4 more specific objectives
<b>Newcastle Disease</b>	<input type="checkbox"/> (detailed)	<input type="checkbox"/>	<input type="checkbox"/>			
<b>Bluetongue</b>	<input type="checkbox"/> (detailed)	<input type="checkbox"/>	<input type="checkbox"/>	specific objective (info exchange with OIE Ref Lab for BT)		
<b>Classical Swine Fever</b>	<input type="checkbox"/> (detailed)		<input type="checkbox"/>			2 more specific objectives
<b>African Horse Sickness</b>	<input type="checkbox"/> (detailed)	<input type="checkbox"/>	<input type="checkbox"/>	specific objective (info exchange with OIE Ref Lab for AHS)		
<b>Swine Vesicular Disease</b>	<input type="checkbox"/> (detailed)	<input type="checkbox"/>	<input type="checkbox"/>			
<b>African Swine Fever</b>	<input type="checkbox"/> (detailed)		<input type="checkbox"/>			3 more specific objectives
<b>Rabies (serology)</b>	<i>specific role: establish the criteria necessary for standardising the serological test to monitor the action of rabies vaccines</i>			specific objective		
<b>Fish diseases</b>	<input type="checkbox"/> (detailed)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
<b>Mollusc diseases</b>	<input type="checkbox"/> (detailed)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
<b>Zootechnics (bovine breeding)</b>	<i>collaborating in rendering uniform the testing methods and the assessment of results for pure-bred breeding animals</i>			specific objective		
<b>TSEs</b>	<input type="checkbox"/> (detailed)	<input type="checkbox"/>	<input type="checkbox"/>			

Note: Columns (a) to (e) above refer to functions and duties as commonly defined for all CRLs in Regulation (EC) 882/2004 (Article 32). The reference to ‘detailed’ in some cases refers to whether the functions/duties are broken down further in sub-functions/duties in the legal base of the individual CRLs (Annex 1).

Source: compilation based on legal base

### 2.3. The financing of CRLs

This evaluation addresses efficiency issues in particular within the context of the financial contributions that the CRLs have received from the Community.

The Community provides financial assistance to CRLs, pursuant to Article 27 and 28 of Council Decision 90/424/EEC. This assistance is in the form of a grant decided every year through a Commission decision. This grant includes the amount necessary to cover “eligible” costs. Commission Regulation (EC) No 1754/2006 of 28 November 2006 lays down detailed rules for the granting of Community financial assistance to CRLs, and establishes eligible costs corresponding to eligible activities defined in the work programmes (WPs) of the CRLs. The costs relate to permanent activities (for example a certain number of staff, basic continuous activities such as identification and characterisation of isolates, preparing reagents etc.) and ad-hoc activities, such as development of methods or the production of standard sera during one or two years. The assistance comprises also a dedicated amount for the organisation of one or several workshops during a given year, in particular to discuss the outcome of proficiency test programmes.

The Community financial assistance relates to specific CRL tasks, within the functions and duties established by Regulation 882/2004, the Directive or Decision that designated each CRL and additional responsibilities decided through comitology. There is a requirement for ensuring at national level the supply of adequate complementary human and financial resources to pay for the costs not covered by the Community assistance, in particular for infrastructure and running costs. These complementary resources may originate from different sources, although they usually come from the national competent authorities.

The Commission provides 100% of the eligible expenditures defined in Regulation (EC) No 1754/2006 within the overall available budget.

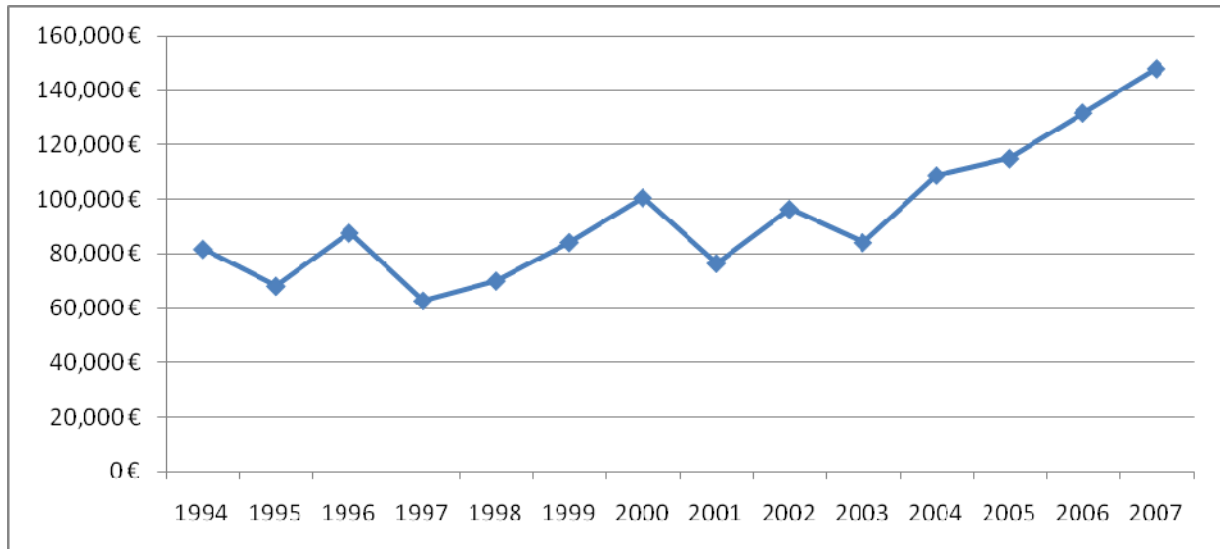
The Community financial assistance to CRLs in the field of animal health (i.e. those covered by the scope of the evaluation, excluding the CRLs for Brucellosis and Foot- and-Mouth Disease) can be summarised as follows.

During the evaluation period, the Community assistance to the CRLs under review has totalled some €11.7 million. The Community financial contribution has grown by almost tenfold during this period, from €245,000 in 1994 to nearly €2.1 million in 2007 (Figure 3). This reflects the increase in the number of CRLs designated for the various animal diseases, from 3 in 1994 to 11 since 2003. It is also due, however, to an increase in the funds dedicated to each CRL during this period, from an average per CRL €81.6k in 1994 to €148k in 2007 (Figure 4). The increase in funds took into account several disease outbreaks including CSF, AI and BT as well as the expanding network of NRLs resulting from EU enlargement.

The total Community contribution to each CRL during the evaluation period has ranged significantly between CRLs, from a total payment of €250k for the CRL for AHS to over €2 million for the CRL for CSF (Figure 5). Nearly half of the total Community payments during this period have been made to three CRLs: CSF, Fish Diseases and AI, which received respectively 18%, 15% and 14% of the total funds (Figure 6). To a significant extent, this appears to have reflected the importance and relevance of each disease for the EU (CRL for Fish Diseases cover several diseases, disease situation in the EU, new field of scientific development, etc). However, these figures do not take into account the fact that some CRLs were designated later than others, therefore the average annual contribution made to its CRL during the period of its existence is also relevant. Five CRLs

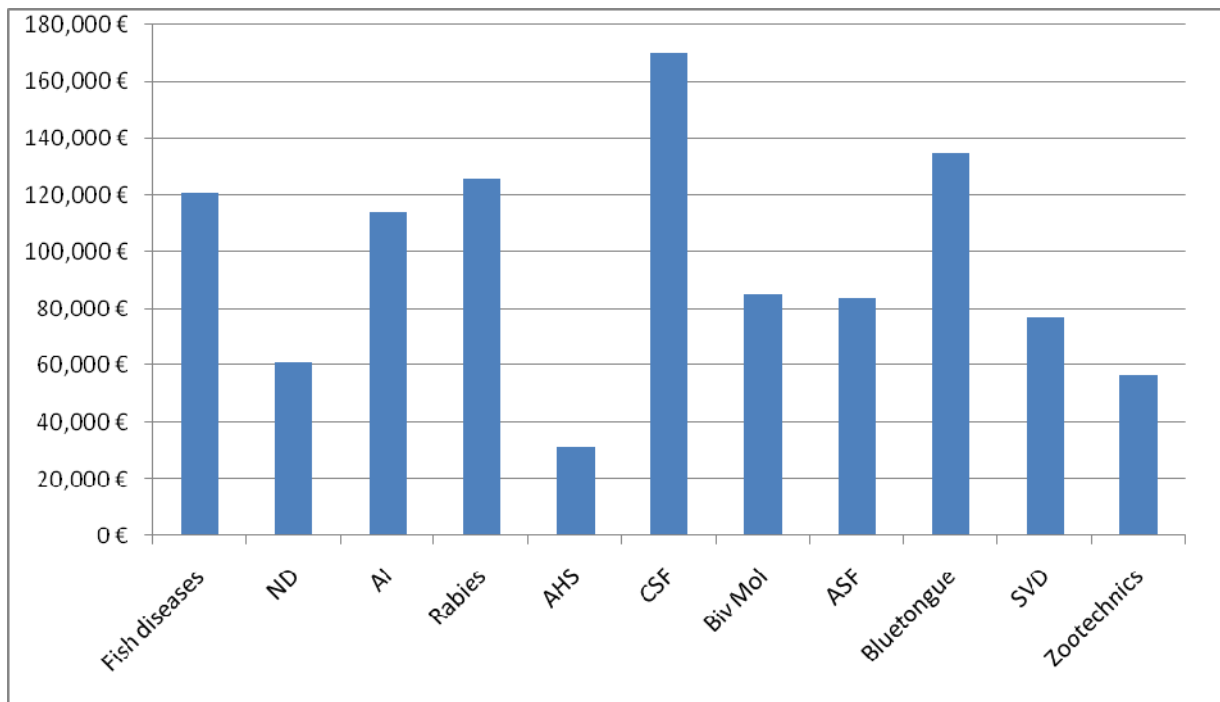
stand out in this respect: CSF (des. 1996) received on average of €170k per year, Bluetongue (des. 2001) received €135k/year, Rabies (des. 2000) €126k/year, Fish Diseases (one of the oldest, des. 1994) €121k/year, and AI (also des. 1994) €114k/year (Figure 7).

**Figure 3 Average Community payment per CRL (excl. Brucellosis and FMD), 1994-2007**



Source: Agra CEAS based on DG SANCO data

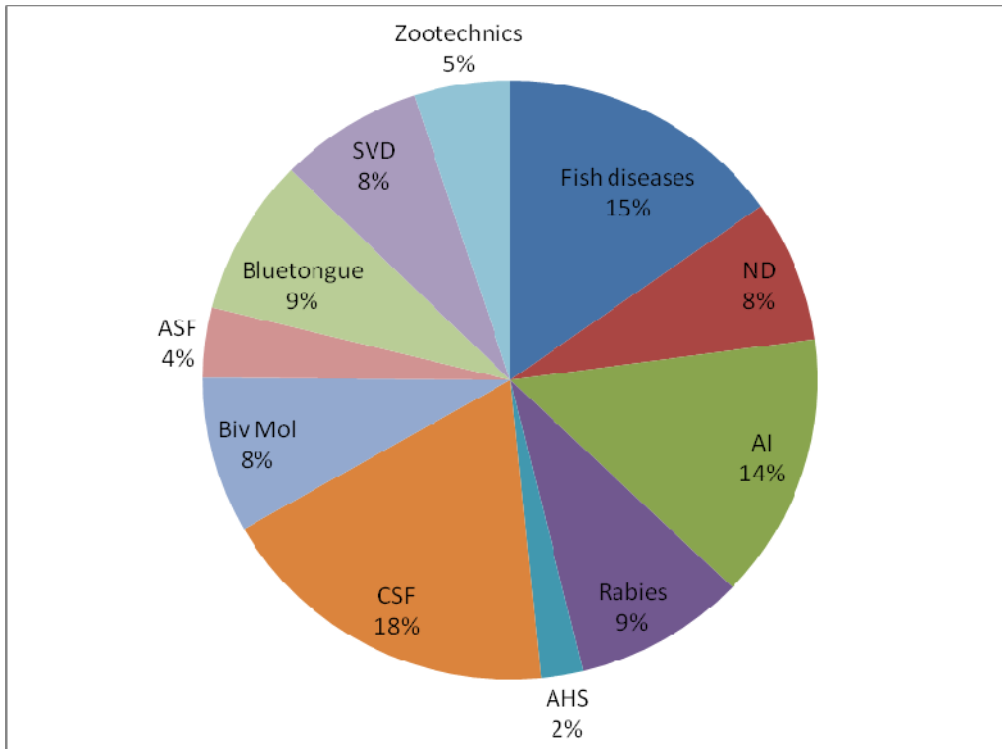
**Figure 4 Average Community payment to each CRL per year, 1994-2007**



Source: Agra CEAS based on DG SANCO data

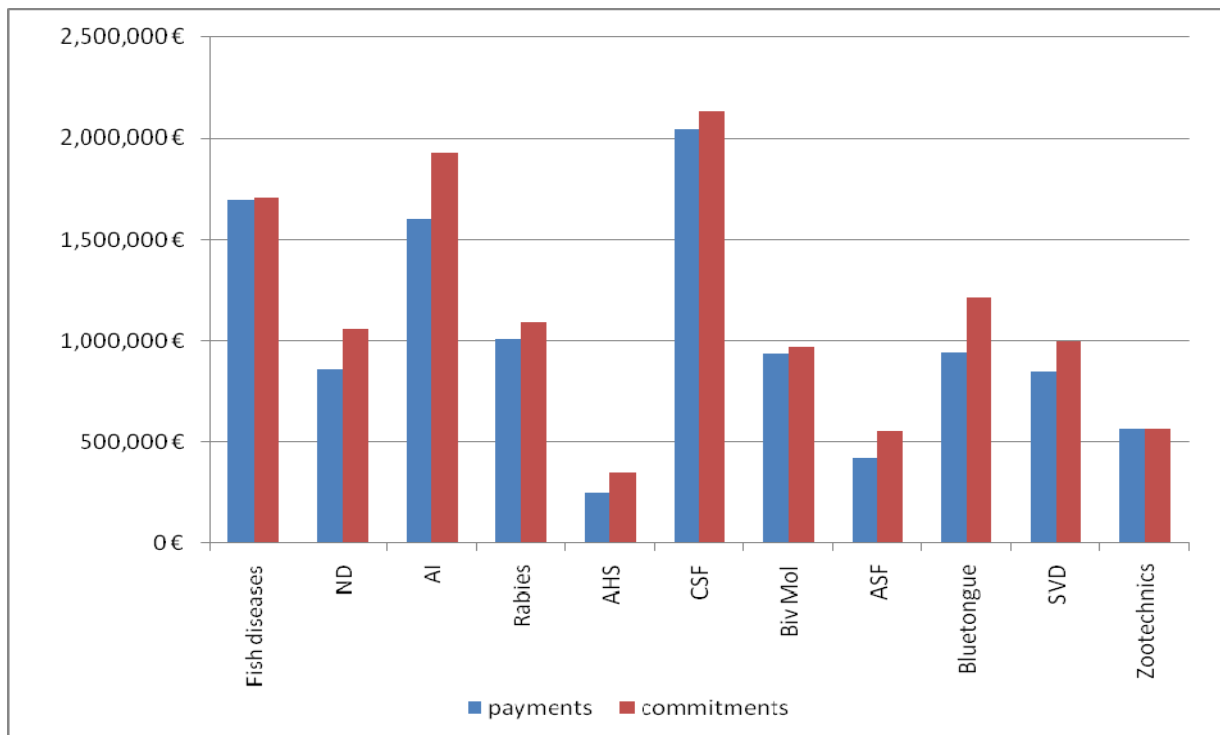


**Figure 5 Distribution of Community payment by CRL, 1994-2007**



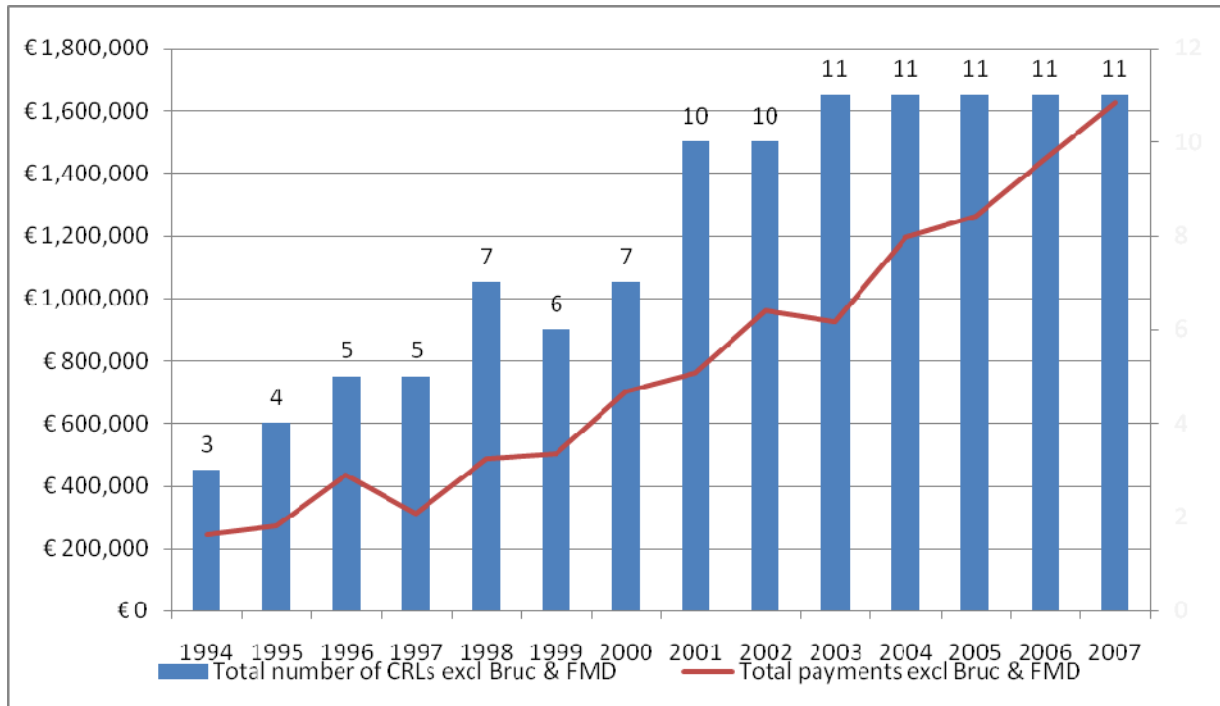
Source: Agra CEAS based on DG SANCO data

**Figure 6 Total Community contribution to CRLs, 1994-2007**



Source: Agra CEAS based on DG SANCO data

Figure 7. Community contribution to AH CRLs and number of CRLs, 1994-2007



Source: Agra CEAS based on DG SANCO data

### 3. Evaluation of the performance of individual CRLs

#### 3.1. Methodology

The evaluation of the individual CRLs corresponds to Task 6.2 of the ToR. Results have been prepared for each CRL for the evaluation sections: A: Diagnosis; B: Training; C: Networking; D: Financial issues; E: Quality issues.

The evaluation methodology uses three independent sources of information for each CRL:

1. Validated evaluation reports for each CRL. These reports were prepared following expert field visits and are the primary source of information for each CRL.
2. Results of the CVO survey of CRLs. This survey covers Member State CVOs responses to questions covering all CRLs.
3. Results of the NRL survey of respective CRLs. This survey asked NRLs to comment on the particular CRL relevant to the specific disease/diseases/genetic evaluation covered by the NRL.

Section 3.2 presents the main findings relating to diagnosis, training, networking and quality issues for each CRL<sup>11</sup>. Section 3.3 provides a composite overview of the main findings and discussion relevant to the main evaluation issues, taking into account CVO and NRL survey findings.

Examples of the questionnaires and survey sheets are included in the annexes of this report.

#### 3.2. Main findings for each CRL

This section includes tables summarising the main findings for each CRL. The principal source of information is the validated CRL evaluation reports, with additional information provided from the CVO and NRL survey reports and information from interviews with stakeholders. The evaluators found considerable differences in the activities and reporting between CRLs. This has resulted in difficulties in compiling the objective indicators (developed for this evaluation, as discussed in section 1.3.3) in a way that will provide a meaningful assessment across CRLs (whereas the indicators are more useful for comparing performance over time or against a benchmark within each CRL). It is important to emphasise that the CRLs are not comparable with each other due to the varying nature and epidemiology of the diseases and some differences in their roles. However, it is possible to score them using a rating system that assesses whether each CRL meets the requirements for its role as laid down by the legal base.

The rating system is explained in the following box and is succeeded by the individual main findings for each CRL:

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<sup>11</sup> Financial issues are dealt with in section 4.8 under the evaluation of the current system of CRLs.

**Figure 8. Rating system to assess performance of individual CRLs**

<b>Rating system to assess performance of individual CRLs</b>		
<b>Rating Codes:</b>		
Outstanding	(provides excellence or added value)	+++
Satisfactory	(meets EU requirements)	++
Underperforming	(some shortcomings identified that require improvement)	+
<b>Notes on rating system:</b>		
The rating system has three levels:		
Level 1: Overall evaluation of the CRL. This is a composite of lower level ratings.		
Level 2: Four main ratings for Diagnosis and Assistance, Training, Networking and Quality Issues. These are derived from Level 3 ratings.		
Level 3: Base level ratings corresponding with individual evaluation issues. These ratings are awarded by the expert evaluators and justified by the corresponding assessments in the individual CRL summary tables. More in-depth information is available in the CRL reports. These ratings contribute to the respective main rating and to the overall rating on a points basis. There is a range of 16 to 48 rating points available at Level 3. From 16 to 26 points gives an Overall rating of +, 27 to 37 points gives ++, and 38 to 48 points gives +++.		
The ‘Satisfactory’ (++) rating can be considered the default rating corresponding to satisfactory performance that is meeting EU requirements.		
Outstanding (+++) and Underperforming (+) ratings have to be justified as more or less than satisfactory. ‘Outstanding’ can be thought of as representing excellence or added value. ‘Underperforming’ indicates that some shortcomings have been identified that require improvement.		
The Level 1 and Level 2 ratings are summarized for all CRLs in Table 3: Overview of CRL evaluations in Section 3.3		

### 3.2.1. CRL for Avian Influenza

<b>Main findings - CRL for AI</b>	<b>Rating</b>
<b>Overall evaluation of the fulfilment of the duties and tasks established in the legislation</b>	+++
The CRL is fulfilling all of its contractual duties, responsibilities and obligations as specified in Annex VII of Council Directive 2005/94/EC.	
<b>1.0 DIAGNOSIS AND ASSISTANCE</b>	+++
Has the assistance of CRLs to other laboratories been adequate in order to improve diagnostic of animal diseases in the Community?	
<b>1.1 Activities and methods used by CRLs to ensure the correct diagnosis of animal diseases by National Reference Laboratories.</b>	+++
The diagnostic methods used in the laboratories are EU and/or OIE approved methods and of high standard. Results of PCR and HI tests are available within 24 hours of the receipt of a sample. All other tests are usually completed and reported within 72 hours.	

<b>Main findings - CRL for AI</b>	<b>Rating</b>
<b><i>1.2 Ring trials carried out and assessment of their effectiveness.</i></b>	+++
The CRL is responsible for organising proficiency tests and this has been done every year since its designation as CRL prior to the annual meeting which is a combined with the meeting of the NRL's for ND. The ring test includes serology as well as molecular methods (PCR). Currently, reagents for the annual proficiency panel are distributed to over 40 countries, including many third countries. The results obtained are classified as unsatisfactory, satisfactory or fully correct. Most NRLs achieve today satisfactory results or even fully correct results (about 87 % of NRLs) which are evidence for harmonization of diagnosis. In the case of NRLs whose results are below the acceptable level of proficiency the CRL endeavours to resolve these by direct dialogue or by offering training. Every year the CRL issues a questionnaire to laboratories concerned with collecting data on use of tests and the number of tests conducted in relation to both diagnosis and surveillance.	
<b><i>1.3 Development of new diagnostic tools by the CRLs.</i></b>	+++
The CRL has a close relationship with the research programmes of the VLA, which is an international centre of excellence. Molecular characterisation of the HA gene cleavage site has remained a research priority over the last 15 years for the VLA. However, through the use of improved detection and sequencing technologies the CRL for AI can now conduct these analyses more rapidly by using clinical specimens as the starting material e.g. cloacal or buccal swabs. Previously isolation in embryonated chicken eggs was required to amplify the virus prior to sequencing. The analysis of internal gene sequences has also become more commonplace.	
<b><i>1.4 Supply of diagnostic tools to other laboratories.</i></b>	++
Reagent requests have significantly increased in line with increased NRL activity since 2005. One CVO stated that the CRL does not have a good reputation for sharing strains with NRLs.	
<b><i>1.5 Assistance to other laboratories for diagnosis in case of an outbreak.</i></b>	+++
The CRL provides seven days a week/18 hours per day support to MS and high priority is given to ensuring that all laboratory results are dispatched to submitters in less than one working day following completion of laboratory analysis. In dealing with emergencies in relation to disease outbreaks, if services are lacking within a MS (i.e. particular techniques or tools) that are critical from a disease control perspective, these are given the highest priority.	
<b>2.0 TRAINING</b>	+++
Has the training carried out by the CRLs been sufficient to improve the diagnosis of animal diseases during the last 15 years?	
<b><i>2.1 The evaluators shall analyse the activities carried out for training and retraining of experts and staff (courses, documents).</i></b>	+++
Training is provided at the CRL for an average of 1 or 2 scientists/technicians from MS and 5 trainees from 3 or 4 third countries per year. Each training course is accompanied by a workshop manual/CD which is provided to each trainee and includes all the protocols and copies of presentations provided during the training. Workshops normally have heavy emphasis on practical opportunity, but are interspersed with key lectures and the conclusion of each workshop is always in the form of a specific proficiency panel conducted by each trainee. Certificates are provided at the end of the workshop to trainees, assuming satisfactory performance in proficiency testing. Workshops at which training in PCR or conventional diagnostic methods is given are held once or twice per year at the CRL. Alternatively, an expert from the CRL may visit a NRL to provide training. Training was deployed e.g. in October 2005 when an expert was sent to a MS in response to the threat of H5N1. This can be done under the auspices of the TAIEX office, an international agency or specific MS. In instances when the request for training is from DG SANCO then they cover the costs.	
<b><i>2.2 Are these training activities sustainable in the long term?</i></b>	++

<b>Main findings - CRL for AI</b>	<b>Rating</b>
A multi-annual budgeting process as it already exists for some CRLs might be helpful for both planning and in order to provide for a greater level of security of tenure for CRL staff.	
<b><i>2.3 The evaluators shall also assess the activities carried out to provide scientific advice and expertise as regards disease surveillance and controls.</i></b>	+++
NRLs are assisted in epidemiology and surveillance of AI. Data obtained from surveys for AI in poultry by MS are analysed from an epidemiological point of view. An epidemiology group has been working within the Avian Virology Department for 2 years and provides advice on improved sampling methods, data gathering, reporting, surveillance strategies, risk assessment and early warning systems. Specialists from the CRL provide support for the development and application of an IT reporting system. All of the 2008 AI survey data from the NRLs was submitted through the on-line system. The reports contain a detailed epidemiological analysis of all results. An epidemiological working group for wild bird surveillance continues to function under the chairmanship of epidemiologists of the CRL.	
<b>3.0 NETWORKING</b>	+++
Have the coordination activities carried out by CRLs been satisfactory?	
<b><i>3.1 Activities carried out to ensure harmonisation of diagnostic methods.</i></b>	+++
The CRL is very active in harmonising diagnostic methods for AI and a lot of effort is directed into this activity, especially during the annual meeting for representatives of NRLs, organised by the CRL. The results obtained with new tests being validated are discussed with a special group of test consultants who assess the data. After approval the methodology is submitted for accreditation. The next step is to inform the NRLs about the new test and include it in a “ring” test.	
<b><i>3.2 Coordination with national reference laboratories.</i></b>	+++
Coordination with NRLs takes place at different levels, by organising the ring trials, the annual meetings, and trainings, either at the CRL or in the EU MS requesting training, as described above.	
<b><i>3.3 Regular consultation to the Commission on these coordination activities.</i></b>	+++
The CRL has frequent contact with the Commission, in organising and coordinating the annual meeting of NRLs, and subsequent reporting and follow up. Since 2005 all the presentations and outputs of the meeting are placed on the Commission website.	
<b><i>3.4 Exchange of information with other international reference laboratories.</i></b>	+++
The CRL is a proactive member of the OFFLU network which promotes information and collaboration in the veterinary sector through OIE and FAO reference laboratories. The list of publications by staff in the CRL in journals, contributions to meetings and conferences, text books and manuals is impressive. Many papers have appeared in peer reviewed journals e.g. Avian Pathology, Veterinary Microbiology, Archives of Virology, etc. In addition, senior staff in the CRL have written key chapters on AI and ND in the OIE “Manual of Diagnostic Tests and Vaccines for Terrestrial Animals published by the World Organisation for Animal Health 2008, 6th Edition.  The network with other CRLs is less well developed and there has been a lack of networking with other CRLs to establish best practice.	
<b>4.0 QUALITY ISSUES (including accreditation)</b>	+++
<b><i>4.1 Have suitably qualified staff with adequate training in diagnostic tests?</i></b>	+++
The CRL is part of the Avian Virology Group headed by Dr Ian Brown. Avian Virology, Mammalian Virology and Rabies and Wild Life Zoonoses are all departments within the Virology Department. This Department is part of the VLA which has around 1250 employees. Training is	

Main findings - CRL for AI	Rating
an important activity.	
<b>4.2 Application of the necessary analytical techniques in their area of competence.</b>	+++
The Quality Manager of the Virology Group is responsible to the VLA Group Quality Manager. Avian Virology has 3 Quality Liaison Officers (Deputies) who are responsible for managing the quality system within the Group.	
<b>4.3 Apply diagnostic methods of satisfactory quality and in line with EC requirements.</b>	+++
UKAS accreditation requires that the laboratory maintains an up-to-date quality manual (QM) – a copy of which was provided by the CRL with the documents for the evaluation. The QM describes the policy, organisation and structure of all the laboratories and the departments at the VLA. Descriptions for the CRL are given for the tests performed, the organisation, administration, the staffing and direction, facilities and equipment, policies and procedures, staff development and education, IQA and EQA, etc. Technical data (SOPs, etc.) are managed by the Virology Quality Manager and her Deputies.	
<b>4.4 Accreditation</b>	++
The CRL is internationally accredited (BS EN ISO/IEC 17025) by UKAS under accreditation number 1769. All CRL tests are accredited, including three molecular tests. UKAS inspection takes place once a year. The SOPs are standardised and clear for the reader.	

### 3.2.2. CRL for Newcastle Disease

Main findings - CRL for ND	Rating
<b>Overall evaluation of the fulfilment of the duties and tasks established in the legislation</b>	++
The CRL is fulfilling all of its contractual duties, responsibilities and obligations as specified in Annex VII of Council Directive 2005/94/EC.	
The CRL is part of the Virology Department of the Veterinary Laboratories Agency (VLA) and as such has many similarities with the CRL for AI, which is in the same Department. Many of the activities are similar and performed by the same staff.	
It should be noted that plans have been made to upgrade the facilities for the CRL for ND and these should be available and in operation within a few years.	
<b>1.0 DIAGNOSIS AND ASSISTANCE</b> Has the assistance of CRLs to other laboratories been adequate in order to improve diagnostic of animal diseases in the Community?	++
<b>1.1 Activities and methods used by CRLs to ensure the correct diagnosis of animal diseases by National Reference Laboratories.</b>	+++
The diagnostic methods used in the laboratories are EU and/or OIE approved methods and of high standard. Results of PCR and HI tests are available within 24 hours of the receipt of a sample. All other tests are usually completed and reported within 72 hours. The SOPs are standardised and clear for the reader (including junior staff who are trained and supervised until they have demonstrated their competency).	
<b>1.2 Ring trails carried out and assessment of their effectiveness.</b>	+++
The CRL is responsible for organising proficiency tests and this is done once a year prior to the annual meeting which is a combined with the meeting of the NRL's for AI. The ring test includes	

<b>Main findings - CRL for ND</b>	<b>Rating</b>
<p>serology as well as molecular methods (PCR). Currently, reagents for the annual proficiency panel are distributed to over 40 countries, including many third countries.</p> <p>The results obtained are classified as unsatisfactory, satisfactory or fully correct. Most NRLs achieve satisfactory results or even fully correct results (about 87 % of NRLs). The data is collated and presented at the combined annual meeting of the CRLs. The results are also presented in the proceedings and on the EC website.</p> <p>In the case of NRLs whose results are below the acceptable level of proficiency the CRL endeavours to resolve these by direct dialogue or by offering training.</p> <p>Every year the CRL issues a questionnaire to laboratories concerned with collecting data on use of tests and the number of tests conducted in relation to both diagnosis and surveillance.</p>	
<b><i>1.3 Development of new diagnostic tools by the CRLs.</i></b>	++
A specific and sensitive NDV real time RT-PCR method based on the L gene has been developed and validated by the CRL and the method will be distributed to all NRLs participating in an inter-laboratory comparison exercise in 2009. However, this development arrives late, because several CVOs reported that development of molecular tool has been slow, and the CRL should have been more pro active in this regard.	
<b><i>1.4 Supply of diagnostic tools to other laboratories.</i></b>	+
There are not yet harmonised molecular techniques, only virological and serological methods. More effort is required by the CRL to promote harmonized molecular methods. This issue was also raised by several CVOs in the CVO survey.	
<b><i>1.5 Assistance to other laboratories for diagnosis in case of an outbreak.</i></b>	+++
<p>The CRL provides seven days a week/18 hours per day support to MS and high priority is given to ensuring that all laboratory results are dispatched to submitters in less than one working day following completion of laboratory analysis.</p> <p>In dealing with emergencies in relation to disease outbreaks, if services are lacking within a MS (i.e. particular techniques or tools) that are critical from a disease control perspective, these are given the highest priority.</p>	
<b>2.0 TRAINING</b>	++
Has the training carried out by the CRLs been sufficient to improve the diagnosis of animal diseases during the last 15 years?	
<b><i>2.1 The evaluators shall analyse the activities carried out for training and retraining of experts and staff (courses, documents).</i></b>	++
<p>Training is provided at the CRL for an average of 1 or 2 scientists/technicians from MS and 5 trainees from 3 or 4 third countries per year. Each training course is accompanied by a workshop manual/CD which is provided to each trainee and includes all the protocols and copies of presentations provided during the training.</p> <p>Workshops normally have heavy emphasis on practical opportunity, but are interspersed with key lectures and the conclusion of each workshop is always in the form of a specific proficiency panel conducted by each trainee. Certificates are provided at the end of the workshop to trainees, assuming satisfactory performance in proficiency testing.</p> <p>Workshops at which training in PCR or conventional diagnostic methods is given are held once or twice per year at the CRL. However, several CVOs reported that dedicated ND trainings were not given, and ND training therefore is requires particular attention from the CRL.</p>	
<b><i>2.2 Are these training activities sustainable in the long term?</i></b>	+



<b>Main findings - CRL for ND</b>	<b>Rating</b>
The UK Department for Environment, Food and Rural Affairs (DEFRA) provides around 36% of the annual budget of the CRL and so should DEFRA change its priorities the viability of the CRL could be seriously threatened. There is some risk of marginalising ND generally due to the focus on AI. Thought should be given to the idea of moving to a multi-annual budgeting process.	
<b><i>2.3 The evaluators shall also assess the activities carried out to provide scientific advice and expertise as regards disease surveillance and controls.</i></b>	+
The CRL has provided input to simulation exercises on AI/ND. However attention from MS is modest, and the Commission is urged to encourage MS to be more proactive and engage with their competent veterinary authority about being involved in simulation exercises.	
<b>3.0 NETWORKING</b> Have the coordination activities carried out by CRLs been satisfactory?	++
<b><i>3.1 Activities carried out to ensure harmonisation of diagnostic methods.</i></b>	++
The CRL is active in harmonising diagnostic methods for ND and effort is directed into this activity, especially during the annual meeting for representatives of NRLs, organised by the CRL. The results obtained with new tests being validated are discussed with a special group of test consultants who assess the data. After approval the methodology is submitted to UKAS for accreditation. The next step is to inform the NRLs about the new test and include it in a “ring” test. A comment from the CVO survey was that the joint AI/ND annual meeting placed more emphasis on AI, and similarly with training. Also CVOs mention that the CRL does not have a good reputation for sharing strains (also the CRL for AI).	
<b><i>3.2 Coordination with national reference laboratories.</i></b>	++
Staff from the CRL have supported simulation exercises and provided expert advice in support to the development of contingency plans at both the national and laboratory level in the UK and several other MS in recent years. In addition, specific missions of support have been provided to member and third countries in relation to dealing with on-going outbreaks of ND.	
<b><i>3.3 Regular consultation to the Commission on these coordination activities.</i></b>	++
The CRL, in conjunction with DG SANCO, organises and coordinates the annual meeting of NRLs. Since 2005 all the presentations and outputs of the meeting are placed on the Commission website.	
<b><i>3.4 Exchange of information with other international reference laboratories.</i></b>	++
Through its recognition as a reference laboratory, VLA has worked closely with other institutes across the globe to promote common standards of harmonisation, reagent exchange, resolving technical problems in diagnosis and surveillance and providing disease consultancy.  Senior staff in the CRL have written key chapters on AI and ND in the OIE “Manual of Diagnostic Tests and Vaccines for Terrestrial Animals published by the World Organisation for Animal Health 2008, 6th Edition.  Lack of networking with other CRLs to establish best practice. There is no provision for Directors of CRLs to meet to share experiences.	
<b>4.0 QUALITY ISSUES (including accreditation)</b>	++
The CRL quality assurance standards are in line with the recommended IEC/ISO 17025:2205 standard.	
<b><i>4.1 Have suitably qualified staff with adequate training in diagnostic tests?</i></b>	++
The CRL is part of the Avian Virology Group headed by Dr Ian Brown. Avian Virology, Mammalian Virology and Rabies and Wild Life Zoonoses are all departments within the Virology Department. This Department is part of the VLA which has around 1250 employees. Training is	

Main findings - CRL for ND	Rating
an important activity, but is less developed for ND.	
<b>4.2 Application of the necessary analytical techniques in their area of competence.</b>	++
The Quality Manager of the Virology Group is responsible to the VLA Group Quality Manager. Avian Virology has 3 Quality Liaison Officers (Deputies) who are responsible for managing the quality system within the Group.	
<b>4.3 Apply diagnostic methods of satisfactory quality and in line with EC requirements.</b>	++
UKAS accreditation requires that the laboratory maintains an up-to-date quality manual (QM) – a copy of which was provided by the CRL with the documents for the evaluation. The QM describes the policy, organisation and structure of all the laboratories and the departments at the VLA. Descriptions for the CRL are given for the tests performed, the organisation, administration, the staffing and direction, facilities and equipment, policies and procedures, staff development and education, IQA and EQA, etc. Technical data (SOPs, etc.) are managed by the Virology Quality Manager and her Deputies.	
<b>4.4 Accreditation</b>	++
The VLA is internationally accredited (BS EN ISO/IEC 17025) by UKAS under accreditation number 1769. All tests used by the CRL are accredited, including three molecular tests. UKAS inspection takes place once a year. The SOPs are standardised and clear for the reader.	

### 3.2.3. CRL for Bluetongue

Main findings - CRL for BT	Rating
<b>Overall evaluation of the fulfilment of the duties and tasks established in the legislation</b>	+++
The CRL is fulfilling all of its contractual duties, responsibilities and obligations as specified in Annex VII of Council Directive 2000/75/EC.	
<b>1.0 DIAGNOSIS AND ASSISTANCE</b> Has the assistance of CRLs to other laboratories been adequate in order to improve diagnostic of animal diseases in the Community?	+++
<b>1.1 Activities and methods used by CRLs to ensure the correct diagnosis of animal diseases by National Reference Laboratories.</b>	+++
Diagnostic methods used in the CRL for BT diseases are described in EU standards and in OIE diagnostic manuals. Over the years, the NRLs have significantly improved their BT diagnostic skills. Hence, the role of the CRL for BT is increasingly to provide confirmatory diagnosis.	
<b>1.2 Ring trails carried out and assessment of their effectiveness.</b>	+++
Over the past 4 years the CLR has sent out 5 panels of samples for proficiency testing. All the NRLs for EU Member States have taken part in the studies. When BTV came to northern Europe in 2006 many NRLs did not have BT diagnostic tests in place. The organisation of these proficiency tests has enabled nearly all EC countries to develop BT diagnostic facilities in their labs. Annual meetings have been held in Brussels for the last three years. Proficiency panel test results were communicated at these meetings through a presentation and dissemination of a booklet containing all the results and analysis. NRLs were invited to present information regarding the BTV situation in their country, updates on diagnostic assays etc and these presentations are collated and added to the booklet. A final report of the meeting was written and distributed to NRLs.	
<b>1.3 Development of new diagnostic tools by the CRLs.</b>	+++

<b>Main findings - CRL for BT</b>	<b>Rating</b>
A sudden top priority occurred at the event of the unexpected BTV-8 outbreak in northern Europe in 2006, when the need for a quick confirmatory diagnosis became apparent, that had to be quicker than the time consuming OIE prescribed serum neutralisation test (SNT). The CRL for BT responded prompt by adopting the real time BT-specific PCR (required time 24-48 hours) that was already developed by the bluetongue research group. Real-time RT-PCR assay is not yet adopted by the OIE. The EU CRL for BT therefore has proven to be capable to introduce quick, new tests in the EU NRL network, while takes more time for the OIE to adopt the test. This illustrates that the CRL and NRL network of laboratories is an efficient network of laboratories fully capable of harmonising and modernising the diagnosis of notifiable diseases across Europe by its own merit.	
<b><i>1.4 Supply of diagnostic tools to other laboratories.</i></b>	++
There was varying number of request to supply viruses. Between 2004-2009 there were 1-12 requests for strains per year from MS, 1-3 from TCs and 1-2 from industry. In addition some 50 shipments are organized each year for the ring trials. Recently laboratories have been requesting antiserum to all 24 serotypes of BTV for setting up SNT. Some laboratories have asked for greater than 10 ml of each antiserum. The CRL is unable to supply these large volumes as characterised stocks are limited and expensive to reproduce. Requests have been met with a full explanation and the supply of 1-2ml of each of the antisera free of charge, with an understanding that the receiving laboratory will produce and characterise their own reference antiserum once the SNT is established as a method in their laboratory. The majority of the antisera the CRL sends can be used at dilutions greater than 1/32 therefore 1 ml should serve a NRL a significant amount of time. Some requests for viruses could not be responded to because the laboratories proved unable to handle live BTV, and subsequently alternatives were used whenever possible such as supply of non infectious RNA. Over the years the biosecurity regulations at IAH have become stricter and the rules for supplying strains and antigens to other laboratories have become more stringent as well. The CRL is not able to supply infectious agents to laboratories if they are not accredited at a sufficient biosecurity level and the process of gaining approval for sending samples has lengthened over the years. In terms of responsiveness to requests, the CRL replies quickly to all requests, however often laboratories do not appreciate the paperwork that is required to supply reagents. Biosecurity regulations set out by DEFRA are very strict, and sometimes licences do take a month to be granted which slows response time.	
<b><i>1.5 Assistance to other laboratories for diagnosis in case of an outbreak.</i></b>	+++
The CRL has characterised approximately 150 isolates/strains in the last 4 years. Many of these were from Europe (BTV-8) but also included multiple strains from Israel, USA, North Africa and India. The CRL assisted many MS countries and third countries during outbreaks. Examples are the following: in 2006, the CRL confirmed the presence of BTV-8 in the Netherlands, Belgium and Germany, and BTV-16 and BTV-8 in Greece in 2008-2009.  In 2008 the diagnosis of BTV and serotype identification by serology and real-time RTPCR was performed for Slovenia, Czech Republic, Switzerland, Netherlands, Cyprus, Denmark, Hungary, Sweden, Austria, Libya, Greece, Algeria, Estonia, Israel, and Belgium. The CRL also identified the presence of BTV-6 and BTV-11 in various countries in northern Europe in 2008.	
<b>2.0 TRAINING</b> Has the training carried out by the CRLs been sufficient to improve the diagnosis of animal diseases during the last 15 years?	+++
<b><i>2.1 The evaluators shall analyse the activities carried out for training and retraining of experts and staff (courses, documents).</i></b>	+++
The CRL for BT has very well structured its trainings, and the data are prepared ell in advance. In the most recent years courses and programmes have been structured in a way to meet the increasing demand for training. Since 2007, a two-week training course is organised every year at the CRL, and announced on the CLR website ( <a href="http://www.iah.ac.uk/events/transbo.shtml">www.iah.ac.uk/events/transbo.shtml</a> ). Six participants attended in 2007 and in 2008. Beyond these, 'ad hoc' training courses are organised, as well specific courses for TCs, with approximately 5-10 scientists/technicians from MS trained per year. Other examples of training provided include: July 2008: training of 20 scientists; training of 5 members African Reference	

<b>Main findings - CRL for BT</b>	<b>Rating</b>
Laboratory. The CRL also provides individual training in the MS countries requiring so.	
<b>2.2 Are these training activities sustainable in the long term?</b>	+++
The CRL has structured its trainings and operates it with admission fees. This provides a financial basis, supported by Sanco and DEFRA funding.	
<b>2.3 The evaluators shall also assess the activities carried out to provide scientific advice and expertise as regards disease surveillance and controls.</b>	+++
The Laboratory maintains reference collections and sequence databases, which enables the identification of the origin of the viruses (e.g. the origin of 2006 outbreak in Europe was recognised as coming from West Africa). The sequence comparison database can be accessed directly and used by the NRLs via a dedicated website.	
<b>3.0 NETWORKING</b>	+++
Have the coordination activities carried out by CRLs been satisfactory?	
The staff of the CRL for BT is internationally very active in scientific networks, also because the EU CRL for BT is a regional OIE Reference lab for BT. For example the head of the CRL for BT attended and presented at the first meeting of the OIE Bluetongue Reference labs Network held in Italy in May 2007 and also attended and presented at the meeting of the 2nd Meeting of OIE Bluetongue Network (1-2 June 2009, Cerrano, Teramo, Italy). Representatives of all the OIE Bluetongue Reference labs attended both the meetings and have started up a network of OIE Ref Labs with the agreement of all the OIE Reference labs. As such, the network expands towards many African countries, and samples are also sent by African countries to the CRL. The CRL staffs also make BT information public via ProMED, an acknowledged international email service on transboundary infectious diseases. Data on new strains are only published on ProMED with the agreement from the relevant laboratory. The networking can be considered as more than adequate. For dissemination of knowledge, intra-EU and elsewhere, the CRL employs several websites. For dissemination of knowledge, intra-EU and elsewhere, the CRL employs several websites; <a href="http://www.iah.ac.uk">www.iah.ac.uk</a> – public website of the Institute for Animal Health with information about the research carried out at IAH and the reference labs; <a href="http://www.bluetonguevirus.org">www.bluetonguevirus.org</a> – website with limited access for NRL members; <a href="http://www.culicoides.net/culicoides">www.culicoides.net/culicoides</a> - public information website on all aspects of culicoides biology including ecology and surveillance, taxonomy and general information; <a href="http://www.reoviridae.org/dsRNA_virus_proteins/ReoID/viruses-at-iah.htm">www.reoviridae.org/dsRNA_virus_proteins/ReoID/viruses-at-iah.htm</a> - public website for the Bluetongue and related Orbivirus Reference collection. These are very valuable sources of information.	
<b>3.1 Activities carried out to ensure harmonisation of diagnostic methods.</b>	+++
The CRL is very active in harmonising diagnostic methods for BT and a lot of effort is directed into this activity, especially during the ring trials and subsequent annual meeting for representatives of NRLs, organised by the CRL, as described above.	
<b>3.2 Coordination with national reference laboratories.</b>	+++
Coordination with NRLs takes place at different levels, by organising the ring trials, the annual meetings, and trainings, either at the CRL or in the MS requesting training, as described above. There is an issue however about the ownership and rights of the strains submitted and resulting sequence data. This has led to some contractual arrangements with some NRLs, but there is no generally accepted guideline that works in practice. Over the years, the NRLs have significantly improved their BT diagnostic skills. Hence, the role of the CRL for BT is increasingly to provide confirmatory diagnosis. An issue is that the CRL for BT has difficulties to identify properly all EU MS laboratories relevant for BT diagnosis, because in several countries more than one laboratory is involved in NRL tasks. It was not possible for the CRL to obtain unambiguous information of the NRL laboratories and relevant contact persons of some EU countries.	
<b>3.3 Regular consultation to the Commission on these coordination activities.</b>	+
There is regular contact with the Commission, in line with the epidemiological evolution of the disease. However, the in order to obtain an updated list of NRLs and their contact persons, more support of the Commission is needed. Furthermore, there are no meetings organised with the DG	

<b>Main findings - CRL for BT</b>	<b>Rating</b>
SANCO officer, other than the annual meeting, which does not really allow for enough time to discuss. Setting up a regular meeting with the Commission would be very much welcomed. Another need expressed is to have an emergency number at the Commission.	
<b>3.4 Exchange of information with other international reference laboratories.</b>	++
The EU CRL for BT is itself an OIE Reference lab for BT, and it has good contacts with other laboratories working on BT particularly in Europe and Africa. Contacts with other CRLs are scarce. This does not so much impair the effectiveness of the CRL but it could impair sharing of best practices and harmonisation of actions across the EU CRL system. More coordination by the Commission is needed on this: the setting up of a coordination body within the Commission would be supported.	
<b>4.0 QUALITY ISSUES (including accreditation)</b>	++
<b>4.1 Have suitably qualified staff with adequate training in diagnostic tests?</b>	+++
The CRL has a very high calibre of staff, who also participates in research activities.	
<b>4.2 Application of the necessary analytical techniques in their area of competence.</b>	++
Molecular techniques have become more important over the years, for which the CRL staff has excellent competences, backed by IAH researchers.	
<b>4.3 Apply diagnostic methods of satisfactory quality and in line with EC requirements.</b>	++
As mentioned above, the diagnostic methods used in the CRL for BT diseases are described in EU standards and in OIE diagnostic manuals.	
<b>4.4 Accreditation</b>	++
The CRL and all the BT assays used are accredited by the United Kingdom Accreditation Service (UKAS) ISO 9001, and the CRL obtained the accreditation in April 2007.	

### 3.2.4. CRL for African Horse Sickness

<b>Main findings - CRL for AHS</b>	<b>Rating</b>
<b>Overall evaluation of the fulfilment of the duties and tasks established in the legislation</b>	+
The evaluators found a number of areas of underperformance, most particularly with regard to training and networking, where improvement is required. This is not due to professional inadequacy or insufficient technical skills. The problems have now been largely overcome due to the provision of new laboratory facilities and there is every reason to expect improved performance of the CRL for AHS in the near future.  Taking these factors into account, the evaluators are able to conclude that the CRL is fulfilling all of its contractual duties, responsibilities and obligations as specified in Annex III of Council Directive 92/35/EEC of 29 April 1992 laying down control rules and measures to combat African horse sickness. However, the rating shows that it is a borderline case.	
<b>1.0 DIAGNOSIS AND ASSISTANCE</b> Has the assistance of CRLs to other laboratories been adequate in order to improve diagnostic of animal diseases in the Community?	++
<b>1.1 Activities and methods used by CRLs to ensure the correct diagnosis of animal diseases by National Reference Laboratories.</b>	++

<b>Main findings - CRL for AHS</b>	<b>Rating</b>
<p>The CRL for AHS is included in the structure of the Laboratorio Central De Veterinaria (LCV), which belongs to the Ministry for Environment, Rural and Marine Affairs (MARM). Diagnostic methods used in the CRL for AHS are described in the OIE diagnostic manual. The detection of AHS virus is performed by real-time RT-PCR and conventional RT-PCR. An antigen capture ELISA is also available. Serotyping of AHS virus isolates can be performed by a conventional RT-PCR in which RT-PCR amplification of the serotype-specific genome segment 2 is performed. Virus neutralization could also be used for serotyping but this procedure is much more time consuming than RT-PCR methods.</p> <p>A blocking-ELISA is used for the detection of antibodies to AHS virus. The assay uses a VP7 recombinant protein and a monoclonal antibody against the VP7. Serum neutralisation tests are also available for the 9 serotypes of AHS virus; using reference sera and BHK-21 cell cultures. Therefore, the CRL has the capability to perform the range of tests that are recommended by OIE for AHS diagnosis and for surveillance.</p>	++
<b><i>1.2 Ring trails carried out and assessment of their effectiveness.</i></b>	++
<p>The CRL organises the annual meeting of NRLs and collaborates with OIE Reference Laboratories for AHS. Proficiency tests for NRLs have been held on 5 occasions; during the years 2000, 2001, 2004, 2006 and 2008. The CRL started doing proficiency testing for PCR in 2006. At that time all the MS NRLs that had PCR used conventional PCR techniques, and few had PCR facilities in any case. In 2008 the inter-laboratory comparative tests were focused on serological investigations and determination of the genome of the AHS virus by RT-PCR. A total of 14 NRLs participated in the PCR test in 2008 (13 EU plus Morocco); in 2006 it was only 7.</p> <p>Additional related work in this domain has been undertaken more recently to harmonise RNA extraction, by explaining to NRLs which techniques worked better with AHS (2008 meeting), and/or sending extracted RNA to NRLs so as to avoid differences with extraction techniques affecting results (2009 Ring Trial); to continue inactivating viruses; this work has been more complex than initially foreseen, but the CRL aim to continue so that only inactivated viruses are sent to MS as is currently the case. This is considered as evidence of effectiveness of the ring trials.</p>	++
<b><i>1.3 Development of new diagnostic tools by the CRLs.</i></b>	++
<p>In 2000, the CRL for the first time performed an inter-laboratory proficiency testing for the use of ELISAs, on the basis of an ELISA that was validated in 1998. Following this testing and a meeting with the Commission to discuss results, it was decided in 2002 to modify the relevant legislation (Annex D to Council Directive 90/426/EEC), to introduce ELISA as the prescribed serological test (to replace Complement Fixation which was commonly used until then). More recently the ELISA has been adjusted to improve its consistency throughout the EU and the CRL intends to do a ring trial this year to test the new version.</p> <p>Currently, a real time RT-PCR is being developed that will allow a more rapid identification than currently based on Taqman probes for 3 serotypes (2, 4 and 9).</p>	++
<b><i>1.4 Supply of diagnostic tools to other laboratories.</i></b>	++
<p>There were limited request to supply viruses. However when requests were obtained they have been responded to. MS which have been provided with diagnostic reagents for AHS are Belgium (2005); Czech Republic (2008), Poland and Portugal (2009).</p>	++
<b><i>1.5 Assistance to other laboratories for diagnosis in case of an outbreak.</i></b>	++
<p>Due to the lack of outbreaks, of AHS, the CRL has received no requests from EU MS to investigate suspected cases of AHS during the last 15 years.</p>	+
<b>2.0 TRAINING</b>	+
<p>Has the training carried out by the CRLs been sufficient to improve the diagnosis of animal diseases during the last 15 years?</p>	+
<b><i>2.1 The evaluators shall analyse the activities carried out for training and retraining of experts and staff (courses, documents).</i></b>	+
<p>Accommodation in the present laboratory is limited and so in recent years only two scientists have been accepted for in-house training. These have included scientists from Austria (2004) and Morocco (2008) who both received training in viral and molecular diagnosis. The CRL plans to</p>	+

<b>Main findings - CRL for AHS</b>	<b>Rating</b>
hold a joint workshop with IAH, Pirbright, OIE Reference Laboratory for AHS, in 2010.	
<b>2.2 Are these training activities sustainable in the long term?</b>	+
The training activities of the CRL for AHS need to be increased to be sustainable in the long term.	
<b>2.3 The evaluators shall also assess the activities carried out to provide scientific advice and expertise as regards disease surveillance and controls.</b>	++
Although AHS poses a risk to EU MS, no outbreaks have so far been notified, and hence little or no surveillance activities employed in EU MS with the exception of Spain where an active programme of surveillance for AHS is carried out with regional laboratories in the 17 autonomous regions (see below).	
<b>3.0 NETWORKING</b>	+
Have the coordination activities carried out by CRLs been satisfactory?	
The CRL has contacts with NRLs mainly for the organisation of ring trials and annual meetings. The CRL, which is also an OIE Reference Laboratory for AHS, has further established a system of surveillance and control for AHS in Morocco and neighbouring countries with the Reference Laboratory for AHS in Casablanca, Morocco. The CRL is in regular communication with the regional laboratories in the 17 autonomous regions of Spain; in total around 55 laboratories. From the CVO survey and from stakeholders it was mentioned that the network of the CRL for AHS is more regional oriented, and should be more developed across Europe to better serve MS.	
<b>3.1 Activities carried out to ensure harmonisation of diagnostic methods.</b>	++
The CRL is active in harmonising diagnostic methods for AHS and a lot of effort is directed into this activity, especially during the ring trials and subsequent annual meeting for representatives of NRLs, organised by the CRL, as described above.	
<b>3.2 Coordination with national reference laboratories.</b>	+
The CRL for AHS has most of its contacts in the region, and less with other NRLs, except for the CRL for BT. Coordination with NRLs takes place at different levels, by organising the ring trials, the annual meetings, and, although in a low frequency, at trainings, either at the CRL or in the MS requesting training, as described above.	
<b>3.3 Regular consultation to the Commission on these coordination activities.</b>	+
There is contact with the Commission, in line with the epidemiological evolution of the disease. However, the contacts are considered too scarce.	
<b>3.4 Exchange of information with other international reference laboratories.</b>	+
The EU CRL for AHS is itself an OIE Reference lab for AHS, and it has established contact with the Reference Laboratory for AHS in Casablanca, Morocco. Contacts with other CRLs are scarce, and more coordination by the Commission is needed. The setting up of a coordination body within the Commission would be supported.	
<b>4.0 QUALITY ISSUES (including accreditation)</b>	++
<b>4.1 Have suitably qualified staff with adequate training in diagnostic tests?</b>	++
The CRL has a high calibre of staff, who also participates in research activities.	
<b>4.2 Application of the necessary analytical techniques in their area of competence.</b>	++
The CRL has chosen diagnostic work as its major priority with research as a secondary role. Research is supported by an inter-laboratory agreement with CISA, which has been formalised since 2008 by a Specific Agreement. In the near future this will be done by a Royal Decree and regular personal contacts with the research staff in CISA (there have been some key staff transfers from CISA to the LCV and vice versa in recent years). The LCV has, nevertheless, contributed to applied research, e.g. by developing tools for BT diagnosis through its own PCR department.	
<b>4.3 Apply diagnostic methods of satisfactory quality and in line with EC requirements.</b>	+

<b>Main findings - CRL for AHS</b>	<b>Rating</b>
As mentioned above, the diagnostic methods used in the CRL for AHS diseases are described in OIE diagnostic manuals. The accreditation implies that the CRL has a quality manual (QM). The QM describes the laboratory policy, organisation and structure of the laboratories and departments within the CRL.	
<b>4.4 Accreditation</b>	+
The LCV has been accredited to ISO standard 17025 since January 2009. Accreditation was certified by the National Accreditation Organisation (Entidad Nacional de Acreditacion; ENAC). The quality system applies to the laboratories, staff and equipment but not the tests employed in the CRL. However, SOPs have been prepared for these and they will be submitted to ENAC in September 2009. There is no accreditation for performing ring trials.	

### 3.2.5. CRL for Swine Vesicular Disease

<b>Main findings - CRL for SVD</b>	<b>Rating</b>
<b>Overall evaluation of the fulfilment of the duties and tasks established in the legislation</b>	++
The CRL is fulfilling all of its contractual duties, responsibilities and obligations as specified in Council Directive 1992/119/EEC laying down specific provisions for the control and the eradication of swine vesicular disease (OJ L 62 of 15.3.1993), as amended.	
<b>1.0 DIAGNOSIS AND ASSISTANCE</b> Has the assistance of CRLs to other laboratories been adequate in order to improve diagnostic of animal diseases in the Community?	++
<b>1.1 Activities and methods used by CRLs to ensure the correct diagnosis of animal diseases by National Reference Laboratories.</b>	++
The CRL for Swine vesicular disease is part of the Institute for Animal Health, based at the Pirbright, UK. The CRL for SVD uses the following prescribed tests according to the OIE guidelines: antigen ELISA, virus isolation, real-time RT-PCR, and performs sequencing and phylogenetic analysis. For serology, the CRL uses the 5B7 Mac ELISA and virus neutralisation test that both are prescribed in the OIE guidelines. In addition, the CRL uses isotype-specific ELISAs for specific purposes, which are in-house standards.	
<b>1.2 Ring trails carried out and assessment of their effectiveness.</b>	++
The CRL for SVD has organized proficiency tests (PTs) at Community level 12 times in total (in 1995/1996, 1998, 2000, and then every year since 2001). Presentations are given at the annual NRL meetings, the reports of the NRL meetings are placed on the CRL website for FMD, since the PTs are during the last years organised jointly with the FMD meetings. Feed-back letters following each PTS round are sent to each laboratory (since 2006). The results from the most recent PT showed that the all EU MS performed the SVD tests up to the standard. Information dissemination on the disease, new strains, and diagnostic tests is organised as follows: questionnaires are circulated with the PT panels, and presentations on the results are made at the annual NRL meetings. Subsequently, the information is included in the Proceedings of the NRL meetings, and put on a secured website. Also, since 2006 feedback letters are sent to each laboratory after each proficiency test.	
<b>1.3 Development of new diagnostic tools by the CRLs.</b>	++
A new test development for SVD (and also for FMD) is the availability of on-site tests, based on the principle of lateral flow, developed by the IAH and funded by DEFRA. Using this device, a preliminary diagnosis can be performed in the field, for instance on the farm. This would then have to be followed by a confirmatory diagnosis in an NRL.	



<b>Main findings - CRL for SVD</b>	<b>Rating</b>
The possibilities of using this method in the field are under discussion.	
<b><i>1.4 Supply of diagnostic tools to other laboratories.</i></b>	++
The CRL has received limited numbers of requests to supply SVD strains or test reagents. For example, the last years the following requests were responded to: 4 strains in 2005; 1 strain in 2007; 9 strains in 2007 and 1 strain in 2009. The response time is reported as 4 weeks on average but is dependent upon how rapidly the consignee sends the CRL the correct documentation to facilitate an application and how quickly this application is processed through the external system. For the CRL, this process necessitates documentation to be submitted via the Biosecurity Officer to the Ministry of Agriculture (Defra) for a virus transfer licence, and subsequently it is dependent upon how quickly Defra responds to the application for authorisation of movement of the material, and may be significantly longer than 4 weeks. This has occasionally led to complaints.	
<b><i>1.5 Assistance to other laboratories for diagnosis in case of an outbreak.</i></b>	++
The CRL for SVD receives relatively low numbers of samples from NRLs. This is due to the limited number of (suspected) outbreaks, but may also be due to under reporting. The CRL does not receive strains from all outbreaks in the EU. Notably from Italy, that has a well equipped and up-to date NRL for SVD, that is also OIE RL for SVD, and despite the collegial relations, new SVD strains are not routinely sent to the CRL for SVD in Pirbright for confirmation or inclusion in the SVD strain collection. For instance in 2008 Italy reported 64 SVD outbreaks, but no strains were received by the CRL for SVD for confirmation or characterisation. The CRL has no mandate or authority to impose this, and would be helped in this regard by support from SANCO. The CRL has received only a few strains from Portugal and Italy in recent times. The time needed to type the strain varied between 4 hours and 4 days, depending on the test used (antigen ELISA, or virus isolation and subsequent sequencing). The data on the strain collection are contained at the CRL laboratory, but this is not easy to disseminate at the moment but will become easier as a lot of work has gone into setting up a dedicated website for the CRL for SVD. The CRL has to date in total characterised 256 isolates of SVD, which represents >90% proportion of strains received. In addition the CRL website ( <a href="http://www.iah.ac.uk/research/diagvesdis/diavesdis.shtml">www.iah.ac.uk/research/diagvesdis/diavesdis.shtml</a> ) contains instructions and information on sample submission.	
<b>2.0 TRAINING</b> Has the training carried out by the CRLs been sufficient to improve the diagnosis of animal diseases during the last 15 years?	++
<b><i>2.1 The evaluators shall analyse the activities carried out for training and retraining of experts and staff (courses, documents).</i></b>	++
The CRL offers training on SVD as part of the annual FMDV training courses. An overview and training in SVDV detection methods is contained therein. The annual FMD/SVD trainings are attended by approximately 8 people per year from many EU MS and TCs. Also an exotic disease training module is offered by IAH Pirbright that includes SVD. Approximately 30 veterinarians per year attend the exotic disease training course at IAH Pirbright. In addition, ad hoc training is offered occasionally upon request as long as resources are available. The CRL SVD provides training material for these courses for related to SVD diagnosis and control.	
<b><i>2.2 Are these training activities sustainable in the long term?</i></b>	+++
The CRL has structured its trainings and operates it with admission fees. This provides a financial basis, supported by funding from the Commission and DEFRA.	
<b><i>2.3 The evaluators shall also assess the activities carried out to provide scientific advice and expertise as regards disease surveillance and controls.</i></b>	+
As described above, the CRL for SVD is not offered much possibility to provide scientific advice and expertise because in the region where most SVD outbreaks occur, this is dealt with by a state-of-the-art NRL that is also an OIE RL for SVD.	
<b>3.0 NETWORKING</b> Have the coordination activities carried out by CRLs been satisfactory?	+

<b>Main findings - CRL for SVD</b>	<b>Rating</b>
<p>CRL key staff are embedded in the IAH Research institute, and as such attending over the years of numerous international conferences and seminars, including as invited speaker for EU, FAO, OIE and WHO. Furthermore the CRL for SVD participates in the EPIZONE research network. Also scientific collaboration is maintained with OIE and FAO reference laboratories for SVD.</p> <p>The receipt and supply of strains and reference reagents, the organisation of the proficiency testing programmes and annual meetings, and participation in the FMD trainings, have provided the CRL for SVD a good intra-EU network. However, the CRL for SVD has apart from the organisation of the PT programmes and the annual meetings relatively little extra activities for intra-EU networking, due to the limited incidence and importance of SVD compared to FMD.</p> <p>Also, the availability of the highly qualified NRL and OIE RL for SVD in Brescia, Italy, in which country most of the SVD outbreaks have occurred over the last 15 years, does not require heavy diagnostic support from the CRL, although the further collaboration and information exchange is collegial. A minority of EU MS have not been very supportive to the CRL in sending strains for confirmation or attending the meetings. Apart from this, the networking as a whole can be considered as adequate for the particular circumstance for SVD disease, but needs improvement.</p> <p>The communication and collaboration with NRLs is in general good and positive.</p> <p>Remarkably, the correctness and up-to date keeping of the contact details seems an issue for SVD NRLs, as it is for other CRLs. EU MS are not always concerned about supplying correct or updated information on contact persons for SVD NRLs, and it costs much time for CRL staff to find this out. There is a need to better organise this in the future with some form of central coordination.</p>	++
<p><b>3.1 Activities carried out to ensure harmonisation of diagnostic methods.</b></p> <p>The CRL is active in harmonising diagnostic methods for SVD and a lot of effort is directed into this activity, especially during the proficiency tests and subsequent annual meeting for representatives of NRLs, organised by the CRL, as described above.</p>	++
<p><b>3.2 Coordination with national reference laboratories.</b></p> <p>Coordination with NRLs takes place at different levels, by organising the proficiency tests, the annual meetings, and trainings at the CRL, as described above.</p>	++
<p><b>3.3 Regular consultation to the Commission on these coordination activities.</b></p> <p>There is limited contact with the Commission, in line with the epidemiological evolution of the disease.</p>	++
<p><b>3.4 Exchange of information with other international reference laboratories.</b></p> <p>The CRL has several contacts for scientific collaboration is maintained with OIE and FAO reference laboratories for SVD.</p> <p>Contacts with other CRLs, except for FMD, are scarce, but this does not so much impair the effectiveness of the CRL rather than that it could lead sharing of best practices and harmonisation of actions across the EU CRL system. More coordination by the Commission is needed on this: the setting up of a coordination body within the Commission would be supported.</p>	++
<p><b>4.0 QUALITY ISSUES (including accreditation)</b></p>	++
<p><b>4.1 Have suitably qualified staff with adequate training in diagnostic tests?</b></p> <p>The CRL has a very high calibre of staff, who also participates in research activities.</p>	+++
<p><b>4.2 Application of the necessary analytical techniques in their area of competence.</b></p> <p>Molecular techniques have become more important over the years, for which the CRL staff has excellent competences, backed by IAH researchers. There is according to the accreditation rules a quality manager, who reports directly to CRL director.</p>	++
<p><b>4.3 Apply diagnostic methods of satisfactory quality and in line with EC requirements.</b></p> <p>As mentioned above, the diagnostic methods used in the CRL for BT diseases are described in EU</p>	++

<b>Main findings - CRL for SVD</b>	<b>Rating</b>
standards and in OIE diagnostic manuals. The accreditation implies that the CRL has a quality manual (QM). The QM describes the laboratory policy, organisation and structure of the laboratories and departments within the CRL. All tests are performed according to SOPs.	
<b>4.4 Accreditation</b>	++
The CRL is accredited according to ISO 9001 since 2001 by BIS (Business Innovation and Skills, UK). Accreditation to ISO 17025 was awarded by UKAS in December 2008 subject to finalisation of some minor issues currently in progress. All the SVD diagnostic tests applied are accredited according to ISO 17025 or ISO 9001. There is no accreditation to perform SVD proficiency tests.	

### 3.2.6. CRL for African Swine Fever

<b>Main findings - CRL for ASF</b>	<b>Rating</b>
<b>Overall evaluation of the fulfilment of the duties and tasks established in the legislation</b>	++
The CRL is fulfilling all of its contractual duties, responsibilities and obligations as specified in Annex V of Council Directive 2002/60/EC of 27 June 2002 laying down specific provisions for the control of African swine fever and amending Directive 92/ 119/EEC as regards Teschen disease and African swine fever.	
<b>1.0 DIAGNOSIS AND ASSISTANCE</b> Has the assistance of CRLs to other laboratories been adequate in order to improve diagnostic of animal diseases in the Community?	++
<b>1.1 Activities and methods used by CRLs to ensure the correct diagnosis of animal diseases by National Reference Laboratories.</b>	++
The tests used most often for ASF virus detection are: direct immunofluorescent (DIF); haemadsorption (HA) test; antigen (Ag)-ELISA and the detection of the viral DNA genome by the PCR method. The CRL for ASF uses porcine macrophage cultures for the isolation of ASF virus and tests for the presence of infected cells using porcine erythrocytes in a HA test. Isolates which produce a cytopathic effect without haemadsorption are identified using PCR or DIF test on sediments of the cell cultures. These tests are those recommended by OIE. The CRL for ASF recognises that the DIF and Ag-ELISA are acceptable for the diagnosis of acute forms of the disease but not recommended for chronic forms where antigen-antibody complexes can interfere and reduce the sensitivity of detection. A standardised “in house” OIE ELISA and a commercial ELISA, both of which have been validated by the CRL, are used for large-scale serological investigations. Confirmatory testing is done by an immunoblotting (IB) assay, an indirect immunofluorescent antibody (IFA) test or an immunoperoxidase test (IPT). Again, these methods are those recommended by OIE. The CRL has been active in employing these methods for surveillance programmes both for NRLs and third countries from 2003 - 2009.	
<b>1.2 Ring trails carried out and assessment of their effectiveness.</b>	++
Since 2003, when CISA-INIA started working as a CRL for ASF, it has promoted the harmonisation of ASF diagnostic techniques in the EU. Ring trials on ELISA have been performed each year since the CRL establishment. The majority of NRLs have been involved and a significant improvement in capability has been observed year by year. The CRL is of the opinion that most NRLs have the capability to use at least one validated antibody detection technique to perform the serological diagnosis of ASF. In addition, and as a result of different actions taken by the CRL, an increasing number of NRLs have incorporated new ASF serological	

<b>Main findings - CRL for ASF</b>	<b>Rating</b>
<p>diagnostic procedures with a significant number now having the capability to use the IB assay as a confirmatory test.</p> <p>In 2003 very few NRLs were using the ELISA but by 2009 all 22 NRLs that reported to the CRL in 2009 (of a total of 25) could perform this serological test without difficulty.</p> <p>While work on ELISA continues in order to understand the status quo of countries that do not report, the emphasis for proficiency testing has shifted to include the harmonisation of confirmatory serological tests, such the IB test.</p> <p>In the last two years significant improvement has also been made in the capability of NRLs to use the PCR method for the diagnosis of ASF. Despite this there is a small number of MS about which the CRL does not have information because they have never participated in ILCTs. One NRL recently informed the CRL that they have delegated ASF diagnosis to another NRL.</p> <p>At the EU level, the current situation is that around 75% of NRLs have the capability to perform the complete diagnosis of ASF; comprising both serological and at least one virus detection techniques.</p> <p>The ASF situation in the Caucasus region poses a risk for the EU and as the strains circulating there vary in virulence, with some causing subacute forms of the disease, recent priorities have included the objective that all NRLs should have PCR capability because it can identify animals infected with strains of ASF virus of low virulence. The PCR can also identify the different genotypes of ASF virus. Currently, a total of 20 laboratories in 18 MS can perform the PCR method. However, a shortcoming is that NRLs perform very different PCR techniques, and do not give final results. There is, therefore, a need to have more harmonisation of the technique and the interpretation of results. In addition, there is still a need to improve virus isolation, which is more difficult since it required cell culture capability.</p> <p>The majority of the progress made in harmonisation has been in Eastern Europe. In continuation of this the CRL intends to propose at the Annual Meeting of 2009 in June 17 a workshop at the end of 2009 on viral detection techniques.</p>	
<b><i>1.3 Development of new diagnostic tools by the CRLs.</i></b>	++
<p>The PCR method, based on conventional and real-time procedures has been used since 2002. This technique is recommended by the CRL as the method of choice for virus detection because its high sensitivity, specificity and robustness. The methods use primer pairs selected from a highly conserved region of the ASF viral DNA. A conventional procedure has been validated and published. Work is in progress to further develop and improve the real-time method. The CRL has employed PCR methods to characterise over 100 ASF virus isolates from several countries to improve the understanding of ASF epidemiology. These have included isolates from Italy (2004-2006), Kenya (2006-2007), Uganda (2007) and the Caucasus Region (2007-2008).</p>	
<b><i>1.4 Supply of diagnostic tools to other laboratories.</i></b>	++
<p>The CRL supplies regularly diagnostic tool to other laboratories. Between 2002-2008 every year tools were supplied to 5-10 countries, mostly in Europe and Africa, and occasionally to South America and China. Reagents supplied were antigen for ELISA, immunoblotting (IB) strips, ASF-positive reference serum, ASF-negative reference serum, FITC-Conjugate and others.</p>	
<b><i>1.5 Assistance to other laboratories for diagnosis in case of an outbreak.</i></b>	++
<p>The CRL has employed PCR methods to characterise over 100 ASF virus isolates from several countries to improve the understanding of ASF epidemiology. These have included isolates from Italy (2004-2006), Kenya (2006-2007), Uganda (2007) and the Caucasus Region (2007-2008). The CRL has provided assistance by the molecular characterization to clarify the epidemiological situation of ASF in Sardinia during the 2004/2006 outbreaks.</p> <p>Outside Europe, the CRL has performed the confirmatory diagnosis on samples received from suspected ASF outbreaks in different sub-Saharan African countries, where the disease is endemic since 1920. In each case, a diagnosis report has been sent to the head of the laboratories to confirm the presence of the disease.</p>	

<b>Main findings - CRL for ASF</b>	<b>Rating</b>
<p><b>2.0 TRAINING</b> Has the training carried out by the CRLs been sufficient to improve the diagnosis of animal diseases during the last 15 years?</p>	+++
<p><b>2.1 <i>The evaluators shall analyse the activities carried out for training and retraining of experts and staff (courses, documents).</i></b></p> <p>The CRL developed training over time. It has organised two training workshops on ASF for participants from the NRLs, accession countries and third countries. The first of these, held at the CRL, CISA-INIA, Valdeolmos, Madrid from 17- 19 October 2005, included 18 representatives from NRLs and 3 from non-EU countries. Training was focussed on virus isolation and the HA and IB tests.</p> <p>The second workshop, held at Valdeolmos from 11-15 December 2006, included 6 participants from NRLs in 3 MS. The training was on the virological and serological diagnostic techniques for ASF virus (PCR, virus isolation, HA, ELISA and IB).</p> <p>Individual training has also been provided for scientists from third countries e.g. Poland (2003), Russia (2006), Ivory Coast (2008) and to groups of scientists (EU and non-EU) under the auspices of the Spanish Government and other EU projects.</p>	+++
<p><b>2.2 <i>Are these training activities sustainable in the long term?</i></b></p> <p>The CRL for ASF has been providing training courses for many years that are executed in international collaboration with established course materials and as such are sustainable.</p>	+++
<p><b>2.3 <i>The evaluators shall also assess the activities carried out to provide scientific advice and expertise as regards disease surveillance and controls.</i></b></p> <p>The CRL has been active in employing “in house” OIE ELISA and a commercial ELISA for surveillance programmes both for MS and with significant impact in TCs from 2003 - 2009.</p>	+++
<p><b>3.0 NETWORKING</b> Have the coordination activities carried out by CRLs been satisfactory?</p> <p>The CRL has a large network of international links which includes for example: ILRI, Nairobi, Kenya; NVRC, Vom, Nigeria; OVI, Onderstepoort, South Africa; National Institute of Veterinary Virology and Microbiology, Pokrov, Russia. Collaboration has begun with Vietnam and China through the EU ASFRISK project.</p> <p>The CRL has contributed to the development of contingency plans for ASF in third countries and has assisted FAO in responding to outbreaks of ASF in the Caucasus region and Russia by providing diagnostic reagents and two experts for a mission to Russia.</p>	++
<p><b>3.1 <i>Activities carried out to ensure harmonisation of diagnostic methods.</i></b></p> <p>The CRL is active in harmonising diagnostic methods for ASF and a lot of effort is directed into this activity, especially during the proficiency tests and subsequent annual meeting for representatives of NRLs, organised by the CRL, as described above.</p>	+++
<p><b>3.2 <i>Coordination with national reference laboratories.</i></b></p> <p>Coordination with NRLs takes place at different levels, by organising the proficiency tests, the annual meetings, and trainings at the CRL, as described above.</p>	++
<p><b>3.3 <i>Regular consultation to the Commission on these coordination activities.</i></b></p> <p>There is regular contact with the Commission, in line with the epidemiological evolution of the disease.</p>	++
<p><b>3.4 <i>Exchange of information with other international reference laboratories.</i></b></p> <p>The CRL communicates regularly with: OIE Reference Laboratory for ASF at the Veterinary Faculty, UCM, Madrid; OIE Reference Laboratory for ASF at IAH, Pirbright and IZS, Perugia, Italy; Communication is also done through conferences, meetings, congresses and networks e.g. EPIZONE - the EU-funded network project.</p>	++

<b>Main findings - CRL for ASF</b>	<b>Rating</b>
<b>4.0 QUALITY ISSUES (including accreditation)</b>	++
<b>4.1 Have suitably qualified staff with adequate training in diagnostic tests?</b>	+++
The CRL has highly qualified staff, who also participates in research activities.	
<b>4.2 Application of the necessary analytical techniques in their area of competence.</b>	++
For ASF different techniques are used (immunoblotting, ELISA, molecular techniques and immunoperoxidase techniques), for which the CRL staff has excellent competences, backed by CISA-INIA researchers.	
<b>4.3 Apply diagnostic methods of satisfactory quality and in line with EC requirements.</b>	++
As mentioned above, the diagnostic methods used in the CRL for ASF diseases such as ELISA, immunoblotting (IB) assay, indirect immunofluorescent antibody (IFA) test and immunoperoxidase test (IPT) are of satisfactory quality, and described in OIE diagnostic manuals.	
<b>4.4 Accreditation</b>	+
At present neither the laboratory nor the equipment or the tests used by the CRL are accredited according to the ISO 17025, however, SOPs have been prepared for the calibration of equipment and these will be audited/inspected by ENAC (the official Spanish national accreditation organisation) in September 2009. The expectation is that accreditation will be granted for this section of the CRL by December 2009.	

### 3.2.7. CRL for Rabies (serology)

<b>Main findings - CRL for Rabies (serology)</b>	<b>Rating</b>
<b>Overall evaluation of the fulfilment of the duties and tasks established in the legislation</b>	++
The CRL is fulfilling all of its contractual duties, responsibilities and obligations as specified in Council Decision 2000/258/EC laying down specific provisions for the standardization of the serological tests to monitor the effectiveness of rabies vaccines (OJ L 79/40 of 30.3.2000).	
<b>1.0 DIAGNOSIS AND ASSISTANCE</b>	+++
Has the assistance of CRLs to other laboratories been adequate in order to improve diagnostic of animal diseases in the Community?	
<b>1.1 Activities and methods used by CRLs to ensure the correct diagnosis of animal diseases by National Reference Laboratories.</b>	+++
The CRL for Rabies (serology) has a particular position in the CRL network, as it is not involved in responses to rabies outbreaks, but only in the appraisal of laboratories in EU and TC for serological testing of antibody levels in domestic carnivores. The CRL is part of the AFSSA Laboratory for Study and Research into Rabies and Wild Animal Diseases in Nancy and focuses on research on occurrence, prevention and control of rabies and wild life animal diseases, such as echinococcosis. The serological diagnostic method of choice in the CRL is the fluorescent antibody virus neutralisation test (FAVN test). This is a prescribed test by the OIE that is also recommended by WHO and recognized by the European Commission to be used in the context of international trade of domestic carnivores. The efforts of the laboratory for appraisal of laboratories and harmonisation of rabies serology can best be illustrated as follows. Before being designated as CRL, the laboratory performed an inquiry among many international rabies laboratories in order to study the state of harmonisation	

<b>Main findings - CRL for Rabies (serology)</b>	<b>Rating</b>
<p>of the serological test. Subsequently, many protocols from participating laboratories were received and analysed. Each laboratory said they used the rapid fluorescent focus inhibition test (RFFIT). This test required many in-house adaptations in those laboratories, and in fact the techniques used were different; this would therefore hamper a growing number of laboratories to be approved. The laboratory subsequently developed a test easier to use, in particular for the reading of fluorescence. This test, the current FAVN test, was demonstrated to around 40 laboratories during three consecutive workshop trainings that the AFSSA Rabies laboratory organised; in this occasion the laboratory also presented a comparison of RFFIT to different laboratories. Today, almost all rabies laboratories are using the FAVN test. During the rabies serology workshop organised by the CRL in 2006, hardly any discussion occurred except for slight adaptations to carry out the test. The FAVN test has been included in the OIE rabies chapter of the Terrestrial Manual (2008)</p>	
<p><b><i>1.2 Ring trails carried out and assessment of their effectiveness.</i></b></p>	+++
<p>The CRL has started with two PT per year since 2001, and one PT per year from 2005 onwards. Every time a report is published, which includes in code the results, and the individual key is sent to each participating laboratory, and the key of all participating laboratories is disclosed to DG SANCO. The report is very technical and a more comprehensive presentation may be considered for better interpretation and understanding of the results, and availability in digital form should be arranged. The CRL has received a total of 86 applications for appraisal of laboratories since its designation as CRL. Since then, 54 laboratories have been approved and take part in the rabies proficiency tests. To date, approval has expired for 2 laboratories, one in Germany and one in Japan. The suspected reason is that they lost interest in the activity due to increased competition. The full list of approved laboratories are publicly available on the DG SANCO website; <a href="http://ec.europa.eu/food/animal/liveanimals/pets/approval_en.htm">ec.europa.eu/food/animal/liveanimals/pets/approval_en.htm</a>. The distribution of the laboratories is worldwide, and there is no indication at the moment for shortage of an approved rabies laboratory. Annual meetings were not foreseen, because of the specific nature of the CRL for rabies (serology), but, depending on the need, the CRL has organised several meetings. One workshop was organised in 2004 on the use of the ELISA developed in the AFSSA Rabies Laboratory as a serological tool to check the effectiveness of oral vaccination campaigns for foxes. The CRL received 19 scientists from 15 different countries. Subsequently, a meeting entitled “Rabies Serology Proficiency Test Meeting” has been organised in 2006 in Nancy (France). The meeting gathered a total of 49 participants from 35 laboratories and 26 countries and a representative of the European Commission. In this case the meeting was not included in the Working programme of 2006, this caused some financial difficulties. Several oral presentations have been given concerning: rabies serology and the proficiency testing; technical analysis of serological tests used in the approved laboratories; a new ELISA for rabies serology; the EU legislation regarding the international movements of pets. A report has been produced gathering the minutes of the meeting and the presentations. It has been sent to each approved laboratories as well as to the European Commission. Also this report is not available in digital form.</p> <p>For 2009, a meeting is planned in November for laboratories involved in the serology network. The EC will be represented as well as the OIE.</p>	
<p><b><i>1.3 Development of new diagnostic tools by the CRLs.</i></b></p>	+++
<p>A new ELISA is being validated at the CRL that has significant advantages over the current FAVN test. The test is a commercial ELISA, but considered an attractive new test. Also from the CVO survey it was mentioned the CRL should quickly evaluate this new test.</p>	
<p><b><i>1.4 Supply of diagnostic tools to other laboratories.</i></b></p>	++
<p>The CRL produces and maintains stocks of naïve serum, positive reference serum, CVS-11 virus, and BHK21 cells. New productions of BHK21 cells are prepared every week to insure CRL tests and laboratory demands.</p> <p>Strains and reagents are shipped to participating laboratories regularly for the annual proficiency testing programmes, and occasionally on demand. In addition strains and reagents are supplied. In 2008 for example the following items were supplied: 278 vials of OIE serum, 215 vials of naïve serum, 8 flasks of BHK21, and 2 vials of lyophilized CVS virus.</p>	

<b>Main findings - CRL for Rabies (serology)</b>	<b>Rating</b>
	na
<b>1.5 Assistance to other laboratories for diagnosis in case of an outbreak.</b>	na
As mentioned above, the CRL for Rabies (serology) has a particular position in the CRL network, because it has no duty in responses to rabies outbreaks, thus this question is not relevant for this evaluation. Noteworthy, the AFSSA Rabies laboratory of which the CRL is a part is involved in assistance to other laboratories in case of rabies outbreaks, and it has been designated in 2008 as CRL for rabies (diagnosis).	
<b>2.0 TRAINING</b>	++
Has the training carried out by the CRLs been sufficient to improve the diagnosis of animal diseases during the last 15 years?	
<b>2.1 The evaluators shall analyse the activities carried out for training and retraining of experts and staff (courses, documents).</b>	++
The CRL does not offer regular annual training but arranges training courses on demand. Experts from laboratories from EU and TCs visit the CRL to participate in side-by-side activities. This makes the training very practical, but on the other hand less structured. Between 2003 to mid-2009 8 persons were trained from EU, 19 from TCs, and 5 from industry. Four to six people in total are trained on average every year, mostly on the FAVN test, and/or on the ELISA techniques. Training materials have been prepared for trainees, such as several Power Point presentations for the FAVN test, virus production, cells culture, control cards, calculation of titres as well as a short presentation of the rabies proficiency tests.	
<b>2.2 Are these training activities sustainable in the long term?</b>	++
The CRL has received persons for training for many years, is experienced in it, and in this form can be performed also in the future, because they do not depend much on additional funding. With the new laboratory facilities under construction these activities could increase due to additional laboratory space.	
<b>2.3 The evaluators shall also assess the activities carried out to provide scientific advice and expertise as regards disease surveillance and controls.</b>	na
The CRL has not a duty in this field so this question is not relevant.	
<b>3.0 NETWORKING</b>	++
Have the coordination activities carried out by CRLs been satisfactory?	
<b>3.1 Activities carried out to ensure harmonisation of diagnostic methods.</b>	++
The receipt and supply of strains and reference reagents, the organisation of the proficiency testing programmes and annual meetings, and the trainings, have provided the CRL an excellent intra-EU network. The CRL has received a total of 86 applications for appraisal of laboratories since its designation as CRL. Since then, 54 laboratories have been approved and take part in the rabies proficiency tests. To date, approval has expired for 2 laboratories, one in Germany and one in Japan. The suspected reason is that they lost interest in the activity due to increased competition. The full list of approved laboratories is publicly available on the DG SANCO website. The distribution of the laboratories is worldwide, and there is no indication at the moment for shortage of an approved rabies laboratory. The harmonisation of diagnosis is effective for approved laboratories, because currently every year about 49 of 50 laboratories perform adequately in the PT organised by the CRL.	
<b>3.2 Coordination with national reference laboratories.</b>	++
The CRL relates to laboratories in the rabies network and not only with NRLs. Coordination with takes place at different levels, by organising the proficiency tests, the annual meetings, and trainings at the CRL. The communication and collaboration with participating laboratories is good and positive. The CRL has not held annual meetings on a regular basis (twice since its establishment); however, this is not a task laid down in the legislation nor working programme, but should instead be organised when needed. However, the meetings constitute an important moment of exchange of information and further building up and improving the relationship with	



<b>Main findings - CRL for Rabies (serology)</b>	<b>Rating</b>
<p>the participating laboratories.</p> <p>The CRL has not a dedicated website for participating laboratories. The website of DG SANCO lists approved laboratories, but there is no easy accessible website for participating laboratories for reference and share of documents and protocols where applicable.</p>	
<p><b><i>3.3 Regular consultation to the Commission on these coordination activities.</i></b></p>	++
<p>The communication with the Commission is considered satisfactory. However, meeting the test criteria by the participating laboratories remains sensitive. When incidentally approved laboratories do not fulfil the criteria, and receive the score “red” in the proficiency testing reports, the CRL depends on the Commission to withdraw the laboratory from the list. In the past this took a long time to happen or did not occur at all. A new agreement has been introduced in 2008, which foresees the withdrawal of a laboratory from the list when it fails to pass the criteria during two consecutive proficiency tests; this should solve the issue. In general, out of the 50 participating laboratories one laboratory annually fails to pass the criteria in every PT.</p>	
<p><b><i>3.4 Exchange of information with other international reference laboratories.</i></b></p>	+++
<p>Experts from the CRL are also present in many international fora, and attend meetings organised by WHO, meetings organised by EFSA, FVI, OIE, European Pharmacopeia, Ministry of Agriculture, and publish every year in internationally peer-reviewed journals, and also in the Rabies Bulletin Europe, edited by the WHO. The staff of the CRL is internationally active in scientific networks, also because the EU CRL is a OIE Reference laboratory for rabies and WHO collaborating centre. The CRL’s staff is represented at the annual Rabies in the Americas (RITA) meetings, held since 1990. Also the South East African Rabies group (SEARG) meetings are attended, where CRL staff participates as tutors in practical sessions of rabies diagnosis. Experts of the CRL are invited to actively participate to working groups on request of the Commission and EFSA. Therefore, the international network of the laboratory is very strong.</p>	
<p><b>4.0 QUALITY ISSUES (including accreditation)</b></p>	++
<p><b><i>4.1 Have suitably qualified staff with adequate training in diagnostic tests?</i></b></p>	+++
<p>The CRL has and internationally recognised and experienced multidisciplinary team of experts on its staff. The list of publications of the CRL staff is impressive, and includes 59 peer reviewed publications of which 57 are classified as highest impact factor. This is evidence of a sound academic centre of excellence.</p>	
<p><b><i>4.2 Application of the necessary analytical techniques in their area of competence.</i></b></p>	++
<p>The CRL applies the FAVN tests, and also executes other analytical techniques such as immunofluorescence tests and molecular techniques for which the CRL staff has excellent competences, backed by other AFSSA Rabies Laboratory researchers.</p>	
<p><b><i>4.3 Apply diagnostic methods of satisfactory quality and in line with EC requirements.</i></b></p>	++
<p>As mentioned above, the serological diagnostic method of choice in the CRL is the fluorescent antibody virus neutralisation test (FAVN Test). This is a prescribed test by the OIE that is also recommended by WHO and recognized by the European Commission to be used in the context of international trade of domestic carnivores.</p> <p>A Laboratory Information Management System (LIMS) is absent, which is remarkable for the high number of national and international samples that are being received. In the new laboratory a establishment of LIMS is foreseen.</p> <p>The AFSSA Rabies Laboratory has contracted an external company that has developed a database, which is dedicated to the registration of serum samples received, automatic edition of different mailings to the veterinarians and pet owners as well as edition of results of serological testing. This database is part of the accredited process dealing with serology and has been then subjected to COFRAC evaluation.</p> <p>The facilities of the CRL are old, but new laboratories are under construction.</p>	
<p><b><i>4.4 Accreditation</i></b></p>	++

<b>Main findings - CRL for Rabies (serology)</b>	<b>Rating</b>
<p>The AFSSA Rabies Laboratory where the CRL is located is accredited by the French accreditation organisation Cofrac (Comité Français d'Accréditation) according to NF EN ISO/CEI 17025 version 2005, since February 1st, 2008 (nr 1-1961).</p> <p>The CRL is accredited for the rabies serological controls by FAVN test.</p> <p>Proficiency testing programmes have not been accredited yet but steps are being taken in this direction.</p>	

### 3.2.8. CRL for Mollusc Diseases

<b>Main findings - CRL for Mollusc Diseases</b>	<b>Rating</b>
<b>Overall evaluation of the fulfilment of the duties and tasks established in the legislation</b>	++
The CRL is fulfilling all of its contractual duties, responsibilities and obligations as specified in Annex IV of Directive (EC) No 088/2006.	
<b>1.0 DIAGNOSIS AND ASSISTANCE</b> Has the assistance of CRLs to other laboratories been adequate in order to improve diagnostic of animal diseases in the Community?	++
<b><i>1.1 Activities and methods used by CRLs to ensure the correct diagnosis of animal diseases by National Reference Laboratories.</i></b>	+++
<p>The CRL for Mollusc Diseases is part of the Ifremer Laboratoire de Génétique et Pathologie (LGP). The LGP is a part of the larger research Department of Genetics, Pathology and Environment Department (Département Amélioration Génétique, Santé Animale et Environnement), one of the Directorates of Operations of Ifremer. It depends on the Ministry of Agriculture and Fisheries.</p> <p>The CRL employs a wide variety of tests which is typical for mollusc diseases, necessary to perform diagnosis for screening, presumptive diagnosis, and confirmation of the non-exotic pathogens <i>Bonamia ostreae</i>, and <i>Marteilia refringens</i>, and exotic pathogens <i>Bonamia exitiosa</i>, <i>Perkinsus marinus</i> and <i>Mikrocytos mackini</i>. The main techniques employed are cytology, histology, molecular techniques such as PCR, restriction fragment length polymorphism (RFLP), and sequencing, in situ hybridisation (ISH), Ray's fluid thioglycollate medium (RFTM) culture and transmission electron microscopy (TEM).</p> <p>The diagnostic tests employed by the CRL for surveillance, presumptive diagnosis and confirmation for the pathogens are listed in the OIE Manual of Diagnostic Tests for Aquatic Animals (2006 version) and by the Aquatic Animal Health Code (2007 version). Standard operating procedures (SOPs) are available for all histo-/cytology techniques as well as for molecular biology techniques. The CRL is also active supporting the accreditation of NRLs which are not yet accredited in their country and provides a number of SOPs for such laboratories. The following SOPs are available (also on the website) for NRLs: Molluscs processing for diagnosis by histology, standard diagnostic techniques for <i>Bonamia ostreae</i> diagnosis in the flat oyster <i>Ostrea edulis</i>, standard diagnostic techniques for <i>Marteilia refringens</i> diagnosis in the flat oyster <i>Ostrea edulis</i>, standard diagnostic techniques for <i>Perkinsus olseni</i> diagnosis in the clams <i>Ruditapes decussates</i> and <i>R. Philippinarum</i>, <i>Bonamia ostreae</i> detection by PCR, and <i>Marteilia refringens</i> typing by PCR-RFLP.</p> <p>The CRL has a website: <a href="http://www.ifremer.fr/crlmollusc">www.ifremer.fr/crlmollusc</a>, with very descriptive, useful and accessible information on the diseases and laboratory (address, how the lab can be visited) and on its</p>	

<b>Main findings - CRL for Mollusc Diseases</b>	<b>Rating</b>
activities as CRL (staff, events, legislation, news regarding the diseases, information on the network of NRLs, etc.). The website does not contain information how samples should be submitted to the CRL, but this is currently addressed.	
<b><i>1.2 Ring trails carried out and assessment of their effectiveness.</i></b>	++
<p>The CRL organises a proficiency test every two years, and therefore six PTs were organized since 1997. A first PT test was organised in 2004 for candidate countries. The PT for mollusc diseases was organised as follows: slides (n=30) were sent to one NRL for evaluation; the NRL is expected to analyse the slides within a week and communicate the results to the CRL, and then send the slides to another NRL (according to the program of the CRL). The time to complete the PT should therefore correspond to 20 weeks. However, this usually takes longer (12-16 months) due to the summer breaks.</p> <p>When the final results are reported to the CRL, all the NRLs receive a response for their particular NRL, as well as the general level of results, including the reference results. Copies are sent to the Commission and a synthesis of the results is also presented at the annual meeting. The results are presented with a code identifying the NRL, in order to maintain the confidentiality. Since 2008 a PCR PT is sent to all NRLs, which means that, from 2008 there will be a yearly external proficiency test with discussion at the annual meeting. As noticed before these proficiency tests are used also to harmonize the diagnostic tests in the NRLs. Given the differences among the various inter comparative tests organised, it is not possible to summarise the results over the years. However, the percentage of good responses has increased over time, especially for detection of bonamiosis and marteliosis; more difficulties are encountered for the detection of exotic diseases and for the detection of low levels of infections (also for non-exotic diseases).</p>	
<b><i>1.3 Development of new diagnostic tools by the CRLs.</i></b>	+++
Histology (the standard method of diagnosis) is highly dependent on the scientists' capacity; therefore changes of staff in the NRLs greatly influence the results. New techniques are proposed by the CRL and introduced in the PT, such as the PCR since 2008. As regards detection by PCR, thirteen NRLs participated to the (optional, since PCR for detection of Bonamia spp. is not yet used routinely by all the NRLs.) test and the percentages of good responses were above 60% for all participating laboratories. According to responses to the annual questionnaire more and more laboratories are well equipped and are able to perform PCR and in situ hybridization assays.	
<b><i>1.4 Supply of diagnostic tools to other laboratories.</i></b>	++
The CRL supplies regularly diagnostic tools to other laboratories. The materials requested were histological slides, histological blocks, tissues, DNA suspensions, and cultures. The number of requests ranged from about 50-250 request per year, the vast majority being for EU, and about 25-30% for TCs. Average time to respond was estimated for the last 3 years between 28-44 days. This time fluctuates according to the type of requested material and the official documents necessary to send such material to some countries.	
<b><i>1.5 Assistance to other laboratories for diagnosis in case of an outbreak.</i></b>	++
The CRL is very active providing assistance in case of an outbreak. An example is the emergency plan in response to the identification of Bonamia exitiosa in a MS. This example emphasizes the coordination between CRL and various NRLs. In 2007, there were several epidemiological studies due to outbreaks in third countries, namely with Tunisia, about Perkins infection in clams; countries in the Mediterranean sea, about potential pathogens in flat oysters in the Mediterranean sea; and Russia: about possible pathogens in flat oysters in the Black Sea.	
<b>2.0 TRAINING</b>	+++
Has the training carried out by the CRLs been sufficient to improve the diagnosis of animal diseases during the last 15 years?	
<b><i>2.1 The evaluators shall analyse the activities carried out for training and retraining of experts and staff (courses, documents).</i></b>	+++
The CRL is very active in training activities. This is pursued through individual training courses	

<b>Main findings - CRL for Mollusc Diseases</b>	<b>Rating</b>
<p>(on request), sessions on new findings on mollusc diseases during the Annual meetings and the organization of a technical workshop every two years (for histological diagnosis and molecular biology techniques). On average, 16-18 scientists and technicians from MS and 2-3 from TCs have been trained yearly since 1997 at the CRL (individual trainings and workshops). In addition, experts from TCs are trained outside the activities of the CRL. The CRL developed in 2002 a CD-ROM with training material (“Handbook for diagnostic procedures on Mollusc diseases”) for the diagnosis of Mollusc diseases. The CD-ROM is primarily addressed to NRLs but is available on request to the CRL for everybody (free of charge). The CD-ROM is regularly updated. The CRL is very committed to the accreditation of NRLs of the MS. Therefore a number of Standard Operating Procedures for diagnostic techniques have been made available via the website.</p> <p>The slides prepared for the EQA (7 collections of slides) are conserved and they can be used by NRLs and visitors for training. Slides from the last tests (including their interpretation) are available via the website <a href="http://www.ndpserve.com">www.ndpserve.com</a> (restricted access). There are no statistics available on the access of the website by the NRLs, but the initiative was welcome with enthusiasm when proposed to the NRLs.</p>	++
<p><b>2.2 Are these training activities sustainable in the long term?</b></p> <p>The CRL has developed training in mollusc diseases in a very structure manner with well developed training materials including a secured website, and the training is a normal part of the CRL activities, which makes it a sustainable activity in the long term.</p>	+++
<p><b>2.3 The evaluators shall also assess the activities carried out to provide scientific advice and expertise as regards disease surveillance and controls.</b></p> <p>The CRL is very active in surveillance studies. An epidemiologist supports the activities of the CRL in terms of epidemiology. The epidemiologist develops risk based studies, participates in the statistical validation of the diagnostic tools and defines, when necessary, sampling strategies. In 2008, in response to the identification of <i>Bonamia exitiosa</i> in Spain, the CRL proposed a surveillance program for <i>Bonamia</i> in Europe (also for co-infection with different parasite species). About 10 NRLs participate in this study, which number is relatively low, and this should increase in the future.</p>	++
<p><b>3.0 NETWORKING</b></p> <p>Have the coordination activities carried out by CRLs been satisfactory?</p>	++
<p><b>3.1 Activities carried out to ensure harmonisation of diagnostic methods.</b></p> <p>The receipt and supply of strains and reference reagents, the organisation of the proficiency testing programmes annual meetings, and training activities, have provided the CRL an excellent intra-EU network. However, the receipt of strains for confirmation of outbreaks from MS seems low. The number of samples received during 2006-2008 was between 3000-6000 from France, 82-139 from Europe, and 54-125 from TCs. The trend with samples from Europe is increasing (82 in 2006; 139 in 2008), but deserves attention. It may be that some NRLs are also specialised in shellfish diseases, but the ring test results imply too that other labs certainly need help in their diagnostic service. The confirmation task of the CRL is rather complicated. All NRLs have a good relationship with the CRL and quite a number of them consult the CRL regularly. On the other hand, there are some laboratories who are as well equipped (and may have almost as much expertise) as the CRL and they are therefore able to diagnose mollusc diseases in a comparable way as the CRL. However, in the opinion of the evaluators all NRLs should have a protocol to submit strains/slides/other material to the CRL for confirmation of new outbreaks. This is also the approach that the CRL would like to take. It is difficult for the present CRL coordinator to make this “compulsory” for NRLs to keep a good relationship with them. It should be a task of the Commission to guarantee that outbreaks always should be confirmed by CRLs.</p>	+
<p><b>3.2 Coordination with national reference laboratories.</b></p> <p>The CRL coordinates a network of 21 NRLs. Some Member States don’t have a designated NRL, some have changed their contact person without notification to the CRL and this makes it difficult for the CRL to have communication with them. However, Dir. 2006/088/EC makes the designation of a NRL compulsory, and the Commission would be in the position to address the</p>	++

<b>Main findings - CRL for Mollusc Diseases</b>	<b>Rating</b>
<p>CA of such MS, because the CRL has no authority to do so.</p> <p>The CRL has good professional contacts with the 21 NRLs due to the PT and annual meetings, and support with surveillance studies. As already mentioned earlier, quite a number of specialists of NRLs (and from laboratories from TCs attend training courses/workshops on surveillance and diagnosis of Mollusc Diseases. The CRL is also active to resolve technical problems in diagnosis and surveillance in MS (on request of NRLs), provides disease consultancy, and has an excellent website for dissemination of information and even training. A distribution list (RefLabNet) is used to communicate with the NRLs and the Commission about news and announcements. In addition, the CRL support accreditation of NRLs where required. As such this is evidence for satisfactory coordination. However, the distant location of the CRL, and lack of instructions how to submit samples, and high technical level of several NRLs with significant mollusc industry in their home countries, makes that specific effort is required for the CRL to further develop its coordination role.</p>	
<b>3.3 Regular consultation to the Commission on these coordination activities.</b>	+
<p>The communication with the Commission is considered satisfactory. However the CRL is not always fully informed about evolution of texts related to surveillance, and the CRL would need to be among the first to receive routinely and all relevant information, so that it can be at the forefront of new development on regulatory issues.</p> <p>Also, there are no specific meetings foreseen to discuss issues relevant to the CRL. Creation of a coordinating body at the Commission would be beneficial in this regard.</p>	
<b>3.4 Exchange of information with other international reference laboratories.</b>	++
<p>The CRL is OIE reference laboratory for infection with <i>Bonamia</i> spp and <i>Marteilia</i> spp. and therefore is in the network of OIE reference laboratories and benefits of the contacts and collaborations within this network.</p>	
<b>4.0 QUALITY ISSUES (including accreditation)</b>	++
<b>4.1 Have suitably qualified staff with adequate training in diagnostic tests?</b>	+++
<p>The CRL has an internationally recognised and experienced multidisciplinary team of experts. The key staff includes an epidemiologist and managers for the three most important duties of the CRL: technical manager for tests and equipment, collection manager for counting and archiving of slides, DNA suspensions, and a technical manager for organising PT in consultation with the head of the CRL and the quality manager. The list of publications by staff members of the CRL is very impressive. New staff members are trained and tested for competency in the CRL before they are allowed to work on their own.</p>	
<b>4.2 Application of the necessary analytical techniques in their area of competence.</b>	++
<p>The CRL has very skilled staff, capable to execute the variety of analytical techniques, including electron microscopy, required for mollusc diseases as described above. Moreover, they have the skills to introduce more molecular techniques tests such as the PCR for mollusc diseases.</p>	
<b>4.3 Apply diagnostic methods of satisfactory quality and in line with EC requirements.</b>	++
<p>As mentioned above, the diagnostic methods for screening, presumptive and confirmatory diagnosis are prescribed test by the OIE and recognized by the European Commission.</p>	
<b>4.4 Accreditation</b>	+
<p>Quality assurance within the CRL is of a high standard but not officially accredited. The CRL is part of the LGP and is dependant on the progress at the parent institution. The application to COFRAC was submitted in 2006. However, because of lack of auditors who need to be specialists in aquaculture, it took almost 3 years before the actual audit could take place. There were few non-conformities and it is therefore expected that accreditation for histopathology will be granted in July 2009. However, it is noticed that only the diagnostic part of the LGP (and more precisely the histopathology part) will be accredited. All molecular biology tests, as well as microbiology are not included in this accreditation. It is therefore advised to start with the preparation for accreditation of these important subjects as soon as possible.</p>	

<b>Main findings - CRL for Mollusc Diseases</b>	<b>Rating</b>
The accreditation for the execution of proficiency testing programmes is not yet obtained but ongoing.	

### 3.2.9. CRL for Zootechnics

<b>CRL for Zootechnics (Interbull)</b>	<b>Rating</b>
<b>Overall evaluation of the fulfilment of the duties and tasks established in the legislation</b>	++
The CRL is fulfilling all of its contractual duties, responsibilities and obligations as specified in Annex II of Council Directive 96/463/EC (Official Journal of the European Union L 192, 02/08/1996, pages 0019-0020).	
<b>1.0 EVALUATION METHODS</b> Has the assistance of the CRL to other participating organisations in EU MS been adequate in order to improve genetic evaluation methods in the Community?	++
<b><i>1.1 Activities and methods used by CRLs to ensure the correct genetic evaluation methods by MS participating organisations.</i></b>	+++
<p>The Interbull Centre is part of the Department of Animal Breeding and Genetics of the Swedish University of Agricultural Sciences and is located in Uppsala, Sweden. As neither the CRL nor the participating organisations of the Member States are laboratories, the terminology “CRL” and “NRL” does not apply for Interbull and therefore the Code of Practice of the Centre does not mention these abbreviations. Furthermore, as the ultimate aim of the Interbull Centre is to facilitate international trade in semen, the geographical dimension of the participating countries is extended beyond EU MS.</p> <p>Evaluations run by Interbull Centre include; International Evaluations, performed three times per year, and test evaluations, performed two times a year. International evaluations are conducted for production traits; conformation traits; udder health traits; longevity; calving traits; and female fertility traits (since February 2007); workability traits (since January 2008). Data from 20 MS are included in the most recent evaluations. Breeding values are at each evaluation calculated for more than 150.000 bulls of usually 6 breed groups: Holstein, Jersey, Brown Swiss, Red Dairy Cattle, Guernsey and Simmental. Conformation traits of national bull evaluations of each of the mentioned breeds are calculated and published for: stature, chest width, body depth, angularity, rump angle, rump width, rear leg set, rear leg rear view, foot angle, fore udder, rear udder height, udder support, udder depth, front teat placement, teat length, rear teat placement, overall conformation, overall udder, overall feet and legs, locomotion and body condition score.</p> <p>Development and testing of new methodologies is included in its function. Many alternative methodological approaches have been developed worldwide and Interbull is the logical forum for the exchange of experience, the validation of methods and results, and also the standardization of procedures. Training and networking (including the organisation of workshops and courses as well as of the annual meeting) are directly related to the aforementioned priorities.</p> <p>The highest priority for the CRL is the provision of international genetic evaluations, as mentioned before, three times a year. This accounts for 70% of the staff’s time and, since the centre is “service driven”, this has always represented a priority over the years.</p> <p>Development and testing of new methodologies are also included in this function.</p> <p>International evaluations are computed by a linear Multiple-trait Across Country Evaluation (MACE) model analysis of the national evaluation results from the participating countries.</p>	

<b>CRL for Zootechnics (Interbull)</b>	<b>Rating</b>
<p>Data on all bulls evaluated in each country are considered in the international evaluations, if the bulls fulfil a number of requirements and criteria, which are carefully described in the Code of Practice. Conversion coefficients among all participating countries and for all traits are computed based on international predicted genetic merits of bulls that are progeny tested in only one country with a number of criteria to be followed as well.</p> <p>All participating countries are informed that they should send their data for routine international evaluations to the Interbull Centre no later than by the Tuesday, 14 days prior to a scheduled release of results. The target dates for the release of results for official publication are the first Tuesday after January 11, the first Tuesday in April and the third Tuesday in August.</p> <p>Currently the routine international genetic evaluations comprise 6 breed groups of 27 countries in Europe, North-America, Oceania, Asia and Africa, and more than 150,000 bulls are evaluated three times a year.</p>	++
<p><b><i>1.2 Ring trails carried out and assessment of their effectiveness.</i></b></p> <p>Test evaluations for the aforementioned traits are organised two times a year. The participation in a test evaluation run is required to countries in case of modifications, for instance for modified trait definitions, modified models or genetic parameters in breeding value predictions and the modification of pre-adjustment factors. Countries participating for the first time need to submit their data to Interbull for inclusion in a test evaluation run before the participation in international evaluations.</p> <p>Importantly, Interbull has neither duty nor task in performing direct software checks at the national genetic evaluation units.</p>	++
<p><b><i>1.3 Development of new evaluation tools.</i></b></p> <p>Interbull Centre is facing a new big challenge, i.e. the “genomic era” (role of genomic information in genetic evaluations), and new developments are already happening in this field at the member country level. Therefore, the Interbull Steering Committee decided to establish a task force with two main objectives: 1. to set the scientific framework for the use of genomic data in national and international genetic evaluations and 2. to promote the idea and benefits of international collaboration, under the auspices of Interbull, relating to genomic evaluation and selection.</p> <p>Another current development is the Interbeef Project. Up to now only dairy breeds have been evaluated. Interbull Centre has planned to develop a system for international evaluations of beef traits and breeds in cooperation with French and Irish scientists. The first breeds (Charolais and Limousin) and traits have already been selected, and trials for evaluations are already running. However, this project might pose some problems related to the fact that dairy breeds are almost always pure-bred, whereas beef breeds are often cross breeds. Moreover, many countries have their “own” beef breeds with, therefore, less international interest in such breeds and also in the semen of their bulls (e.g. the Belgian Blue).</p>	++
<p><b><i>1.4 Including new evaluation tools.</i></b></p> <p>Interbull usually responds quickly to requests regarding the inclusion of new breeds and/or traits into the international evaluations. However, the ITC supervises all changes and developments and provides recommendations to the Steering Committee. Sometimes national data do not have the quality required by the CRL, and this may jeopardise fast responses to the requests of participating organisations/countries. It should be stated here that the Interbull staff is rather small: the Centre is a service provider and does not have the opportunity (neither financial nor with research staff) for “pure” research. However, the Centre is part of a large University department and is therefore, in this sense very closely connected to research. Interbull also plays an important role internationally as coordinator of research projects; this is also demonstrated by the open seminars organised annually by the CRL.</p> <p>Interbull usually responds quickly to requests regarding the inclusion of new breeds and/or traits into the international evaluations. However, the ITC supervises all changes and developments and provides recommendations to the Steering Committee. Sometimes national data do not have the</p>	++

<b>CRL for Zootechnics (Interbull)</b>	<b>Rating</b>
quality required by the CRL, and this may jeopardise fast responses to the requests of participating organisations/countries.	
<b><i>1.5 Assistance to other laboratories for diagnosis in case of an outbreak.</i></b>	na
Not relevant	
<b>2.0 TRAINING</b> Has the training carried out by the CRLs been sufficient to improve the genetic evaluation methods during the last 15 years?	++
<b><i>2.1 The evaluators shall analyse the activities carried out for training and retraining of experts and staff (courses, documents).</i></b>	++
<p>The Interbull Centre has the responsibility of training and assisting “new” countries (member states as well as third countries) to become involved in the international genetic evaluations. In recent years, assistance has been given to more than 5 new countries. All these countries are now or will in the near future participate in these evaluations.</p> <p>Staff members of participating countries get the opportunity to attend workshops. The last one was organised in January 2009 in Uppsala. The Interbull website as well as the Interbulletin has a didactic value for “new” participants. The open, international seminar has a high level and many scientists from all over the world (about 40 countries) participate in this congress. In 2008 ICAR and Interbull had a joint session on genomic tools in animal breeding.</p>	
<b><i>2.2 Are these training activities sustainable in the long term?</i></b>	+
There is not a systematic calendar for courses as for meetings and workshops. Training is provided on demand or when there is a need to disseminate new developments. The CRL has developed training but not as a standard activity with training materials although it has developed a secured website, which makes it unsure if it is a sustainable activity in the long term.	
<b><i>2.3 The evaluators shall also assess the activities carried out to provide scientific advice and expertise as regards disease surveillance and controls.</i></b>	na
Not relevant	
<b>3.0 NETWORKING</b> Have the coordination activities carried out by CRLs been satisfactory?	++
<b><i>3.1 Activities carried out to ensure harmonisation of genetic evaluation methods.</i></b>	++
The highest priority for the CRL is the provision of international genetic evaluations, three times a year. This accounts for 70% of the staff’s time and, since the centre is “service driven”, this has always represented a priority over the years.	
<b><i>3.2 Coordination with EU MS participating organizations.</i></b>	+++
<p>The CRL organises annual meetings for participating organizations of Member States and third countries as open meetings, organized as seminars. These seminars may be held in one of the Member States, but the location is not limited to Member States: the last meeting was in Niagara Falls in 2008 with 216 participants from 40 countries. The scientific level of these meetings is high. The Proceedings are usually published within a few weeks after the seminar. They are sent to about 400 official organisations specialised in this field as well as to University libraries. The Proceedings of the Niagara Falls meeting amount to 160 pages and the publication of these proceedings has an ISBN number.</p> <p>Noteworthy, Interbull started already years ago with a network forum on the Internet. There is a closed forum for members of the Steering Committee but also an open forum for all member states/ member organisations.</p>	



<b>CRL for Zootechnics (Interbull)</b>	<b>Rating</b>
<b>3.3 Regular consultation to the Commission on these coordination activities.</b>	++
The communication with the Commission is considered as adequate.	
<b>3.4 Exchange of information with other participating organizations.</b>	++
See above, there is no distinction between EU MS and TCs participating organisations for exchange of information.	
<b>4.0 QUALITY ISSUES (including accreditation)</b>	++
<b>4.1 Have suitably qualified staff with adequate training in genetic evaluation methods?</b>	+++
It should be stated here that the Interbull staff is highly qualified but rather small with eight people: it is a service provider and does not have the opportunity (neither financial nor with research staff) for “pure” research. However, the Centre is part of a large University department and is therefore, in this sense very closely connected to research. Interbull also plays an important role internationally as coordinator of research projects; this is also demonstrated by the open seminars organised annually by the CRL.	
<b>4.2 Application of the necessary analytical techniques in their area of competence.</b>	++
The CRL has very skilled staff, capable to very well execute the genetic evaluations, backed by scientists of the Department of Animal Breeding and Genetics.	
<b>4.3 Apply diagnostic methods of satisfactory quality and in line with EC requirements.</b>	na
Not relevant	
<b>4.4 Accreditation</b>	+
All CRLs of Infectious Diseases have to use every effort to become accredited (or are already accredited). For Interbull, the laboratory accreditation EN ISO/IEC 17025 is not applicable; instead accreditation should be based on ISO 9000. The CRL is planning to take this up.	

### 3.2.10. CRL for Fish Diseases

<b>Main findings - CRL for Fish Diseases</b>	<b>Rating</b>
<b>Overall evaluation of the fulfilment of the duties and tasks established in the legislation</b>	++
The CRL is fulfilling all of its contractual duties, responsibilities and obligations as specified in the Council Directive 2006/88/EC.	
<b>1.0 DIAGNOSIS AND ASSISTANCE</b> Has the assistance of CRLs to other laboratories been adequate in order to improve diagnostic of animal diseases in the Community?	++
<b>1.1 Activities and methods used by CRLs to ensure the correct diagnosis of animal diseases by National Reference Laboratories.</b>	++
The CRL for Fish diseases is part of the National Veterinary Institute (DTU Vet), Technical University of Denmark and was appointed on January 1st, 1994. The CRL function was placed at the Section for fish diseases at the Department for poultry, fish and fur animal in Århus, Denmark.	

<b>Main findings - CRL for Fish Diseases</b>	<b>Rating</b>
<p>The CRL performs diagnosis for the non-exotic diseases; viral haemorrhagic septicaemia (VHS), infectious haematopoietic necrosis (IHN), Koi herpes virus (KHV) disease, and infectious salmon anaemia (ISA); and for the exotic diseases: epizootic haematopoietic necrosis (EHN) and epizootic ulcerative syndrome (EUS) for a variety of fish species.</p> <p>The diagnostic methods used in the CRL for fish diseases are described in EU standards and/or in OIE diagnostic manuals. For detection of VHSV and IHNV, cell culture systems and serological methods laid down in the Commission Decision 2001/183/EC are used. Furthermore, the PCR used for detection of VHSV is described in the OIE diagnostic manual. For ISA, the Commission Decision 2003/466/EC is used based on criteria for zoning and official surveillance following suspicion or confirmation of the presence of infectious salmon anaemia (ISA). For KHV, EHN and EUS, EU Standards are currently not available and diagnostic procedures follow the recommendations described in the OIE diagnostic manuals. This applies for the molecular methods (PCR and real-time PCR) used for detection of KHV; the molecular methods (RT-PCR and real-time RT-PCR) used for detection of ISAV; the cell culturing and molecular methods (PCR and sequencing) for detection of EHN and the PCR used for detection of EUS.</p>	
<b><i>1.2 Ring trails carried out and assessment of their effectiveness.</i></b>	++
<p>Since 1996, the CRL has provided a yearly Proficiency Test (except for 2006, see under Training) to all NRLs in EU. NRLs from non-EU countries in Europe and TCs have also participated in the proficiency tests. The subject of these PTs was diagnosis of VHSV and IHNV. At the CRL, data from NRLs about the disease situation are collated and presented graphically. These data are uploaded on the CRL web-page (see <a href="http://www.crl-fish.eu/survey_and_diagnosis.aspx">www.crl-fish.eu/survey_and_diagnosis.aspx</a>) and are freely accessible for everyone. In addition, the CRL asks participants in the proficiency test (see <a href="http://www.crlfish.eu/proficiency_tests.aspx">www.crlfish.eu/proficiency_tests.aspx</a>) to indicate what diagnostic methods are used in their laboratory. These data and coded test results from the various laboratories are presented in the report that are sent to all participants and is uploaded to the Fishpathogens Database (see <a href="http://www.crl-fish.eu">www.crl-fish.eu</a>) where it publicly available.</p> <p>Furthermore, the CRL has organized two proficiency tests for assessing the abilities of participants to detect ISAV, in 2003 (in collaboration with the NRL from Faroe Island; five laboratories participated), an in 2004 (in collaboration with the OIE reference laboratory for ISAV in Oslo, Norway; nine laboratories participated).</p> <p>After every proficiency test, an official report is made on all the submitted data. The report compiles the results from all the participants of the proficiency test and allows the comparison of results. Each participant is provided with a code. A coded version of the report including all results is sent to all participants and is also uploaded on the web page. Furthermore, the EC receives an uncoded version of the report. The CRL would advocate the publication of uncoded reports, but NRLs object to this. For the proficiency test, the CRL notifies the Commission of the results in an uncoded version. At least in one case an application for approval of a VHS and IHN free zone was rejected due to under performance of the NRL in the proficiency tests. The CRL has noticed that some NRLs show long lasting underperformance. The CRL cannot force an NRL to take action, and it is not considered wise to mandate CRL for this. Instead, the support of the Commission is then needed, when informed on the situation by the CRL, to contact the CA, interfere, and promote training of the NRL by the CRL to improve the harmonization of diagnosis.</p>	
<b><i>1.3 Development of new diagnostic tools by the CRLs.</i></b>	++
<p>The CRL developed new neutralisation and ELISA tests in collaboration primarily with colleagues at AFSSA, France for detection of antibodies against VHS and IHN in rainbow trout. This work will be reviewed and the techniques recommended for inclusion in the OIE and EU standards for future surveillance purposes within the coming year. This topic will be included in the CRL work plan 2010.</p>	
<b><i>1.4 Supply of diagnostic tools to other laboratories.</i></b>	++

<b>Main findings - CRL for Fish Diseases</b>	<b>Rating</b>
<p>The CRL holds very detailed records of reagents supplied and received since 1995. The CRL responded to all request from NRLs or TCs, few requests from commercial companies and non-NRLs were beyond the tasks and duties of the CRL and were referred to other parties. The CRL has shipped in total 1,289 reagents (mainly viruses, polyclonal antibodies, sera, monoclonal antibodies, cells, organs and bacteria) since its establishment as CRL. Out of these shipments, 1,023 were to NRLs. The supply of diagnostic reagents takes considerable resources from the CRL. In some cases samples can be picked up directly from the library of frozen or lyophilised virus isolates, but in other cases the virus first has to be propagated and tested in order to assure the correct content. Requests for Rabbit antisera, monoclonal antibodies and cell lines usually can be supplied quickly because the stored materials are prepared in advance. In the recent years an increasing number of requests for supply of DNA, purified RNA or inactivated virus isolates (antigens) have been received. Studies were therefore initiated in order to assess the best way of virus inactivation without destroying the RNA/DNA. The CRL has a certified shipper according to IATA for Dangerous goods. All shipments are thus performed according to international rules. The time taken to supply the material when the sample is ready is roughly between one hour to one day per sample, and approximately one day per shipment.</p>	
<p><b>1.5 Assistance to other laboratories for diagnosis in case of an outbreak.</b></p>	++
<p>Examples of international support are the outbreaks of VHS in Romania and Slovakia and outbreaks of VHS in sea water farms in Ireland, Scotland (turbot) in Finland, in Sweden, and Norway. The CRL has outstanding experience in Viral Haemorrhagic Septicaemia (VHS), whose causative pathogen was isolated for the first time in Denmark, in Infectious Haematopoietic Necrosis (IHN) disease, and infectious salmon anaemia (ISA). In the course of time, the laboratory extended its activities to other fish diseases such as Koi herpes virus (KHV), epizootic haematopoietic necrosis (EHN) and epizootic ulcerative syndrome (EUS). When invited, the CRL provides assistance to outbreaks, but there are several NRLs in the EU with up-to-date diagnostic skills for these diseases, and support, or confirmation of diagnosis, appears not always to be promptly requested. From the CVO survey there was criticism about the response to a VHS emergence in 2007, which also requires attention.</p> <p>A difficulty for fish diseases is the variety of pathogens and corresponding challenge to have acquired outstanding expertise for all of these pathogens. Mostly laboratories have historically acquired expertise on specific diseases, and it takes time for others to follow.</p>	
<p><b>2.0 TRAINING</b> Has the training carried out by the CRLs been sufficient to improve the diagnosis of animal diseases during the last 15 years?</p>	++
<p><b>2.1 The evaluators shall analyse the activities carried out for training and retraining of experts and staff (courses, documents).</b></p>	+++
<p>Following the results of the proficiency tests, the CRL prioritises follow up activities, including training, according to the feedback of the NRLs. The CRL organises workshops on certain diagnostic procedures when needed. With regards to follow up activities of individual laboratories, (i.e. if a laboratory finds that some of the reagents, methods or procedures in use are not functioning properly) the CRL is consulted directly by the laboratory. In such case the CRL aims to provide new reagents or advise on methods or procedures. Often these requests have resulted in an invitation to the NRL's staff to participate in a training course at the CRL. If a NRL obtains a low score in more proficiency tests, members of the CRL usually go on a mission to the respective laboratory to guide on how to perform diagnostic procedures. In this regard, it is worth mentioning that the CRL in 2006 did not organize a proficiency test but prioritized instead to organize training activities (and did this also in 2008) some new MS. The training activities included visits by the CRL staff and practical assistance in performing the proficiency tests (CRL staff stayed on site).</p> <p>The CRL has collaborated with TAIEX for many years, conducted and participated in several</p>	

<b>Main findings - CRL for Fish Diseases</b>	<b>Rating</b>
workshops; training courses were also organised in Århus including most annual meetings for NRLs in order to train colleagues in accession and other countries and to stimulate collaboration in the accession and development process.	
There are more training requests than the CRL can offer, both for EU and outside EU.	
<b>2.2 Are these training activities sustainable in the long term?</b>	++
The CRL provides training courses on demand, but lacks the staff to meet all the demands. So far there has not been criticism about the delivery of training which therefore seems to be satisfactory, but sustainability is at risk because no standardised training materials are available and training struggles with other priorities in the CRL.	
<b>2.3 The evaluators shall also assess the activities carried out to provide scientific advice and expertise as regards disease surveillance and controls.</b>	++
The CRL is very active in typing of strains for surveillance, using sequencing and phylogeny studies, pathogenicity studies, serotyping, cell sensitivity and temperature dependence testing as well as electron microscopy. The estimated average time taken is two weeks per isolate. The CRL's tools for sequencing and data analysis have greatly improved over time, giving faster and more reliable typing and sequences. The data are collated in the new Fishpathogens Database. Approximately 50% of the strains were typed by sequencing, 20% by pathogenicity testing. All VHSV isolates were serotyped and all VHSV isolates from the recent five years were genotyped.	
The CRL has been very active especially towards new EU MS and TCs that has led to improved harmonisation, but seems less involved in surveillance in the 'old' EU MS, partly because some NRLs are of equal high scientific standard, and partly because the CRL has not equal scientific excellence for all relevant fish diseases.	
<b>3.0 NETWORKING</b> Have the coordination activities carried out by CRLs been satisfactory?	++
<b>3.1 Activities carried out to ensure harmonisation of diagnostic methods.</b>	++
The receipt and supply of strains and reference reagents, the organisation of the proficiency testing programmes and annual meetings, and the trainings, have provided the CRL an excellent intra-EU network. The number of strains and samples received annually during 1995-2008 were between on average 67 from EU MS, 168 from TCS, with high number of samples from the Faroer islands.	
As a result of the CRLs training activity to new MS, six NRLs scored 100% in the proficiency test following the mission: for four NRLs the training led to an improvement of results (in particular for one of them), for two NRLs it was similar to the result from the previous test, whereas one NRL obtained a lower score. This is evidence for improved harmonisation of diagnosis, but three of them did not maintain this score in the following years, so continued effort is needed.	
<b>3.2 Coordination with national reference laboratories.</b>	++
The CRL holds direct contact with the NRLs. The CRL tends to keep an open and active network activity with all NRLs in Europe to provide a quick and open dialogue when new outbreaks emerge in the respective countries. Participants to the annual meetings have increased from 20-30 to 60 (May 2009). All annual meetings include a session on new development in the diseases and on the health situation in each country. All new significant changes are reported and included in the reports of the annual meetings. During the annual meetings, the functions of the CRL are also discussed and the process of the definition of the following year's working programme is led by the NRLs.	
<b>3.3 Regular consultation to the Commission on these coordination activities.</b>	++
The communication with the Commission is considered satisfactory. However, for the proficiency test, in cases of underperformance more support from the Commission would be welcomed to contact the CA, and promote training of the NRL by the CRL to improve the harmonization of	

<b>Main findings - CRL for Fish Diseases</b>	<b>Rating</b>
diagnosis.	
<b><i>3.4 Exchange of information with other international reference laboratories.</i></b>	+++
<p>The CRL is OIE reference laboratory for VHS and therefore is in the network of OIE reference laboratories and benefits from the contacts and collaborations within this network.</p> <p>There has been very close collaboration with the OIE reference laboratory for IHN, in Seattle, USA for more that 30 years, and with the OIE reference laboratory for ISA, in Oslo, Norway. Two inter-laboratory tests on ISA were organised with help from this laboratory, they also keep the CRL abreast with the most updated advance on research within ISA. It was considered whether Noda virus infection should be included as a listed disease in EU and for that purpose a workshop was organised with IZSVe in Padova, Italy, in 2004. IZSVe is the OIE reference laboratory for VNN. Also the CRL has close collaboration with this laboratory dating back to the late 1960s.</p> <p>Several collaborative projects were completed also with CEFAS (UK), who is OIE reference laboratory for KHV, SVC and IPN, and collaborative centre for OIE. A workshop was co-organised on SVC and EUS at CEFAS in 2003.</p> <p>Collaboration was also started recently with the OIE reference laboratory for EUS in Bangkok, Thailand, as epizootic ulcerative syndrome (EUS) was listed as exotic disease in Council Directive 2006/88/EC. EUS is caused by <i>Aphanomyces viridans</i>, that is a fungal-like oomycete infection, it is therefore not a viral infection and so not within the CRL's field of responsibility.</p>	
<b>4.0 QUALITY ISSUES (including accreditation)</b>	++
<b><i>4.1 Have suitably qualified staff with adequate training in diagnostic tests?</i></b>	++
The CRL has an internationally recognised and experienced multidisciplinary team of experts and staff with many years of experience. The list of publications by staff members of the CRL is very impressive.	
<b><i>4.2 Application of the necessary analytical techniques in their area of competence.</i></b>	+
The CRL has very skilled staff, with outstanding skills in analytical techniques for VHS, and IHN, satisfactory skills in ISA, KHV and EHN, but less so in EUS. Skills for these diseases are being strengthened by close collaboration with the OIE RLs and in scientific networks.	
<b><i>4.3 Apply diagnostic methods of satisfactory quality and in line with EC requirements.</i></b>	++
As mentioned above, the diagnostic methods employed are prescribed test by the OIE and/or by the European Commission.	
<b><i>4.4 Accreditation</i></b>	++
The fish section is accredited by the Danish national body for accreditation, DANAK, according to the DS/EN ISO/IEC 17025:2005 standard and ILAC G-13:08/2007. The fish section has 14 accredited methods, including methods for diagnosis of VHS, IHN, IPN and ISA. Accreditation of the diagnosis of KHV and EHN is in progress, and for EUS is planned for the coming years. In addition, the CRL is accredited according to ILAC G-13:08/2007 standards for providing inter-laboratory proficiency tests.	

### 3.2.11. CRL for Classical Swine Fever

<b>Main findings - CRL for CSF</b>	<b>Rating</b>

<b>Main findings - CRL for CSF</b>	<b>Rating</b>
<b>Overall evaluation of the fulfilment of the duties and tasks established in the legislation</b>	+++
The CRL is fulfilling all of its contractual duties, responsibilities and obligations as specified in Annex IV.2 of Council Directive No 2001/89/EC of 23 October 2001 laying down Community measures for the control of Classical Swine Fever (OJ L 316, 1.12.2001, p. 5).	
<b>1.0 DIAGNOSIS AND ASSISTANCE</b> Has the assistance of CRLs to other laboratories been adequate in order to improve diagnostic of animal diseases in the Community?	+++
<b><i>1.1 Activities and methods used by CRLs to ensure the correct diagnosis of animal diseases by National Reference Laboratories.</i></b>	+++
The CRL for CSF is part of The Institute of Virology of the University of Veterinary Medicine of Hannover. The CRL uses tests recognised by the OIE and/or EU for identification of the CSF pathogen and for serology according to the Commission Decision 2002/106/EC and the accompanying Technical Annex which was agreed upon by all NRLs; and include virus isolation, antigen-ELISA, different RT-PCR and real-time RT-PCR protocols (CSFV or panPestivirus-specific), and sequencing and subsequent phylogenetic analyses. Serological tests are neutralization linked peroxidase test with different CSFV strains, neutralization linked peroxidase test with border disease virus (BDV) or bovine viral diarrhea virus (BVDV) for differential diagnosis, and antibody-ELISA. The laboratory has put particular effort in getting the tests included in harmonised protocols.	
<b><i>1.2 Ring trails carried out and assessment of their effectiveness.</i></b>	+++
The CRL does fill in its obligation for the annual proficiency testing programme by organising the inter-laboratory comparison tests, and the annual meetings of CSF reference laboratories, at which the results of the inter-laboratory comparison tests are presented and discussed. Because the CSF CRL is also OIE RL, many more than only EU NRLs participate in these comparison tests, making them a logistic achievement to organise. Since 2004, about 35-40 laboratories participate in the PT originating from 30-35 countries. Remarkably, particular MS have more than one NRL for CSF, and in such event both laboratories are included in the CSF PT.  Evidence for harmonisation is that the NRLs for CSF have agreed upon a “Technical Part” ( <a href="http://viro08.tiho.hannover.de/eg/Technical_Annex_Draft_2007.pdf">http://viro08.tiho.hannover.de/eg/Technical_Annex_Draft_2007.pdf</a> ) accompanying Commission Decision 2002/106/EC known as “Diagnostic Manual for CSF” ( <a href="http://viro08.tiho.hannover.de/eg/decision.pdf">http://viro08.tiho.hannover.de/eg/decision.pdf</a> ). This “Technical Part” providing detailed information on diagnostic tests is regularly updated (last update in May 2007) and was agreed upon by all NRLs during the respective Annual Meeting. Methods described in here are used by the NRLs with good results as demonstrated by the yearly inter-laboratory comparison tests. Under-performance in the inter-laboratory comparison test was seldom found, although there is of course always room for further improvement. As an example, between the years 2006 and 2008, the number of participating European laboratories delivering results of the RT-PCR proficiency test increased from 25 to 30. Whereas in 2006 and 2007 only about 70% of the laboratories reported 100% correct results, in 2008, this rate increased to 87%. The more than 3 failures in the first two years from 1-2 laboratories could be attributed mainly to sample preparation or cross-contamination. In contrast, in 2008 the failures were due to the sensitivity of the RT-PCR protocol used. This clearly shows that in this period the results of the proficiency test prompted the laboratories to optimize handling of samples and laboratory procedures.	
<b><i>1.3 Development of new diagnostic tools by the CRLs.</i></b>	++
The CRL has been particularly active to pursue new molecular techniques, and probes for molecular diagnosis. Also, the CRL is studying the use of new ELISA equipment such as the Luminex that may contain a new improvement of the diagnostic methods employed.	
<b><i>1.4 Supply of diagnostic tools to other laboratories.</i></b>	+++

<b>Main findings - CRL for CSF</b>	<b>Rating</b>
<p>The CRL has been regularly requested to supply CSF strains. Between 1996-2009, the CRL has supplied 1-10 CSF strains to EU MS annually, and 1-3 CSF strains to TCs. Strains were always supplied when first evidence was obtained that the requesting laboratory was permitted to work with the virus, could provide an import permit, and if the CRL was allowed to pass on the respective CSF strain: for instance, some strains are in the possession of the CRL but are not owned by the CRL, and in some instances (i.e. vaccine strains) the owner did not allow transfer of the strain. The time needed for shipment of isolates varied due to the time needed to verify above mentioned issues. The number of CSF strains supplied by the CRL to EU MS or TC on request has been consistent and is illustrated below. In 2005 all 27 NRLs were supplied with 2 CSF strains for diagnostic purposes.</p>	+++
<p><b><i>1.5 Assistance to other laboratories for diagnosis in case of an outbreak.</i></b></p>	+++
<p>The CRL has provided assistance to NRL and TC CSF diagnosis in case of an outbreak on many occasions, and received samples for confirmation, on average between 1-4 from EU MS, and 1-3 from TCs. Also, the CRL has established specific contracts with EU MS without an adequate NRL for CSF, to perform CSF diagnosis. Only if the CRL had to act, the activities were reimbursed by the corresponding countries. This is a good example of added value provided by the CRL.</p> <p>The CRL has received great numbers of samples originating from outbreaks over the years, but in varying numbers, depending on the epidemiological evolution of the disease. From nearly zero to about 50 samples have been received over the last 15 years. An important hallmark of the CSF CRL is the establishment of a CSF virus database, accessible for all NRLs (restricted access) in 1996. This is a good example of added value provided by the CRL. In general, the willingness of the NRLs to submit isolates from recent outbreaks to the CRL in a timely manner has improved, although exceptions still occur. This is considered to be not due to unwillingness, but lack of priorities in some MS, for instance when under pressure of a CSF outbreak. The CRL sometimes does delay publication of scientific data on PCR and subsequent phylogenetic data when this is necessary to allow scientific publication, in agreement with the NRL that has submitted the isolate. Between 1996 and 1998, after the establishment of the database in 1996, about 535 isolates that were obtained in the years before were included in the database, and from 1999 onwards a 'normal' number of strains were received and included annually in the database.</p>	+++
<p><b>2.0 TRAINING</b></p> <p>Has the training carried out by the CRLs been sufficient to improve the diagnosis of animal diseases during the last 15 years?</p>	+++
<p><b><i>2.1 The evaluators shall analyse the activities carried out for training and retraining of experts and staff (courses, documents).</i></b></p>	+++
<p>The CRL for CSF provides individual training on demand and by specific workshops for particular issues. The CRL annually provides training, including workshops, for an average of 20-30 experts from MS, and 10-20 from TCs, but numbers vary considerably. Training activities take the form of periods of training sessions for individual experts at the CRL premises or of workshops organised for small groups of participants. Training is also provided on various topics by the staff of the CRL at the premises of the requesting laboratory. The approach is demand driven but flexible: every request is evaluated, and participants are grouped, or, in some cases, individual training is given, but at a time that is mutually convenient. An individual training approach or programme is prepared in advance. Thus, the capacity of the CRL for training depends on the overall workload, and is prioritised according to other tasks.</p> <p>Another frequent activity of the CRL staff in the last years was the participation to TAIEX missions in Eastern European countries. The effort of the CRL to improve the capacity of the laboratories in these countries, already before their accession, is remarkable. As an example, separate ring trials were already organised for Eastern European countries, separate from the EU PT, in the 1990s. It is also to mention the cooperation with the OIE RL for CSF of Pulawy, in Poland, dating back to the 1990s.</p>	+++
<p><b><i>2.2 Are these training activities sustainable in the long term?</i></b></p>	++

<b>Main findings - CRL for CSF</b>	<b>Rating</b>
The CRL performs training essentially on demand, and this has so far functioned properly. There were no remarks from NRL or CVO survey that the trainings were insufficient. The available staff resources are a point of attention for the sustainability of trainings in the future.	
<b>2.3 <i>The evaluators shall also assess the activities carried out to provide scientific advice and expertise as regards disease surveillance and controls.</i></b>	+++
The CRL chairs the CSF Task Force, which focuses on the situation of CSF in Member States and neighbouring TCs, e.g. Balkan countries. The role of the CRL is to provide recommendations to the countries. For control, the role of vaccination in controlling CSF has received greater attention from the CRL based on the requests, but it is not a task as defined for the CRL at the moment.	
<b>3.0 NETWORKING</b> Have the coordination activities carried out by CRLs been satisfactory?	+++
<b>3.1 <i>Activities carried out to ensure harmonisation of diagnostic methods.</i></b>	++
The receipt and supply of strains and reference reagents, the organisation of the proficiency testing programmes and annual meetings, and training, are all activities directed to harmonisation of diagnostic methods. As mentioned above, this has led to improved harmonisation of methods. However, the CRL operates through consensus-building, and not by imposing rules, which can lead to delayed harmonisation of diagnosis. In case of under performance of CFS diagnosis and control, the support from the Commission towards CA of particular MSs can enforce the technical advice of the CRL. From stakeholder interviews also more attention for technical criteria was asked for, in better balance with political arguments.	
<b>3.2 <i>Coordination with national reference laboratories.</i></b>	+++
The communication and collaboration with NRLs is good and positive. The annual meetings constitute an important moment of exchange of information and further building up and improving the relationship amongst and with the NRLs. There are agreements arranged between the CRL and NRL when needed on the use of results and on publication which greatly reduce generally reluctance in sharing material. Trust is recognised as a fundamental element in a CRL, which is not only made by the expertise of the staff or the level in research. Therefore, competition from other excellent laboratories could exist, but this factor makes a difference, as it is very important and takes a long time to be built.	
Internet based tools of communication are well developed and appreciated tool of communication among NRLs and between NRLs and the CRL. The establishment of a chat forum was proposed on the database, and it might be taken into account for further development in this direction.	
<b>3.3 <i>Regular consultation to the Commission on these coordination activities.</i></b>	+++
Communication with the Commission is very positive. The frequency of communication depends on the situation of the disease. In case of outbreaks, CRL staff has always been available for missions or consultancies on contingency plans.	
<b>3.4 <i>Exchange of information with other international reference laboratories.</i></b>	+++
The CSF CRL acts also as Reference Laboratory for CSF for the OIE since 1970. This provides an extra mechanism by which CRL develops its international contacts outside the EU, and expands here knowledge of CSF worldwide. For instance, due to its function as OIE RL, the CRL exchanges information, isolates and reagents with CSF laboratories in South America, South Africa, and Cuba/The Caribbean. The CRL also has contacts with the FAO RL. The CRL has tried to establish closer contact and cooperation with the OIE RL in Japan, so far without much success. Furthermore there is close cooperation with the USA and Russia as well as with various other international CSF laboratories in Europe, the Caribbean and South America.	
This cooperation also includes study and training visits to and from the other RLs as well as attendance to meetings and exchange of materials and data. In 2009 first contacts were successfully established with China and a group of Chinese scientists visited the CRL. Above mentioned information clearly shows that the CSF CRL has an extensive and active international scientific network. The CRL participated in the OIE World Reference Laboratory meeting, and this was a very useful meeting. Thereafter the CRL participated in a	



Main findings - CRL for CSF	Rating
similar meeting of EU CRLs in Brussels in February 2007.	
<b>4.0 QUALITY ISSUES (including accreditation)</b>	++
<b><i>4.1 Have suitably qualified staff with adequate training in diagnostic tests?</i></b>	+++
The CRL has an internationally recognised and experienced multidisciplinary team of experts with many years of experience. The list of publications by staff members of the CRL is very impressive.	
<b><i>4.2 Application of the necessary analytical techniques in their area of competence.</i></b>	++
The CRL has very skilled staff, and have outstanding skills in analytical techniques for CSF.	
<b><i>4.3 Apply diagnostic methods of satisfactory quality and in line with EC requirements.</i></b>	++
As mentioned above, the diagnostic methods employed are prescribed test by the OIE and/or by the European Commission.	
<b><i>4.4 Accreditation</i></b>	++
The CRL and all the diagnostic methods used at the CRL are fully accredited according to ISO/IEC 17025. Accreditation was obtained in 2000, re-accreditation was granted in 2005. The due QM inspection was passed successfully without any corrections in January 2009. An accreditation for proficiency testing programmes has so far not been obtained.	

### 3.2.12. CRL for transmissible spongiform encephalopathies

Main findings - CRL for TSEs	Rating
<b>Overall evaluation of the fulfilment of the duties and tasks established in the legislation</b>	+++
The CRL is fulfilling all of its contractual duties, responsibilities and obligations as specified in Annex X of Regulation (EC) No 999/200 laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies.  It should be noted that the CRL forms part of the network of public health CRLs and is thus in a different category from most of the other CRLs being evaluated.	
<b>1.0 DIAGNOSIS AND ASSISTANCE</b> Has the assistance of CRLs to other laboratories been adequate in order to improve diagnostic of animal diseases in the Community?	++
<b><i>1.1 Activities and methods used by CRLs to ensure the correct diagnosis of animal diseases by National Reference Laboratories.</i></b>	+++
The CRL for TSEs is comprised of a series of laboratories dispersed among departments at the Veterinary Laboratories Agency (VLA), UK. The VLA is an agency of the UK Department of Environment, Food and Rural Affairs (DEFRA). The director of the CRL for TSEs is a co-author of the chapters on Bovine Spongiform Encephalopathy and Scrapie in the OIE's "Manual of Diagnostic Tests and Vaccines for Terrestrial Animals" (6th edition, 2008), and the diagnostic methods used in the CRL for TSEs are incorporated therein and ensure correct diagnosis by NRLs.  The tests, clearly described in SOPs, include histo- and neuropathology as well as immunochemistry (Western blotting, SAF testing) and rapid tests. Diagnostic ELISAs, mainly for surveillance, are carried out in the regional laboratory at Newcastle. The number of tests	

<b>Main findings - CRL for TSEs</b>	<b>Rating</b>
<p>performed for the UK is around 250,000 per year. Confirmation is always done at the CRL. Currently about 5 samples per month are investigated for confirmation whereas formerly the number was around 10 samples per week.</p> <p>The activities and methods used by the CRL are of very high standard.</p>	
<b><i>1.2 Ring trails carried out and assessment of their effectiveness.</i></b>	+++
<p>The CRL organises a histopathology/immunohistochemistry proficiency test every year prior to the annual meeting of NRLs, a second PT round is organised in October. The panel of reagents for the trial consists of at least 5 unstained histopathological sections, including negative controls. The sections have to be stained and interpreted. Replicates are taken back to the VLA from the venue for the meeting to be analysed by pathologists from the CRL. Generally, about 2/3 of the interpretations provided are satisfactory. This is a good result considering that there are few or even no BSE cases in most EU countries. Any NRLs who fail the PT round are required to investigate the reason for failure and report to the CRL within two weeks. If necessary, training and advice are given. Replicate PT samples may also be supplied. Participation in this ring test, with the exception of one laboratory, is almost 100 %.</p> <p>In 2009, remote slide viewing will be introduced. This will have many advantages: reduced shipment costs, faster completion after the distribution of material, etc. The web-based images will be hosted by a private, specialist company.</p> <p>The CRL also organises annual PTs for rapid tests (BSE and scrapie), confirmatory blotting (BSE and scrapie), genotyping and discriminatory blotting. The CRL does not, however, provide training for rapid tests because they are commercial tests. It is the task of the NRL to monitor the results of other i.e. commercial laboratories in their country and in the case of unsatisfactory results the relevant NRL should be contacted. Should it be necessary, the CRL is willing to assist NRLs to resolve problems.</p> <p>All available data is collated and presented at the annual meeting of the NRLs. The information is also issued electronically. In the near future the results will be also made available (coded so that they are anonymised) via the TSE-LAB-NET (i.e. in the same way as it is already done for the CRLs for ND and AI via FLU-LAB-NET).</p> <p>If the results obtained by an NRL for any PT are beneath the acceptable threshold they are offered training at the CRL. Usually between 7 and 10 trainees attend such courses. The most recent one was held in December 2008. The CRL has a high frequency of communication with NRLs and know the staff so they can usually ensure that the most appropriate people receive training i.e. those who perform the tests.</p> <p>Every year after the annual meeting the CRL sends a questionnaire to laboratories involved with collecting data on the use of tests and the number of tests conducted in relation to both diagnosis and surveillance. The NRLs are also questioned about the annual meeting. It is recommended by the Evaluation Team that the CRL should include some questions to determine their performance as viewed by the NRLs in relation to the following: training facilities, complaints and/or satisfaction relating to CRL activities, etc. In other words perform an active customer satisfaction survey.</p>	
<b><i>1.3 Development of new diagnostic tools by the CRLs.</i></b>	+
<p>The CRL is at the forefront of scientific developments in diagnosis of TSE. However, it is cautious in introducing alternative techniques to histopathology. From the CVO survey it was commented that recent biochemical and immunohistochemical techniques were insufficiently taken in consideration by the CRL.</p>	
<b><i>1.4 Supply of diagnostic tools to other laboratories.</i></b>	++
<p>The CRL fulfils on average 10 requests annually for fixed tissue control material, with demand split 50/50 between EU and non-EU countries. In general, the demand has been much greater for frozen materials. Between 2002 and 2008, in total 215 (per year 17-67) requests have been</p>	

<b>Main findings - CRL for TSEs</b>	<b>Rating</b>
<p>obtained annually from EU MS, and in total 22 from TCs (per year 1-8). The following table is a summary of TSE Archive requests since 2002. Non EU requestors are predominantly Japanese, US and NZ. EU includes internal VLA and CRL as well as other European labs. Commercial requestors were all aspiring test developers. Some requests represent multiple requests from the same requestor in different years, mainly for quality assurance.</p> <p>From the CVO survey comments were made on the difficulty receiving reference TSE material, and although the basis for this was not substantiated, it deserves further attention.</p>	
<b><i>1.5 Assistance to other laboratories for diagnosis in case of an outbreak.</i></b>	++
The CRL does provide assistance for confirmation of diagnosis for about 10 countries per year. Characterisation by immunoblotting and other assays are numerous. Every year about 1-2 times TSEs are characterised by bioassay for other countries.	
<b>2.0 TRAINING</b> Has the training carried out by the CRLs been sufficient to improve the diagnosis of animal diseases during the last 15 years?	++
<b><i>2.1 The evaluators shall analyse the activities carried out for training and retraining of experts and staff (courses, documents).</i></b>	+++
<p>The CRL maintains the TSE reference laboratory webpages (<a href="http://www.defra.gov.uk/vla/science/scitserl.htm">http://www.defra.gov.uk/vla/science/scitserl.htm</a>) on which are posted basic training material and information, together with links to other relevant websites. There is also a reference laboratory mailbox to which generic queries can be sent. The CRL can provide for up to 3 visits to laboratories each year, where representatives of the CRL travel to MS to provide targeted assistance and training for all NRL staff in their own facilities. The NRLs are selected either as a result of poor performance in the PT rounds or if an MS specifically requests such assistance.</p> <p>Staff from other laboratories can at any time also request a training visit to the CRL and such individual requests will be met wherever possible. Around 10 scientists/technicians from MS receive training each year in the CRL.</p>	
<b><i>2.2 Are these training activities sustainable in the long term?</i></b>	++
The CRL has well structured its training and training materials, which is sustainability of trainings in the future.	
<b><i>2.3 The evaluators shall also assess the activities carried out to provide scientific advice and expertise as regards disease surveillance and controls.</i></b>	++
The number of publications in peer and non-peer reviewed journals and contributions to meetings/congresses is impressive. Staff have also written several chapters on TSEs for text books.	
<b>3.0 NETWORKING</b> Have the coordination activities carried out by CRLs been satisfactory?	+++
<b><i>3.1 Activities carried out to ensure harmonisation of diagnostic methods.</i></b>	++
The CRL is very active in harmonising diagnostic methods for TSE and devotes a lot of energy to this activity, in particular during the annual meeting of NRLs, organised by the CRL. The CRL is not directly involved in surveillance studies in MS. However, they usually confirm all index cases in MS (at the request of the relevant NRL) and furthermore they can provide advice for sample preparation, data gathering, reporting procedures and surveillance strategies.	
<b><i>3.2 Coordination with national reference laboratories.</i></b>	+++
A major responsibility of the CRL is to promote common practice, methodology and standards in the diagnosis and surveillance of TSEs throughout the EU thorough close interaction with NRLs in MS. This is done through the supply of reagents, proficiency testing, training, provision of manuals, documents, advice and the organisation of workshops and the annual meeting of NRLs. A web-based forum called "TSE LAB NET" is expected to become operational at the CRL during	

Main findings - CRL for TSEs	Rating
May 2009. It will provide a site for TSE scientist and technicians to seek and exchange information. This is a good example of added value provided by the CRL.	
<b>3.3 Regular consultation to the Commission on these coordination activities.</b>	+++
Communication with the Commission is very positive.	
<b>3.4 Exchange of information with other international reference laboratories.</b>	+++
The CRL is also a reference laboratory for the OIE and FAO and engages actively with the other OIE reference laboratories for TSE. The CRL also has representation on EFSA, WHO and TAFS (TSE and Food Safety) expert groups.	
<b>4.0 QUALITY ISSUES (including accreditation)</b>	+++
<b>4.1 Have suitably qualified staff with adequate training in diagnostic tests?</b>	+++
The CRL has excellent staff with great scientific skills. The number of publications in peer and non-peer reviewed journals and contributions to meetings/congresses is impressive. Staff have also written several chapters on TSEs for text books. In addition, the head of the CRL was an author of the chapters on Bovine Spongiform Encephalopathy and Scrapie in OIE's "Manual of Diagnostic Tests and Vaccines for Terrestrial Animals" (6th edition, 2008).	
<b>4.2 Application of the necessary analytical techniques in their area of competence.</b>	+++
The CRL has very skilled staff, and have outstanding skills in analytical techniques for TSEs such as histopathology, and Western blotting techniques, and several others.	
<b>4.3 Apply diagnostic methods of satisfactory quality and in line with EC requirements.</b>	+++
As mentioned above, the diagnostic methods employed are test that have been prescribed by the CRL staff in OIE publications, showing their high level of competence.	
<b>4.4 Accreditation</b>	++
The CRL is internationally accredited (BS EN ISO/IEC 17025) by UKAS under accreditation number 0004P. UKAS is recognized by the Department of Trade and Industry as the national body responsible for assessing and accrediting laboratories. All CRL tests are accredited For commercial reasons histopathology is certified as GLP.	
There is no accreditation for performance of proficiency tests.	

### 3.3. Overview of main findings for CRLs

Table 3 below summarises the overall ratings for all CRLs indicating the evaluator's assessment of the extent to which these fulfil their tasks and duties. The table also includes subsidiary ratings for the four main technical functions: diagnosis and assistance, training, networking and quality issues. These ratings are justified in the individual CRL tables in Section 3.2 above, and based on detailed information in the individual CRL visit reports (in **Part Two** of this Final Report).

**Table 3 Overview of individual CRL evaluations**

CRL	Overall Rating	Rating for Main Functions		
	Fulfilment of duties and tasks	Diagnosis & assistance	Training	
	Networking	Quality Issues		
AI	+++	+++	+++	+++
ND	++	++	++	++
BT	+++	+++	++	++
AHS	+	++	+	++
SVD	++	++	++	++
ASF	++	++	+++	++
Rabies (serology)	++	+++	++	++
Mollusc diseases	++	++	+++	++
Zootechnics	++	++	++	++
Fish diseases	++	++	++	++
CSF	+++	+++	+++	++
TSEs	+++	++	++	+++

**Rating codes:**

Outstanding (provides excellence or added value)

Satisfactory (meets EU requirements)

Underperforming (some shortcomings identified that require improvement)

Taking together the evaluation reports, the CVO survey and the NRL survey, it can be seen that there are some issues to be addressed at specific CRLs, but there is no pattern of failings across the CRLs and no evidence of systemic failure. On the contrary, the CRL/NRL relationships have proved to be very important in harmonisation of diagnosis.

It is noted that two CRLs tended to receive lower ratings from the CVOs and NRLs throughout the surveys. In the case of the CRL for African Horse Sickness, the CVOs confirmed the expert analysis that the CRL has been underperforming for a number of years as a result of problems with the laboratory buildings. The underperformance was not due to professional inadequacy or insufficient technical skills. However, the evaluators found that these problems have now been largely overcome and there is reason to expect improved performance of the CRL for AHS in the near future. In the case of the CRL for Newcastle Disease, the lower ratings can perhaps be attributed to the fact that the CRL for Avian Influenza, which is in the same institute and utilises most of the same staff, has become a higher priority in recent years and has drawn attention away from Newcastle Disease to some extent. These issues have been addressed in the individual CRL Reports, and are also addressed in a more general context later in this report. Although both CRLs were considered to be fulfilling their functions according to EU requirements, some areas of underperformance have been identified that require attention.

The following sections provide general comments on the main functions of the CRLs, including some illustrative comments from the CVO and NRL surveys. The points raised have been taken into account in the rating of the CRLs. Negative comments have been investigated to assess whether they refer to an isolated circumstance or are representative of a wider viewpoint. This section has been kept brief to avoid duplication with the more in-depth discussion in section 4.

As the CRL for Zootechnics is a special case, its conclusions have been summarised separately in section 3.8.

### 3.3.1. Diagnosis and assistance

The results of the evaluation indicate that harmonised diagnosis has been significantly improved for most diseases under this evaluation since the CRLs became operational. The positive findings of the expert reports from the CRL field missions are supported by the results of the CVO and the NRL surveys.

Concerning harmonisation of diagnosis, it has proven very difficult to measure the level of harmonisation between NRLs quantitatively. Proficiency tests vary in the set up, even for the same diseases, and also test protocols change throughout the years and cannot be simply compared from year to year. In general, harmonisation of diagnosis has greatly improved, as demonstrated from the following examples:

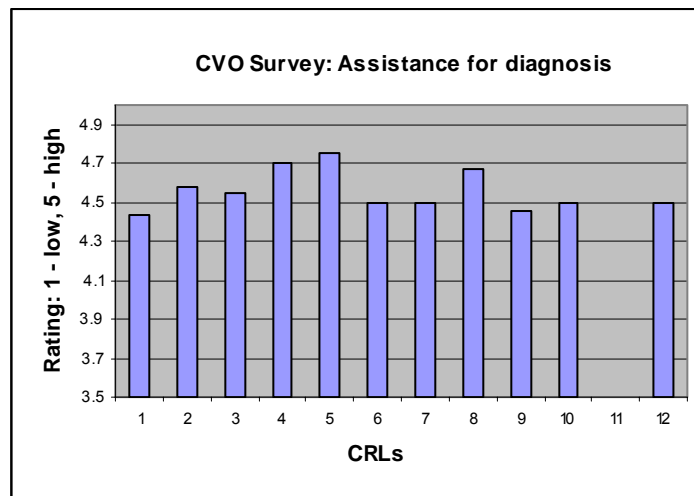
- CRL for BT: in 2006, 23 NRLs took part in the PCR component of the proficiency test and only 14 labs used real time RT-PCR, this rose to 18 out of 24 labs in 2007 and in 2008 22 out of the 25 NRLs used real time RT-PCR. This is a demonstration of effective harmonisation of BT diagnostics across EU.
- CRL for Fish: 7 NRLs were trained between 2006 and 2008, and six NRLs scored 100% in the proficiency test following the training missions, for four NRLs the training led to an improvement of results, for two NRLs it was similar to the result from the previous test whereas one NRL obtained a lower score. However, even though all the NRLs trained in 2006 scored 100% in the proficiency test following the mission, three of them did not maintain this score in the following years.
- CRL for CSF: adequate RT-PCR test results increased from 70 to nearly 90 % in 2006 and 2008

Other examples can be found in the main findings for each individual CRL above.

According to the results of the CVO survey, nearly all respondents indicated that the CRLs have contributed to the development of harmonised diagnostic procedures at Community level. The diagnostic manuals and protocols, and the proficiency testing programmes organised by the CRLs are particularly appreciated, and in most cases CRLs have played a key leading role in adopting or developing tests for use in the CRL-NRLs across EU MS (e.g. on PCR tests). Details of CVO responses to the survey are shown below.

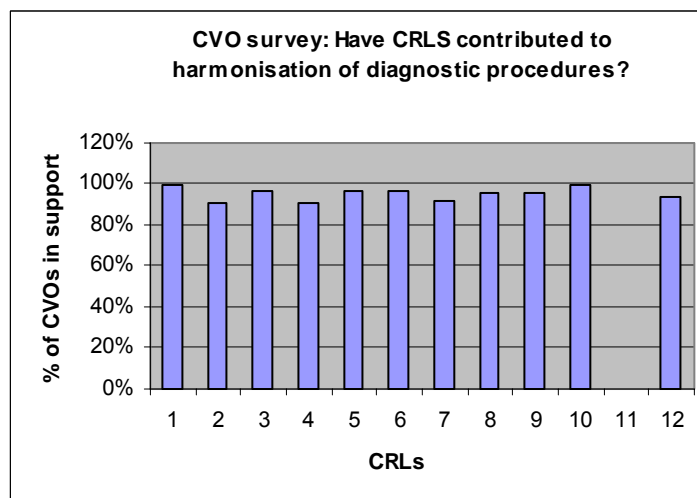
Furthermore, the CVOs that responded to the survey rated the assistance provided by the CRLs for the characterisation and confirmation of pathogens (confirmatory diagnosis), the supply of diagnostic reagents, and their advice on surveillance programmes as 'very good' to 'excellent' in terms of effectiveness and speed.

Figure 9 CVO Survey: diagnosis



**CRL codes:** 1 – AI, 2 – ND, 3 – BT, 4 – CSF, 5 – ASF, 6 – SVD, 7 – AHS, 8 – Rabies Serology, 9 – Fish diseases, 10 – BVM, 11-Zootechnics, 12 – TSEs.

Figure 10 CVO Survey: harmonisation



**CRL codes:** 1 – AI, 2 – ND, 3 – BT, 4 – CSF, 5 – ASF, 6 – SVD, 7 – AHS, 8 – Rabies Serology, 9 – Fish diseases, 10 – BVM, 11-Zootechnics, 12 – TSEs.

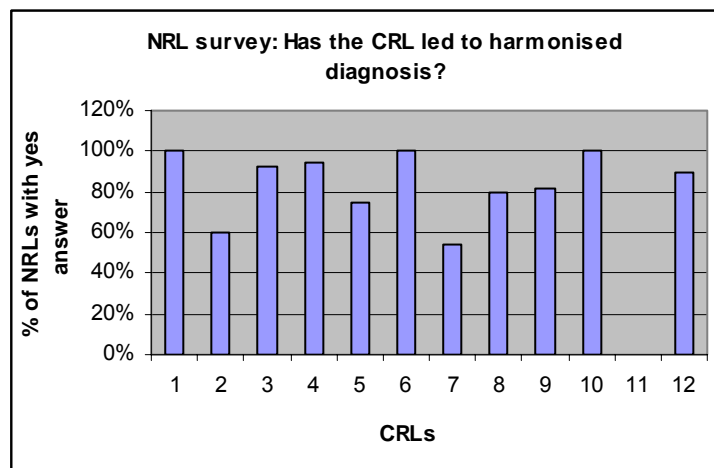
Selected CVO comments include:

- CRLs have contributed to the development of rapid and efficient diagnostic tests. This also allows fast control measures to be taken.

- The work of all CRLs has improved animal health. The improvement is mainly due to the harmonization of diagnostic methods. Pathogen identification and differentiation are important for selecting the appropriate measures, i.e. vaccines.
- CRLs are important for collecting and distributing pathogen strains, to optimise and develop new diagnostic tools.

The NRLs similarly provided a lot of evidence to support their strong collective view (80% of all NRL respondents) that the CRLs contribute to harmonization of diagnostic methods. However, there was some variation between CRLs as the following chart illustrates:

**Figure 11 NRL Survey: harmonisation**

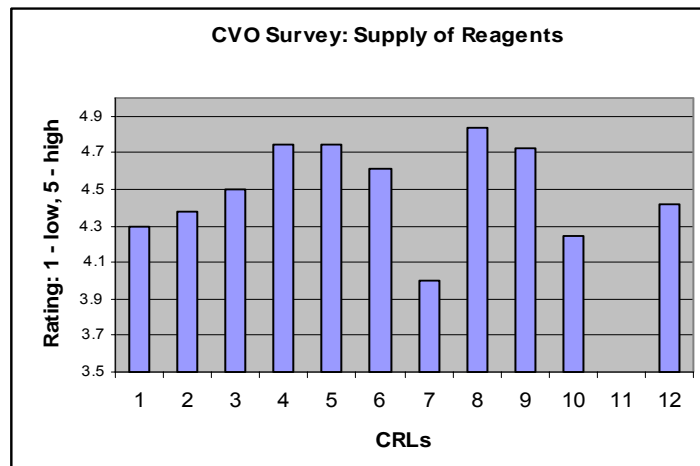


**CRL codes:** 1 – AI, 2 – ND, 3 – BT, 4 – CSF, 5 – ASF, 6 – SVD, 7 – AHS, 8 – Rabies Serology, 9 – Fish diseases, 10 – BVM, 11 – Zootechnics, 12 – TSEs

With regard to supply of reagents, four CRLs received a lower rating from CVOs: AI, ND, AHS and TSEs:



Figure 12 CVO Survey: reagents



CRL codes: 1 – AI, 2 – ND, 3 – BT, 4 – CSF, 5 – ASF, 6 – SVD, 7 – AHS, 8 – Rabies Serology, 9 – Fish diseases, 10 – BVM, 11-Zootechnics, 12 – TSEs.

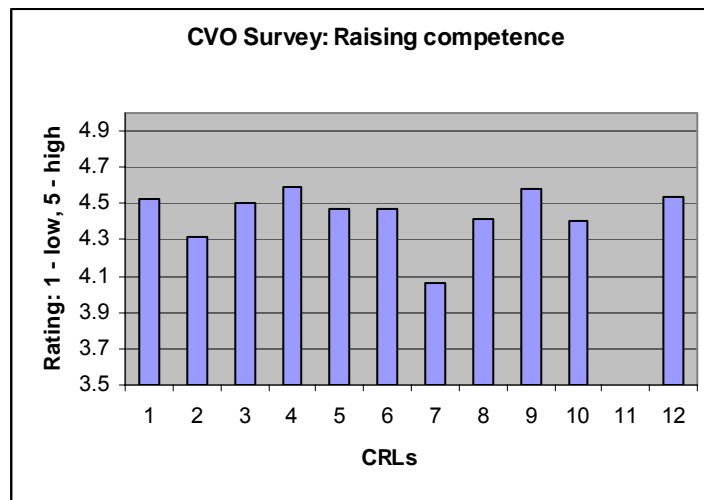
Selected CVO comments include:

- NRLs have to pay for the diagnostic reagents from some CRLs.
- The CRL did not provide reference material, instead the NRL was asked to get in touch with a Tissue Reference Bank. Question rose as to whether the CRL should provide NRLs with reference material.
- Obtaining reference material is becoming more difficult as the number of cases has declined.
- Diagnostic reagents were obtained from the OIE Ref Lab instead of the CRL.
- The Technical Manual of diagnostic methods is seen as very useful reference compendium.
- Proficiency test panels were sent in a timely and efficient manner.

### 3.3.2. Training

In terms of raising competence, the overall response from CVOs was generally positive:

Figure 13 CVO Survey: Training



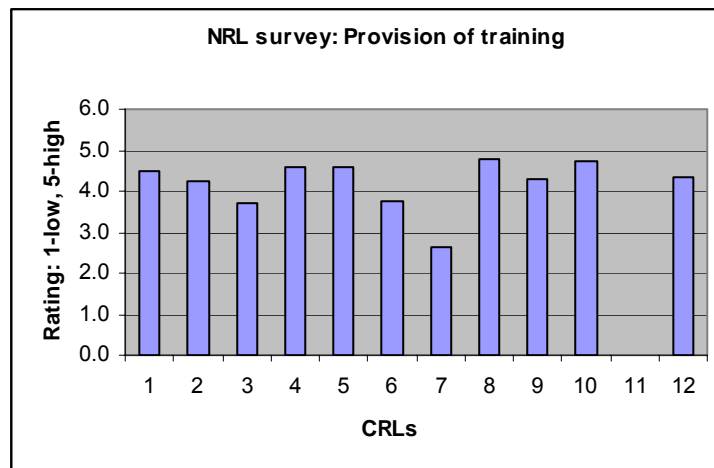
**CRL codes:** 1 – AI, 2 – ND, 3 – BT, 4 – CSF, 5 – ASF, 6 – SVD, 7 – AHS, 8 – Rabies Serology, 9 – Fish diseases, 10 – BVM, 11-Zootechnics, 12 – TSEs.

Comments from CVOs include:

- In general, the different CRLs have raised the competence of the respective NRLs. Nevertheless, differences between individual CRLs can be found. Annual meetings organised by the CRL are helpful for networking, although in depth discussions are often not possible at these occasions. Stronger coordination of the efforts of the different NRLs by the CRLs would be appreciated. Workshops on specific topics and distribution of new emerging strains to the NRLs would be beneficial.
- The NRL had to pay the CRL for training.
- Annual CRL/NRL meetings are considered very useful.
- Support for creating laboratory contingency plans would be highly appreciated.
- The ring trial represents good value but there are some doubts generally about the level of CRL support being sufficient to ensure training across all EU MS.

The NRL rating of the provision of training by CRLs is shown below:

Figure 14 CVO Survey: Training provision



**CRL codes:** 1 – AI, 2 – ND, 3 – BT, 4 – CSF, 5 – ASF, 6 – SVD, 7 – AHS, 8 – Rabies Serology, 9 – Fish diseases, 10 – BVM, 11-Zootechnics, 12 – TSEs

Although the response was generally favourable, a number of NRLs commented that they had not participated in training provided by the CRL. Other NRL comments include:

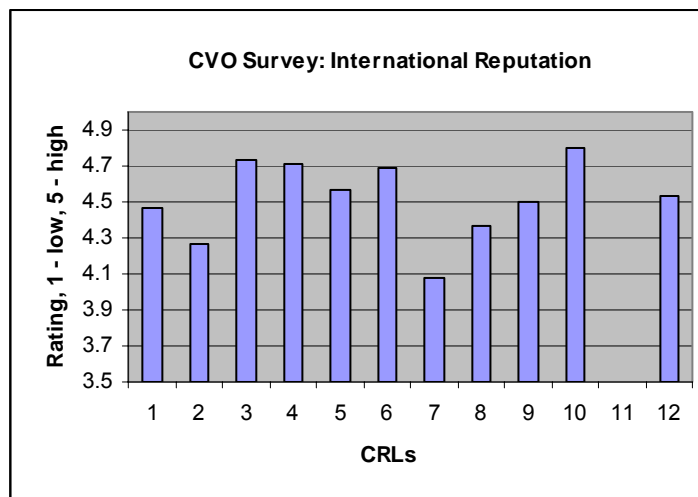
- One NRL had not participated in any training activities or workshops but had always received prompt advice when we have had any questions.
- One had no experience of training activities or workshops organised by the CRL except attendance at Annual Reference Laboratory meetings since 2006, which were considered useful.
- One CRL thought that the CRL had never organised a workshop or any training activity.
- CRL activities within the EU and in general are focused on the laboratory diagnosis. This can be done much better by providing assays and confirmation assays. There is always a need for robust and standardised assays. Technically, many NRLs are well equipped and trained for standard assays, but less for specialised and conventional methods. This is absolutely true for exotic diseases.
- The most important thing that is missing is education material for clinical diagnosis, including videos in order to recognise the disease as soon as possible in the field. This is very critical for exotic diseases.
- The Exotic Disease Diagnostics Courses are very helpful
- The CRL should provide regular training courses (at least once per year) for people from NRLs, if such training is necessary. This should be organised by the CRL.

- One NRL had no experience of training within workshops. The workshops attended were seminars (technical workshops and industry meetings) and very useful with many exchanges.
- One opinion was that workshops have been organised only for certain laboratories and were not open for all MS.
- Annual CRL meetings have been useful with combined training.

### 3.3.3. Networking

With regard to international reputation, most CVOs considered the CRLs had good international reputations.

**Figure 15 CVO Survey: Networking**



**CRL codes:** 1 – AI, 2 – ND, 3 – BT, 4 – CSF, 5 – ASF, 6 – SVD, 7 – AHS, 8 – Rabies Serology, 9 – Fish diseases, 10 – BVM, 11-Zootechnics, 12 – TSEs.

A CVO from one new MS was especially complimentary about the support and collaboration his country had received from the CRL for Fish Diseases before joining the EU. Other CVOs pointed out that the expertise of staff is a major strength of the CRLs and highlighted in particular the CRLs for AI, ND, TSEs, SVD, Fish diseases and CSF. It was also noted that being a Collaborating Centre for WHO or OIE helps a CRL to acquire an international reputation.

### 3.3.4. Quality issues

The evaluators assessed the quality standards of each laboratory, as shown in the overview chart at the beginning of this section, and in more detail in the individual CRL evaluation reports (**Part TWO** of this Report).

The evaluators considered that having laboratory accreditation, a quality manual and Standard Operating Procedures (SOPs) in place is the benchmark for a satisfactory quality rating. In some cases laboratories waiting for accreditation were accepted as satisfactory. Accreditation for test procedures and proficiency tests would elevate the rating to outstanding.

Eight of the laboratories hosting the CRLs are accredited and have at least satisfactory quality standards in place, although in some cases not all tests are accredited. The other four are working towards accreditation and/or improvement of quality standards. Some CRLs also had accreditation for the execution of proficiency testing programmes, which is considered an extra quality criterion that would merit an 'Outstanding' rating.

The staff was suitably qualified in all cases, and the only concern was that appropriate succession was arranged in advance, because some experts of high standing will be difficult to replace. CRLs rely very much on the scientific reputation of their staff. Attention for this very important success factor for CRLs has the risk to be neglected.

Having international experts among CRL staff is considered an advantage, because it expands the professional network outside of the home country. The CRLs all applied the necessary analytical techniques in their area of competence, and all applied diagnostic methods of satisfactory quality and in line with the OIE requirements, with minor variations. Notably, the new PCR for Bluetongue was adopted as the EU diagnostic test by NRLs before it was adopted by the OIE. This illustrates that the CRL and NRL network of laboratories is functionally efficient and fully capable of harmonising and modernising the diagnosis of notifiable diseases across Europe on its own merit.

### **3.3.5. Findings for the CRL on Zootechnics**

A specific analysis was undertaken with respect to the activity of the Zootechnics CRL, whose establishment was aimed at different objectives from the animal health CRLs. In order to liberalise intra-Community trade in pure-bred breeding animals of the bovine species, it was considered necessary to harmonize the testing methods and the assessment of the results. This was aimed at avoiding any national provisions which might constitute a prohibition, restriction or impediment to intra-Community trade relating to the acceptance for breeding purposes of pure-bred breeding animals of the bovine species. The designation of a reference body was therefore instrumental in the acceptance for breeding purposes of pure-bred breeding animals of the bovine species and in the realization of the single EU market for these products<sup>12</sup>.

The initial objectives have been achieved since the establishment of the CRL. Interbull evaluations have become an internationally accepted standard for evaluation of bulls and the Centre has a very good reputation, due to the accuracy of its work and the reliable and unbiased results it is perceived to produce. National evaluation centres rate its performance in organising routine international evaluations, in distributing the results of these evaluations and its overall relevance and usefulness all very highly. The network established over many years, allows for continuous update on research developments, through coordination and review of research done in member countries, as well as through partnerships with research centres worldwide. The capacity for developing new evaluation methods was by contrast rated relatively low, which is mostly due to the fact that the centre coordinates methods instead of conducting research.

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<sup>12</sup> As from Art. 5 of Council Directive 87/328/EEC of 18 June 1987 on the acceptance for breeding purposes of pure-bred breeding animals of the bovine species, as amended by Council Directive 2005/24/EC of 14 March 2005

From the results of the survey among the national evaluation centres it appears that the work of Interbull has facilitated the exchange of experience between countries and that the implementation of validation procedures, harmonised between countries, has in turn also improved national evaluation procedures. It has to be noted, in fact, that the CRL has no power to enforce changes at national level, but the activity undertaken, including the publication of national methods details (and their comparison) has been beneficial at Community level because it has reduced the differences between MS.

The activity of Interbull has also, in the view of the national evaluation centres who responded to the survey, facilitated the trade in semen both at EU and world level. There are also some limits indicated by one respondent, which cannot, however, be considered the responsibility of the centre. In particular it was indicated that since the international evaluations are based on different evaluation systems and even if many efforts have been undertaken to harmonize national genetic evaluations, a foreign bull must have more daughters than a national bull to reach the same level of reliability in the Interbull evaluations. Therefore some countries may favour national bulls because the foreign young bulls do not have enough daughters to reach this level of accuracy after their progeny test.

Genomics represents the most important opportunity – and challenge - for the future. Some member countries are very advanced, Interbull needs therefore to be in line with this rapid evolution, and additional resources – financial and human – have been foreseen for this purpose. The main threat is the risk that multinational companies, who are currently very advanced in this field, take over the role and the function of the Interbull Centre. This could undermine the political neutrality that Interbull has ensured throughout the years, focusing on the technical issues and providing unbiased evaluations, notwithstanding the high level of commercial interest in this activity. This might also be associated with the concept that genomics make international evaluations unnecessary, therefore devaluing the work and the role of Interbull. However, it should be noted that difficulties might also arise from the fact that genomic data are not yet sufficiently scientifically verified and there is still a lack of information for methods for international evaluation of genomic data.

## 4. Evaluation of the current system of CRLs

This analysis corresponds to Task 6.3 of the ToR. Findings and conclusions have been drawn from the different evaluation tools, including the common elements from the individual CRL evaluation reports and the NRL and CVO surveys.

### 4.1. Contribution to the achievement of the objectives of the EU CAHP

#### 4.1.1. Description of the current CAHP

The EU Community Animal Health Policy (CAHP) is currently made up of a set of legislative acts/policy actions<sup>13</sup>. These cover several areas in the field of animal health, in order to achieve the Community objectives in this field.

In particular, the main objectives of the CAHP are:

- To protect and raise the animal health status in the Community, in particular of food-producing animals;
- To ensure intra-Community trade and imports of animals and animal products comply with the EU animal health rules.

To this end, legislation was laid down in the following areas:

- Animal health conditions for intra-community trade of live animals, semen, ova and embryos, and products of animal origin;
- Animal health conditions for imports of live animals, semen, ova and embryos and products of animal origin;
- Control and eradication of animal diseases:
  - Control measures to be taken as soon as the presence of a disease is suspected;
  - Eradication and monitoring programmes, for the diseases that are already present within the Community; and
- Other legislative measures:
  - Animal identification and registration.

Control measures are established for the following diseases that are in the competence of the CRLs covered by this evaluation<sup>14</sup>:

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<sup>13</sup> In the context of the new Animal Health Strategy, one of its pillars is the aim to replace the current body of acts with a single regulatory/policy framework.

- African horse sickness;
- African swine fever;
- Avian influenza;
- Bluetongue;
- Certain fish diseases;
- Certain mollusc diseases;
- Classical swine fever;
- Newcastle disease; and
- Swine vesicular disease.

Eradication and monitoring programmes aim at progressively eliminating animal diseases that are endemic in certain areas of the Community. The diseases covered are:

*Group 1: Endemic disease, subject to mandatory or voluntary control and/or eradication measures on a herd/flock basis:*

- African swine fever;
- Swine vesicular disease;
- Endemic classical swine fever;
- Infectious haematopoietic necrosis (IHN);
- Infectious salmon anaemia (ISA);
- Bluetongue in endemic or high risk areas.

*Group 2: Zoonoses or epizootics (not covered elsewhere) measures on a herd or flock basis:*

- Rabies;
- Bovine spongiform encephalopathy (BSE) or any other slow developing disease.

In addition, measures are established to manage the risk of transmissible spongiform encephalopathies (TSEs), such as BSE. Rules in place relate to monitoring of TSE in bovine, ovine and caprine animals, the removal of Specified Risk Material (SRM) and prohibitions concerning animal feeding. Also, EU legislation foresees measures for the eradication of TSE, intra- and extra-Community trade and establishes criteria to classify the BSE status of MS and TCs.

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<sup>14</sup> Only those control measures related to diseases covered by the CRLs considered in this study are listed here.



Specific Community legislation is also established for zootechnics, with the aim of promoting free trade in breeding animals and their genetic material considering the sustainability of breeding programs and preservation of genetic resources. The rationale for this legislation is that satisfactory results in animal production depend to a large extent on the use of domestic animals of high genetic quality. In particular, this legislation covers the following issues:

- Breeding programmes of approved organisations on the basis of harmonised rules;
- Zootechnical legislation.

#### 4.1.2. The role of the CRLs within the current CAHP

The system of CRLs has been put in place progressively over the years in order to contribute to the achievement of the CAHP objectives.

The designation of the CRLs is aimed in particular at achieving high quality, uniform and reliable analytical results within the EU<sup>15</sup>. The availability of such results would contribute to ensuring appropriate disease diagnosis for the application of control and eradication measures. By means of their work, the CRLs act as a bridge between research and policy, between risk assessment and risk management, at EU and national level.

Other important functions of a CRL include the provision of scientific advice for the development of surveillance, control and eradication plans. Finally the CRLs facilitate capacity building among the NRLs through training and the exchange of knowledge among experts.

CRLs are expected to serve as centres of expertise for the diseases concerned to support the adoption of science based measures to control animal disease by the European Commission, both in the case of outbreaks and in peacetime, while liaising with National Reference Laboratories.

#### 4.1.3. The new Animal Health Strategy and the role of the CRLs

Following the recent evaluation of the CAHP, the EU adopted a new strategy for defining and developing future policy in the field of animal health<sup>16</sup>. The new strategy places greater emphasis on prevention and early response, to allow a cost-effective and efficient approach to animal health. The aim is to put greater focus on precautionary measures, disease surveillance, controls and research, in order to reduce the incidence of animal disease and minimise the impact of outbreaks when these occur. This new strategy has been translated into an Action Plan<sup>17</sup>.

In the context of the Action Plan, the system of CRLs is placed within the “Research and innovation” pillar<sup>18</sup>.

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<sup>15</sup> As envisaged in the horizontal legislative basis defining the role and responsibilities of the CRLs in the animal health sector (Regulation (EC) No 882/2004 on official controls, Article 32.2). The designation of Community and national reference laboratories aims to contribute to a high quality and uniformity of analytical results. This objective is to be achieved by activities such as the application of validated analytical methods, ensuring that reference materials are available, the organisation of comparative testing and the training of staff from laboratories.

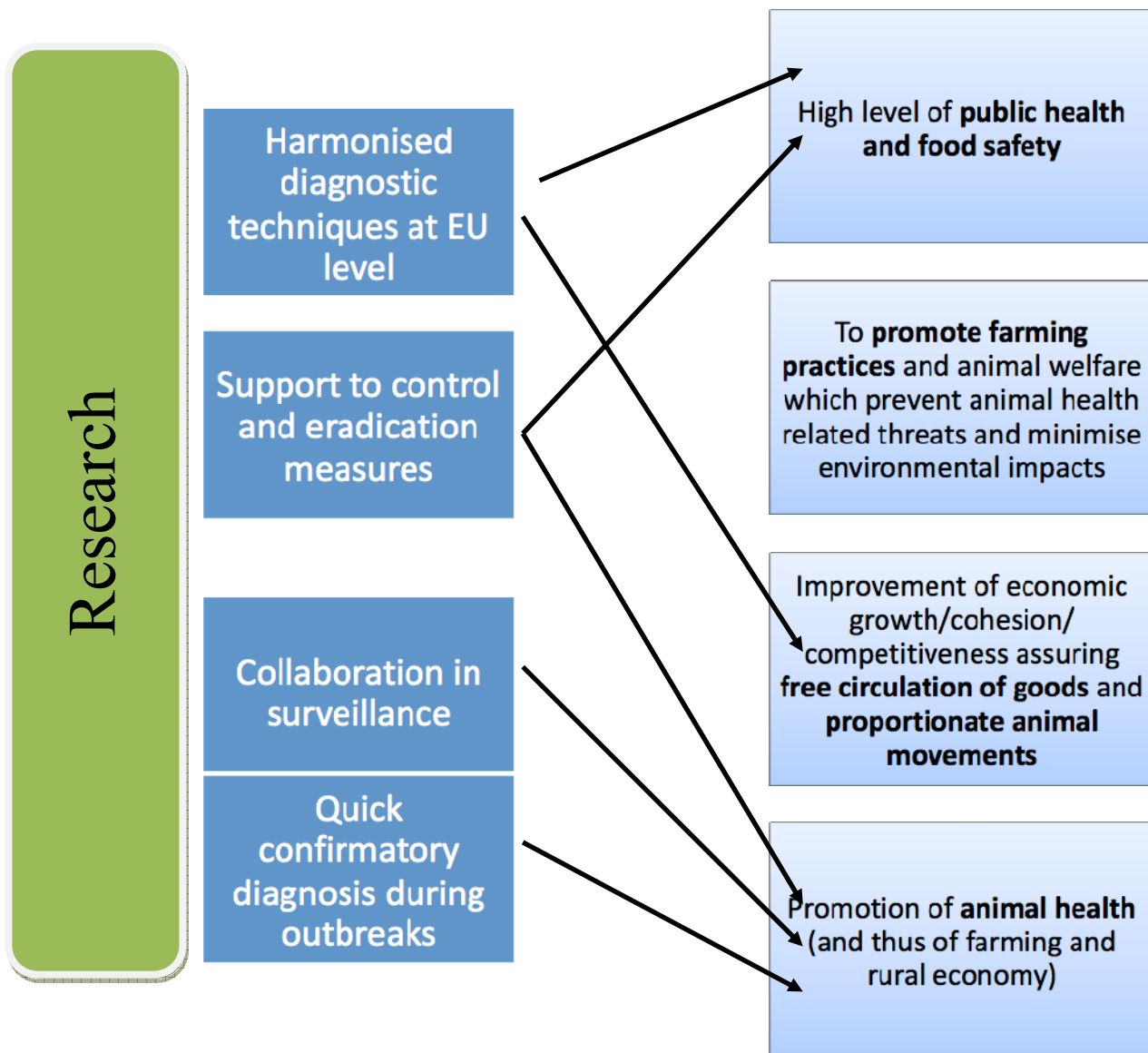
<sup>16</sup> Communication from the Commission to the Council, the European Parliament, the European Economic and Social Committee and the Committee of the Regions: A new Animal Health Strategy for the European Union (2007-2013) where “Prevention is better than cure”. COM 539 (2007) Final, Brussels.

<sup>17</sup> Communication from the Commission to the Council, the European Parliament, the European Economic and Social Committee and the Committee of the Regions: Action Plan for the implementation of the EU Animal Health Strategy. COM(2008) 545 Final, Brussels, 10.9.2008.

<sup>18</sup> The Action Plan is structured around four main pillars or areas of activity: 1. Prioritisation of EU intervention; 2. The EU Animal Health framework; 3. Prevention, surveillance and preparedness; and 4. Science, Innovation and Research.

Figure 16 below describes the contribution of the CRL tasks and duties to the achievement of the objectives of the new Animal Health Strategy.

Figure 16 Contribution of CRLs to the objectives of the new Animal Health Strategy



#### 4.1.4. Overall assessment: contribution to CAHP objectives

In order to assess the contribution of CRLs to the achievement of CAHP objectives, it is important to place the CRLs in the context of the entire network of actors involved in the implementation of the CAHP.

The system of prevention, surveillance, control and eradication of animal diseases relies on different actors at various levels, from livestock farmers, the competent authorities of the Member States and in the EU, to the National Reference Laboratories and the CRLs, among others. The protection of animal health and animal welfare, food safety, and ultimately the functioning of the internal market for live animals and products of animal origin are ensured by the cooperation of all these different actors.

The main role of the CRLs, as defined in the legal bases, is to provide the coordination, guidance, methodology and practical tools that are necessary to achieve high quality and harmonised diagnosis across the Community. If successful, CRLs will have thus indirectly contributed to the effective implementation of the policy, which in its turn contributes to the achievement of the higher level objectives indicated above. The contribution of CRLs to the various levels of objectives is depicted in **Figure 18**.

While the achievement of harmonised diagnosis can be directly attributed to the performance of the CRL and the interaction between the CRL and NRLs, as we move to higher level and more indirect objectives, the direct contribution of the CRLs cannot be established, as the performance of the other actors in the wider system also becomes a contributing factor. In addition, exogenous factors, such as the EU enlargement, increasing trade and globalisation, and climate change effects on disease epidemiology, as well as scientific developments, have increasingly played a role<sup>19</sup>.

As outlined in section 3.3.1, the results of the evaluation indicate that harmonised diagnosis has been significantly achieved by most CRLs. The positive findings of the expert reports from the CRL field missions are supported by the results of the CVO and the NRL surveys.

Overall the CVOs have scored all the CRLs very high in terms of their contribution to improving animal health and food safety, attributing this in most cases to the significant role they have played in the field of diagnosis, early detection and rapid response. More generally, from the comments of CVOs, it can be concluded that the CRLs have played an important role in improving the management of animal health and the effective implementation of EU legislation in this area (Table 5).

Nonetheless, several CVOs commented that the harmonisation of diagnostic tests alone cannot address all the issues of disease surveillance and control, and that appropriate background legislation and field organisation are also needed. This demonstrates the importance of viewing the contribution of CRLs in the context of the wider system in which they operate, as discussed in the introduction.

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<sup>19</sup> The impact of these factors is discussed in more length in the CRL performance over time (section 4.3) and the challenges for the future (section 5.1).

**Figure 17 CRL's contribution to improved animal health, veterinary public health and food safety, results from the survey among CVOs, average ratings.**

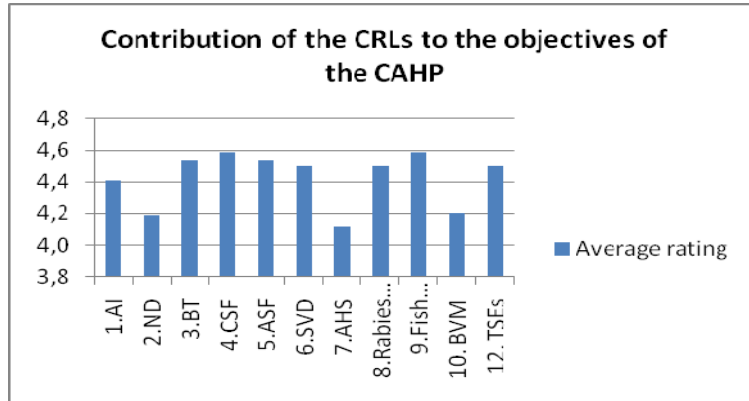
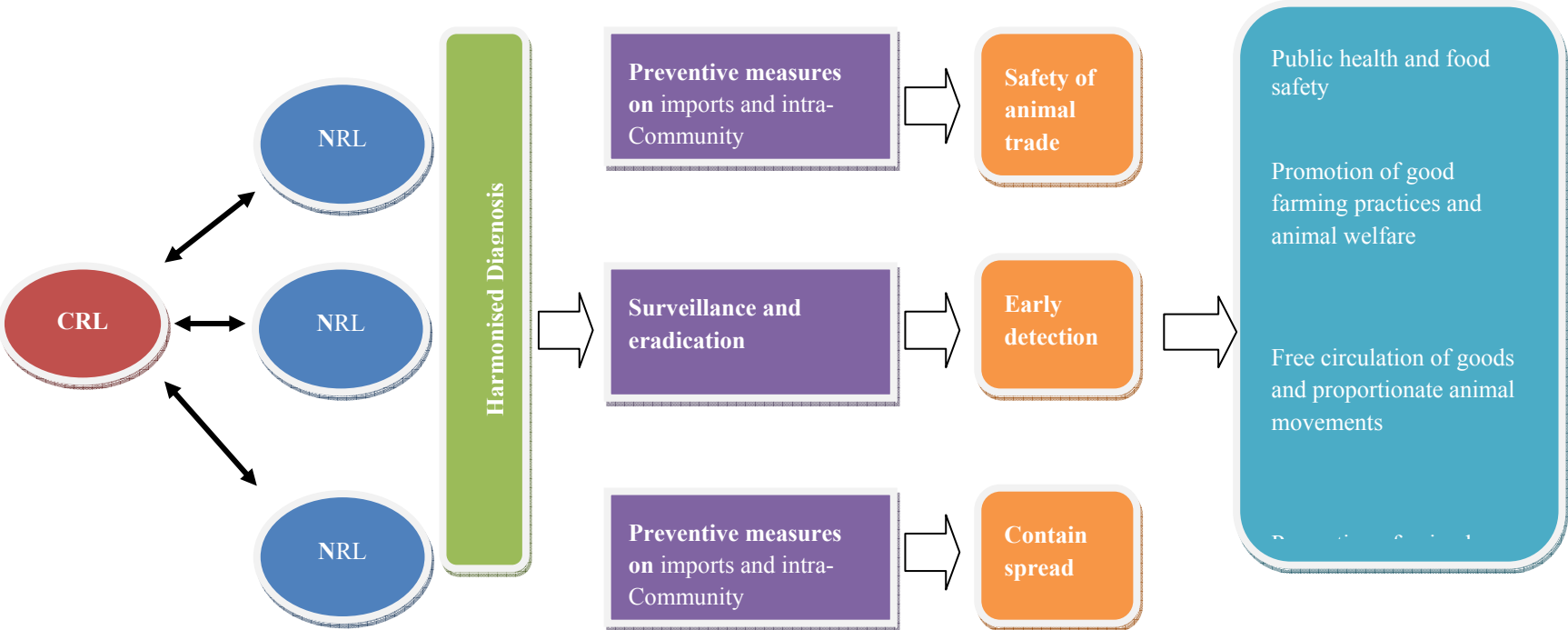


Figure 18 Contribution of the CRL / NRL network to the achievement of EU CAHP objectives



## 4.2. Contribution to the improvement of the animal health situation in the EU

### 4.2.1. The animal health situation in the EU during the evaluation period

The animal health situation for the various diseases covered by the CRLs, in the reference period covered by this evaluation, is shown in the table below.

As can be seen from Table 4, the situation of animal diseases in the Community has changed over time:

- Certain diseases, such as AHS, did not occur in the Community in the reference period (the last outbreaks were reported in 1989 in Portugal and in 1990 in Spain);
- Some diseases formerly widespread in some (ASF) or many (SVD) countries of Europe have been eradicated, except for some regions of Italy where outbreaks still occur and were reported in the reference period (ASF in Sardinia and SVD in mainland Italy). However sporadic outbreaks have also occurred in other countries (ASF in Spain in 1994 and in Portugal in 1999; SVD in Belgium in Portugal in 2007) but the disease was contained and the virus eradicated;
- Outbreaks of H5N1 avian influenza (AI) still occur in several countries e.g. Egypt and south East Asia and represent a continuing threat to Europe. Incursions of H5N1 into Europe have been eradicated but other strains of AI, both of HPAI and LPAI have been registered in many EU countries, and the disease is still of concern in some of them.
- During the last 15 years the EU has also experienced some major epidemics, such as the introduction and spread of several different serotypes of BTV and (although not considered here) the outbreaks of FMD; the persistence of an endemic situation of FMD in Asiatic Turkey represents a threat for the EU;
- Although many EU countries are free from CSF and eradication campaigns have been conducted, the disease has recurred in several countries with large outbreaks taking place in the Netherlands, Germany, Belgium, Italy and United Kingdom. Also, certain risk factors could not be fully eliminated (such as the spread of the disease among wild boars) and increased with the accession of new MS;
- Rabies has been eradicated in wildlife as a result of the successful implementation of rabies eradication programs in many countries (Finland 1991; the Netherlands 1991; France 2000; Belgium and Luxembourg 2001; Czech Republic 2004), but the disease remains endemic in some areas of the Community and poses a significant threat in the Central European and Baltic States;
- With regards to mollusc diseases, *Bonamia ostreae* is present in several countries (DK, FR, IE, UK, IT and ES) and *Marteilia refringens* in FR, ES and PT. An outbreak of *Bonamia exitiosa*, listed as an exotic disease, occurred in Spain in 2007 and in France and Italy in 2008.
- The situation for fish diseases is mixed, as many diseases are concerned: VHS has become a concern in the last years for many fish farms in various MS; IHN and KHV

have a more limited geographical distribution, ISA occurred in Norway and in the UK, IE, EHN and EUS are listed as exotic diseases.

The accession of new MS to the EU has changed the epidemiological situation as some diseases are still present in the new Member States while the EU external borders have shifted further to the East towards higher risk neighbouring countries (e.g. ASF in the Caucasus region; CSF and rabies in Eastern Europe). On the other hand, some major threats of the past (e.g. TSEs) have shown positive results and declined due to the success of control measures.



**Table 4 Number of outbreaks in EU by disease, 1993-2008**

	1993	1994	1995	1996	1997	1998	1999	2000	2001	2002	2003	2004	2005	2006	2007	2008
<b>AI*</b>		0	0	1	7	1	67	351	0	0	250	0	32	685	287	21
<b>ND</b>	137	242	65	30	58	25	7	257	2	135	2	4	23	41	54	22
<b>BT</b>	0	0	0	0	0	84	1478	7227	6370	430	2101	499	93	2298	40926	6066
<b>AHS</b>																
<b>SVD</b>	15	31	0	19	5	25	14	5	11	171	32	126	13	51	90	65
<b>ASF</b>	143	104	145	65	23	28	17	11	9	11	12	248	198	0	31	6
<b>VHS**</b>										1	3	17	29	30	44	39
<b>IHN</b>		1	17	14		8	28	32	27	27	13	7	9	10	5	7
<b>ISA**</b>										12	6	15	11	3	7	5
<b>CSF</b>	125	191	98	55	611	55	13	20	43	43	9	5	1	201	158	4

Source: Animal Disease Notification System ADSN system (DG SANCO)

\*Includes HPAI and LPAI outbreaks in poultry and wild birds

\*\* Includes data on Norway

Notes:

**The table reports the number of outbreaks occurred in the EU during the reference period. It does not attempt to provide an exhaustive information on the animal health situation in EU, as this would require a deeper analysis, whereas the number of outbreaks only provides information on the risk and not on the status of the disease.**

The Animal Disease Notification System (ADNS) application is a notification system that has as its main purpose the registration and documentation of certain important infectious animal diseases. It is mainly a management tool that ensures detailed information about outbreaks of these animal diseases in the countries connected to the application.

Includes data for the years and diseases for which data are available. Mollusc disease outbreaks are reported in the EU Animal Disease Notification System (ADNS) since 2009.

#### 4.2.1. The role of the CRLs

When a highly contagious disease emerges, rapid measures must be taken to contain the spread. Such measures may include the pre-emptive culling infected animals and the establishment of movement restrictions for live animals and animal products. The measures to contain the disease can have severe consequences for the economy. A rapid and accurate diagnosis allows the adoption of appropriate surveillance and control measures and can contribute significantly to minimize the consequences of the outbreak by limiting the spread of the disease and to reducing the number of animals likely to be culled if a ‘stamping out’ disease control policy would be necessary.

The role of the CRLs has to be put in the context of the specific disease covered by their activities (this aspect is discussed further in section 4.2.2.2) and CRL relation and interaction with the other partners in the animal health system.

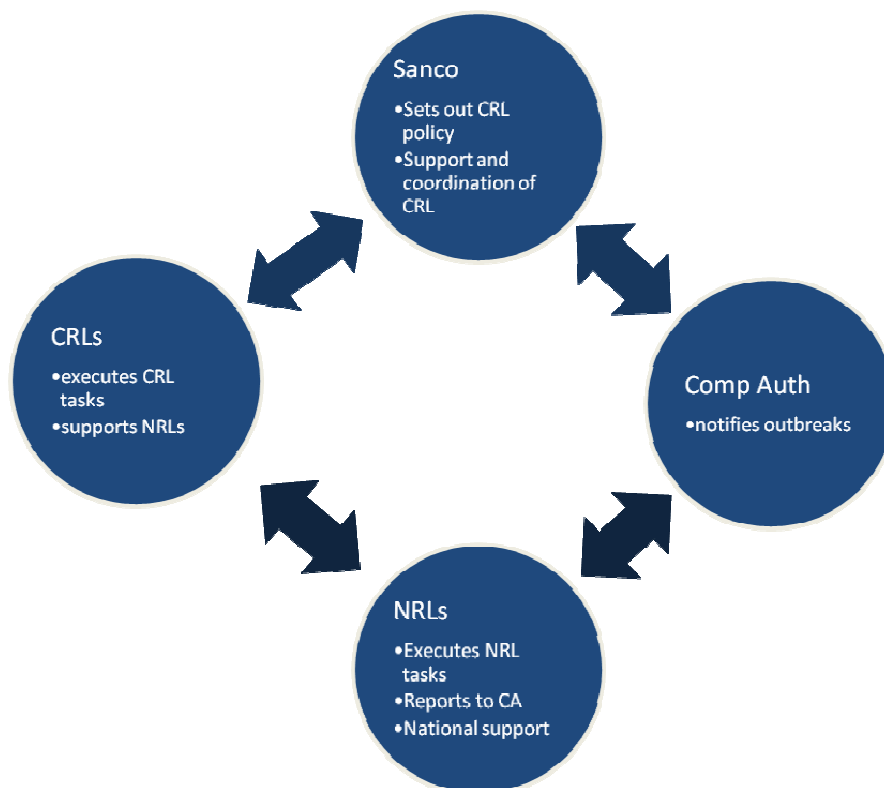
Although this evaluation largely concludes that the harmonization of diagnosis for all the diseases covered has improved, to solve the underperformance of NRLs (e.g. in the proficiency testing programmes) can take considerable time. Despite the obligation (according to Article 33 of Regulation 882/2004) of NRLs to collaborate with CRLs, the latter do not have authority nor mandate to impose a test procedure. The relationship between CRLs and NRLs is based on trust and collegial collaboration. The European Commission has issued a protocol covering issues of collaboration between the CRLs and NRLs<sup>20</sup>. However, the evaluation has found that the existence of the protocol, although valuable, has not been sufficient to foster the spirit of collaboration needed. In such cases more support from the Commission to CRLs, would be needed (e.g. by addressing the underperformance to the CA of the particular NRL). Increasing authority to CRLs is not considered as an option, because this would jeopardize the current collegial collaboration that is required for unbiased exchange of information between CRLs and NRLs. Thus, the effectiveness of the harmonization of diagnosis could be improved if CRLs receive more support from the Commission by addressing shortcomings of NRLs to EU MS.

The relation between the Commission, CRL, CAs and NRLs is illustrated in **Figure 19** below.

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<sup>20</sup> “Protocol for the management of underperformance in comparative testing and/or lack of collaboration of NRLs with CRL activities”.

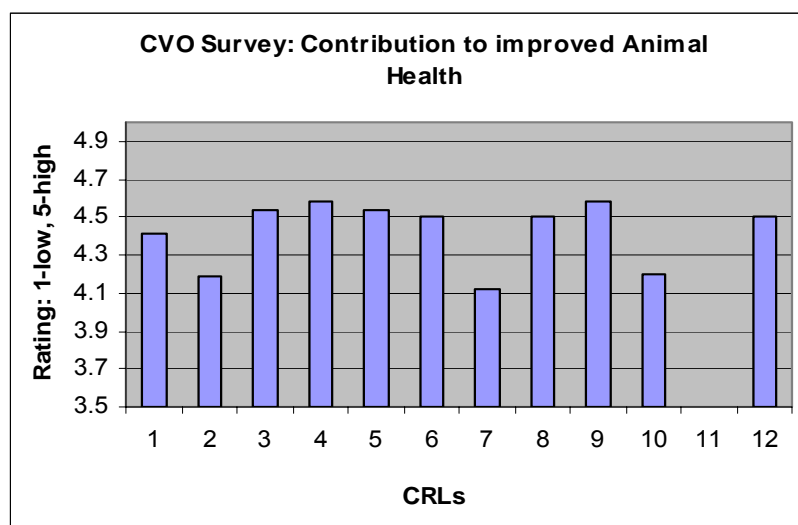
**Figure 19 Relations between the Commission, CRLs, CA and NRLs**



#### **4.2.2. Overall assessment: contribution to the animal health situation**

##### **4.2.2.1. General conclusions for all CRLs**

The value of CRLs for improving animal health clearly emerged from the CVO survey. Results demonstrate that CVOs are very positive about the CRL contribution, rating it as very significant for all 12 CRLs (above 4, on a scale of 1 to 5) (**Figure 20**).

**Figure 20 Contribution of CRLs to improving animal health**

**CRL codes:** 1 – AI, 2 – ND, 3 – BT, 4 – CSF, 5 – ASF, 6 – SVD, 7 – AHS, 8 – Rabies Serology, 9 – Fish diseases, 10 – BVM, 11- Zootechnics, 12 – TSEs.

As has already been discussed under the previous section, the beneficial impact of CRLs in achieving an improved animal health situation cannot be isolated from other factors. The success of any eradication or control policy and the preparedness and response to emergencies of the MS and of the Community as a whole depends *inter alia* on the availability of good veterinary infrastructure, expertise, diagnostic and surveillance capabilities and capacities. As CRLs have significantly led to improved diagnostic capability and supported animal diseases' surveillance across the Community, as demonstrated in the previous section, they have indirectly contributed to improvement of the animal health situation in the EU.

In this context, the following conclusions can be drawn<sup>21</sup> for the main areas for which the CRLs were evaluated:

- Concerning **diagnosis and assistance**, the evaluation found that the CRL activities and the methods used by them to ensure correct diagnosis of animal diseases are satisfactory; this assessment was generally supported by the CVO and NRL surveys. In most cases diagnostic activities are the priority for the CRL and they tend to be the most demanding activity in terms of time and resources.
- **New diagnostic tools** have been adopted by many CRLs and transferred to NRLs. In most cases new methods were developed in the institution hosting the CRL and not by the CRL as such<sup>22</sup>. In other cases, they were developed in other laboratories in the EU and adopted and developed as standard diagnostic tools for NRLs by the CRL.

<sup>21</sup> For analysis on the individual CRLs and more details, please see section 3.

<sup>22</sup> An example here it the PCR for Bluetongue, developed by the Bluetongue Research Group within IAH.

- The CRLs have all **supplied diagnostic tools** to other laboratories, but in different frequencies depending on the demand and on the availability of diagnostic tools (in some cases reagents have to be produced by CRLs which is costly and time consuming). Some laboratories demand large volumes or large numbers of strains, which consume unacceptable time and resources from a CRL. Guidelines on the amounts that can be supplied free of charge, and when costs must be compensated, would help to harmonise this activity among CRLs.
- **Biosafety and transport regulations:** some CRLs have specifically trained staff familiar with IATA regulations and clear instructions for sending diagnostic materials on their website. Local authorities may prevent CRLs from sending diagnostic tools including strains to laboratories if they are not accredited at a sufficient biosecurity level. Guidelines on shipment of diagnostic tools and requirements for receiving laboratories would help to harmonise this activity among CRLs.
- CRLs provide assistance for diagnosis **in case of an outbreak** to other laboratories on demand. However, for some diseases, NRLs are fully capable of diagnosing the outbreaks themselves. Due to the assistance of the CRLs, many NRLs have greatly improved their skills and this has reduced the demand for the CRL to assist them with diagnosis. Assistance is now mostly confined to new EU MS, and CRLs are mainly focused on confirmation of diagnosis.
- In most cases CRLs are **embedded in centres of excellence** with a good international reputation for research on particular diseases and capitalise this situation by incorporating technological advances in their portfolio of activities. Furthermore, several directors and senior scientists of CRLs are recognised experts in their field and have participated on the drafting of chapters for the OIE Manual and other authoritative publications.
- Concerning **training**, the type of training provided and the number of trainees varied considerably between CRLs. Some CRLs have dedicated training weeks and training materials available; others receive trainees on demand for engaging in side-by-side working or undertake missions to assist underperforming NRLs; others organize workshops open to all the NRLs. It is not possible therefore to identify common practices or a defined structure. Exchange of information between CRLs for the organization, provision of training and training materials, coordinated by the Commission, would help to harmonise this activity among CRLs.
- Concerning **quality**, eight of the laboratories hosting the CRLs are accredited and have at least satisfactory quality standards in place, although in some cases not all the tests are accredited. The other four are working towards accreditation and/or improvement of quality standards. Increasingly, CRLs (see section 3) are gaining accreditation for the execution of proficiency testing programmes, which is considered an extra quality criterion and performance indicator.
- The CRLs **staff** are suitably qualified in all cases, and the only concern was that appropriate succession was arranged in advance, because some experts of high standing will be difficult to replace. It should be noted that the OIE procedures

require immediate notification to the OIE when the designated key expert of an OIE Reference Laboratory leaves. CRLs rely very much on the scientific reputation of their staff. There is a risk that attention to this important success factor for CRLs may be neglected.

- Having **international experts among CRL staff** is considered an advantage, because it expands the professional network outside the home country. All the CRLs evaluated apply the necessary analytical techniques in their area of competence and diagnostic methods of satisfactory quality and in line with the OIE standards, with minor variations. Notably, the new PCR for Bluetongue was adopted as the EU diagnostic test by NRLs before it was adopted by the OIE. This illustrates that the CRL and NRL network of laboratories is functionally efficient and is fully capable of harmonising and modernising the diagnosis of notifiable diseases across Europe on its own merit.
- The organisation of **Proficiency testing programmes** is one of the main tasks of the CRLs as it allows assessing the technical capacity of the NRLs to detect the virus or pathogen causing the disease and the sensitivity and the specificity of the tests in use. Nearly all the CRLs have organised and followed up inter-laboratory comparative tests on a yearly basis (see tables on individual CRLs in 3.2 above). According to the comments received from CVOs and NRLs these tests are one of the most important contributions of CRLs towards harmonisation of diagnostic procedures across the Community. In some cases, for a variety of reasons, not all the MS participate in the proficiency tests or achieve satisfactory results. Only in one case the organisation of tests followed a more discontinuous pattern. This has been indicated by some NRLs as a factor that has hindered harmonisation for the particular disease; specifically, it is claimed that the relevant molecular diagnostic techniques have not yet been harmonised.
- An indicator of the increased diagnostic capacity of NRLs is the performance of the participant laboratories in the proficiency tests. Proficiency tests determine the capability of NRLs to perform the analysis of samples and provide NRLs with the possibility to evaluate other techniques and reagents in order to improve their performance. For the majority of the diseases covered by this evaluation a positive trend in terms of NRLs performance) has been observed over the last years (see tables on individual CRLs in 3.2 above). Although there is still room for improvement, both CRLs and NRLs recognise a positive development in this sense. The CRLs play an important role here, in collecting and distributing pathogen strains to optimise and develop new diagnostic tools. The organisation of proficiency tests, the follow up activities, the discussions at the annual meeting and the training provided are all factors that have contributed to the achievement of this result (see section 3 on individual CRLs).
- Another indicator of improved harmonisation is the **production and availability of standard operating procedures** that can be incorporated into EU diagnostic manuals. Furthermore some of test protocols described in these manuals have been subsequently adopted in the OIE manuals used at international level. Diagnostic Manuals have been established for the following diseases:

- African swine fever (Commission Decision 2003/422/EC);
  - Avian influenza (Commission Decision 2006/437/EC);
  - Classical swine fever (Commission Decision 2002/106/EC, as amended by Commission Decision 2002/359/EC);
  - Fish diseases (Commission Decision 2001/183/EC), for VHSV and IHNV and to the diagnostic manual (Decision SANCO/6084/2009) to the new 2006/88/EC (annex under approval of the European Parliament);
  - Some mollusc diseases (Bonamiosis and Marteilirosis). (Commission Decision 2002/878/EC establishing the sampling plans and diagnostic methods for the detection and confirmation of *Bonamia ostreae* and *Marteilia refringens*); and
  - Swine vesicular disease (Commission Decision 2000/428/EC).
- The Directors of the CRLs have contributed to the drafting of the above-mentioned diagnostic manuals and this indicates the excellent level of expertise and significant international recognition in the field of diagnostic techniques of the staff of these laboratories.
  - The CRLs cannot impose any particular test to NRLs but can provide recommendations<sup>23</sup>. For the majority of the CRLs, the challenge has been to ensure that the NRLs in MS have the capability to conduct routine diagnostic processes using the latest molecular tests and for some CRLs this is still an ongoing process. In fact, a positive development during the evaluation period to which CRL work has made a direct contribution has been the shift from lengthy tests such as virus neutralisation tests for pathogen identification to PCR. In recent years new diagnostic tests such as Real-Time PCR and specific immunoassays have been developed or are being developed for rapid detection of infected animals and to discriminate infected from vaccinated (uninfected) animals – so-called DIVA tests. CVOs comments indicate that some CRLs together with NRLs have played a key role in the introduction and development of such techniques. Despite the progress made the need for further improvements in this area was pointed out by some NRLs and CVOs.

As already indicated in section 4.1.4, in the view of the CVOs, the harmonisation of diagnosis<sup>24</sup>, the international cooperation and communication, are the factors that have contributed most to the achievement of the objectives of the CAHP.

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<sup>23</sup> Even when a diagnostic manual is in use, the manual is not prescriptive for the MS to use the protocols within the manual. Any alternative methods used by NRLs, however, must, at a minimum, meet the same test performance criteria in terms of specificity and sensitivity as those tests in the manual itself.

<sup>24</sup> Intended as standardisation and development of methods; harmonisation of results interpretation.

#### 4.2.2.2. Conclusions for individual CRLs

The CRLs evaluated were assessed as having contributed to the improvement of animal health in various ways as indicated in **Table 5**.

**Table 5 Contribution of the CRLs to the management of animal health**

<b>CRL</b>	<b>Improved aspects in the management of animal health</b>
<b>AHS</b>	Harmonisation of diagnosis, proficiency tests, annual meetings and workshops. Diagnostic techniques for early detection of the disease, identification and characterisation of the agent by molecular biology techniques. All the diagnostic aspects are covered, involvement in new developments by active participation in research projects such as ASFRISK.
<b>AI</b>	Early diagnosis, mass screening, surveillance programmes. More examinations in commercial poultry flocks and in wild birds. Surveillance in AI birds in the Community, inputs in outbreak management, development of diagnostic procedures.
<b>ASF</b>	Harmonisation of diagnosis, proficiency tests, annual meetings and workshops. Diagnostic techniques for early detection of the disease, identification and characterisation of the agent by molecular biological techniques. All the diagnostic aspects are covered, involvement in new developments by active participation in research projects such as ASFRISK.
<b>BT</b>	Diagnostic techniques for early detection of the disease, identification and characterisation of the agent by molecular biological techniques.
<b>CSF</b>	Harmonisation of diagnosis, Proficiency tests, annual meetings and workshops. Diagnostic techniques for early detection of the disease, identification and characterisation of the agent by molecular biological techniques. Led the way in introducing molecular methods of diagnosis across all MS. All the diagnostic aspects are covered, involvement in new developments by active participation in research projects such as ASFRISK.
<b>Fish Diseases</b>	Monitoring of fish diseases as well as diagnostic methods converged to current scientific knowledge. Improvement of health status of finfish.
<b>Mollusc Diseases</b>	Improvement of the health status of molluscs.
<b>ND</b>	Early diagnosis, mass screening, surveillance programmes.
<b>Rabies</b>	(world travel with pets) Rabies serological testing in animals for European countries (VNT a new proficiency testing organised every year).
<b>SVD</b>	New diagnostic methods, laboratory diagnostic procedures.
<b>TSEs</b>	Diagnostic techniques for early detection of the disease, identification and characterisation of the agent by molecular biological techniques
<b>Zootechnics</b>	As discussed in section 3.3.5, the establishment of the zootechnics CRL was aimed at different objectives from the animal health CRLs. The evaluation has concluded that the initial objectives have been achieved since the establishment of the CRL, and Interbull work has become an internationally accepted standard in this domain.

Source: results from the CVO survey



More details on the contribution of CRLs to improved animal health are presented in the text boxes below.

### ***Avian Influenza***

Mandatory surveillance programmes in domestic poultry and wild birds were introduced by the EU as part of the measures to control avian influenza in 2002<sup>1</sup>. The CRL plays a relevant role in this context as it is involved in the development of surveillance guidelines, in the implementation of the surveys and analysis of the data (epidemiology). The results of the CRL survey showed that CRLs liaise closely with the NRLs in the MS in order to ensure rapid diagnosis, to subtype viruses and characterise isolates genetically. The CRL also provides standard antigens and serum control reagents to all NRLs carrying out the mandatory programme and contributes to collection, collation, analysis and dissemination of the data. The activities of surveillance undertaken in 2005 and 2006 provided an early warning system for the introduction of HPAI in the MS; once the disease was identified in wild birds, EU strengthened prevention measures. The efforts in this sense have proven to be successful to reduce the impact of the disease thus demonstrating the importance of surveillance and early detection in order to tailor prevention and control measures.

### ***African swine fever***

African swine fever is a disease endemic in most of Sub-Saharan Africa. In Europe the disease became endemic in the 1960s in Spain and Portugal and was completely eradicated in 1995. A highly significant role was played in this process by the activity of the CRL. Sporadic outbreaks occurred in 1993 and 1994 (ES) and in 1993 and 1999 (PT) but these were contained. Currently, the disease is endemic in feral pigs in one region of Italy (Sardinia), where outbreaks have been reported since 1993. The CRL is actively working (with success to date) in harmonizing the diagnostic techniques at EU level to increase preparedness of MS that have never experienced outbreaks of the disease and collaborating with the Italian NRL. Currently, the CRL is focusing on prevention by strengthening cooperation and assistance to African countries affected by ASF (mainly Kenya, Uganda, Tanzania, Nigeria and Senegal). Cooperation has also been established with the Russian NRL, in order to understand the characteristics of the disease in the Caucasus region. The aim is to act at the source of the disease in order to understand the threat it may represent for the EU and to increase preparedness, while preventing introduction.

### ***Bluetongue***

In 2006 BTV-8 was detected in the Netherlands, Belgium and Germany. The incursion of the disease into northern Europe had never been observed and so the region was not considered to be at risk. In this context, the CRL collaborated actively in the confirmation of the presence of BTV-8 in the Netherlands, Belgium and Germany. Experts of the CRL were sent to these countries to assist them in the identification of centres of BT infection. The results of the survey conducted among the NRLs highlighted the prompt response of the CRL in this situation. The CRL also assisted all EU NRLs in establishing routine diagnosis (serological as well as at the molecular basis). The CRL also receives viral isolates from the MS: the classification and the study of these isolates provide the basis for better understanding of the epizootiology of BT. The multidisciplinary research on the transmission and the factors influencing the spread of the disease, allows the CRL to gain and diffuse to MS epidemiological information, in order to help them control the spread of the disease. The CRL also identified the presence of BTV-16 and BTV-8 in Greece in 2008/9 and it identified the presence of BTV-6 and BTV-11 in various countries in northern Europe in 2008. CRL experts trained NRL staff in Netherlands on the use of the Serum Neutralisation Test. The CRL carried out confirmatory diagnosis in 2008 of BTV and serotype identification for Slovenia, Czech Republic, Switzerland, Netherlands, Cyprus, Denmark, Hungary, Sweden, Austria, Greece, Estonia and Belgium.

### *Classical Swine Fever*

Outbreaks of the disease occurred in several countries in Europe during the reference period and the CRL provided assistance by confirming the presence of the disease. Overall, the improvement of diagnostic capacity through the use of new molecular analysis technologies has reduced the time taken to detect the disease and the number of samples needed. Furthermore, the availability of a database with more than 900 virus isolates allows the scientist to identify the type of virus responsible and its likely source (for instance Asia was identified as the most likely source of the UK outbreak in 2000). Currently, the CRL works closely with the countries in Eastern Europe presenting problems with the disease in their domestic/feral populations (HU, BG, RO, SK). This collaboration was started before the countries' accession to the EU (the inclusion of some of the NRLs in the proficiency tests dates back to 1999) and it has contributed to the build up and improvement of the diagnostic capability of these laboratories. The Director of the CRL is part of the DG SANCO Task Force for monitoring animal disease eradication. Currently, the CRL focuses (among other aspects) on measures to control and eradicate the disease, specifically on the development of a new generation of (live) marker vaccines. The CRL participates in the project GoDIVA, with the role of developing a new accompanying assay for the marker vaccines.

#### **4.3. Performance of the CRLs over time**

The CRLs covered by this evaluation have faced specific challenges related to the evolution of the specific disease(s) under their responsibility (e.g. changes in the epidemiological situation, major outbreaks etc.). Nonetheless, a common feature in all cases is their progression over time on a “learning curve” and continuous improvement since their designation in performing their tasks and in understanding the functioning of the system, and allocating and using funds from the Community.

In general, the cooperation and the informal networks created through CRL activity have strengthened over the years. This is largely attributed to the attitude of the CRLs, NRLs and of the scientific Community to share and discuss challenges and problems. Building reciprocal trust has facilitated the exchange of know-how and reagents. In this regard, it is important to note that the yearly CRLs Working Programmes are based on suggestions of the NRLs made during the annual meetings. However, in practice the WPs are similar for every year and flexible enough to allow CRLs considerable margin of manoeuvre on the content of the activities.

The majority of the CRLs consider the NRLs as their “customers” and accept that they have a role to play in identifying needs. Some CRLs, however, indicated that the time devoted to discuss the working programme in the annual meetings is not sufficient. It appears that the annual meetings have become important fora for discussion, with increasing numbers of participants and widening range of issues. They are open to the broader international scientific community, which contributes to increase the profile of the CRLs and of the EU. Many factors show the international reputation and the wide network established internationally; this is also confirmed by the high rates given by the NRLs and the CVOs in the survey on this issue.

Despite significant trust developed between participants to these formal and informal networks, full transparency and information sharing has not yet been fully reached in all cases as scientific and academic rivalry continues to exist between the various organisations involved. In some cases, the CRLs are accused of not being open enough on sharing the information and data in their disposal (several comments were made on this

during the NRL survey). The CRLs defend their position by arguing that balance has to be reached between achieving scientific excellence, which is one criterion for their designation as a CRL, and sharing data, which is one their functions as a CRL.

It is important to note that certain exogenous factors which have occurred in the reference period have had an impact on the activities of all the CRLs.

In recent years one major factor influencing the operation of the CRLs has been the enlargement of the EU. Some of the CRLs have shown a proactive attitude towards the new MS, for instance including them in the participation in the Proficiency Tests in the years preceding accession and providing *ad-hoc* training through missions in cooperation with TAIEX. The accession of new MS resulted in an increase of requests for reference material and for training and therefore, additional inputs from the laboratories in terms of staff and the supply of consumables. This has been supported by a raise in financial assistance from DG SANCO. As a result of these activities, it is evident that the CRLs have played a significant role in improving - in some cases building - the diagnostic capability of the NRLs in the new MS. This process is still ongoing.

In general, the requests for training have increased for all CRLs and this has resulted in a different structuring of the supply of training (i.e. through workshops within the Annual Meetings), or the organisation of *ad-hoc* courses throughout the year. Also, some CRLs charge fees for the training organised (e.g. BT, SVD) or are considering this option for the future (Mollusc Diseases), whereas in some other cases not all the requests for training could be satisfied (e.g. Fish Diseases, CSF). The possibility of sub-contracting training activities to NRLs in MS is also being considered by some CRLs (e.g. SVD).

Increased international trade and movement of goods has also resulted in increased activity for some CRLs to prevent the re-introduction of certain diseases in disease-free countries and has led, *inter alia*, to the establishment and strengthening of the networks with laboratories in non-EU countries. Nowadays, the activities of the CRLs are expanding well beyond the EU borders and include cooperation at several levels with countries where the diseases are endemic and therefore could represent a threat for the EU. Third country laboratories participate in the Annual Meetings of the CRLs, in the ring-trials<sup>25</sup> and in cooperation aimed at increasing CRL staff's knowledge on certain diseases (e.g. fish diseases). In addition, CRLs, through activities beyond their specific mandate take part in projects (for instance, within DG RTD funded projects) or are part of networks of scientists (e.g. through their mandate as Reference Laboratories for the OIE). All these activities are beneficial to their role as CRLs.

As regards disease prevention and control, changes in technology have also affected the activities of the CRLs.

New methods of diagnosis have shifted the focus from conventional virological methods to molecular techniques and this has accelerated the speed of diagnosis and increased the capability and refinement with which isolates are characterised. In addition, when live

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<sup>25</sup> The participation of TCs is subject to the payment of the shipment of consumables by the participating country.

virus is no longer required for the diagnostic test work can take place under less stringent biosafety conditions. CRLs have increasingly worked on the standardisation and harmonisation of diagnostic techniques in order to introduce PCR techniques as routine tests for the NRLs<sup>26</sup>.

Also, advances in vaccinology have promoted the availability of marker vaccines, which allow Differentiating between Infected and Vaccinated Animals (DIVA). However, marker vaccines are not available for all diseases. Research is therefore focusing on the development and validation of these vaccines and of the accompanying diagnostic tests (ELISA). Also, EU legislation has evolved in this field, from a ban on the use of certain vaccines to those tailored for specific cases<sup>27</sup>. However, there is debate whether CRLs should be involved in use of vaccines and vaccination schemes. From this evaluation, there was no definite opinion and more discussion on this issue is necessary.

In certain cases changes in legislation have increased the range of activities for specific CRLs, either because other diseases have been added to those to be covered within the activity as CRL (Fish Diseases, Mollusc Diseases), or because additional tasks have been included in their duties (epidemiology for the surveillance activity for AI). This has entailed the need to set up diagnostic tools for the additional pathogens, an increase of staff numbers (and more requests for reagents as the activity of surveillance increased in the NRLs (AI)) or more inputs required from existing staff to perform the required activities.

In the majority of the cases the aspect of communication and sharing of information with the NRLs has received increasing interest. This has *inter alia* been pursued through the establishment of a website, with documents related to the activity of the CRL, SOPs and proceedings of the Annual Meeting. However, this process is still in development for many CRLs, as indicated in the table below.

**Table 6 Status of CRLs websites**

CRL	Website	Restricted area	Available material
AHS	-	-	-
AI	Presentations and outputs of the meetings on the EC website FLU-LAB-NET <sup>28</sup>	✓	
ASF	✓	✓	Legislation Virus Sequence database
BT	CRL page within the website of	✓	

<sup>26</sup> It is clear here that many NRLs will continue using cheaper serological tests as routine tests, notwithstanding the capacity of performing a PCR.

<sup>27</sup> Vaccination may be used for Bluetongue (emergency measure) Avian Influenza (Emergency and preventive vaccination, Council Directive 2005/94/EC), Newcastle Disease (prophylactic and emergency vaccination) and Classical Swine Fever (Annex VI of Directive 2001/89/EC and Commission Decision 2007/682/EC).

<sup>28</sup> FLU-LAB-NET is a private community funded by the European Union as part of the Sixth EU Framework Programme for Research and Technological Development (FP6) to provide enhanced collaboration facilities for veterinary and public health laboratories and scientists to discuss Avian Influenza. It is coordinated by VLA Weybridge. Following a successful pilot in December 2007, FLU-LAB-NET was officially extended to include the EU laboratories in February 2008.

CRL	Website	Restricted area	Available material
	IAH Bluetonguevirus.org		
<b>CSF</b>	✓	✓	Legislation Annual meeting and workshops presentations Data on performance on diagnostic tests, ring test results List of contacts Training material Other
<b>Fish Diseases</b>	✓	-	News Legislation Reports from Proficiency tests, Annual Meetings, Technical Reports Data on survey and diagnosis Other
<b>Mollusc Diseases</b>	✓	-	News Legislation Network of NRLs Tutorials SOPs
<b>ND</b>	Presentations and outputs of the meetings on the EC website	-	
<b>Rabies (serology)</b>	-*	-	-
<b>SVD</b>	-	-	-
<b>TSEs</b>	Within DEFRA website		Basic training material and information
<b>Zootchnics</b>	✓	-	News Information on evaluations Training material Presentations from meetings and workshops Other

\*Information presented on the DG Sanco website

A recent achievement for some CRLs has been the establishment of online reference virus databases for phylogenetic analyses and comparison. These databases create the possibility of centralising the data on genetic information, and allow a greater sharing of knowledge gathered by the individual NRLs and the CRL itself. Currently, such databases exist for the following CRLs: AI, ND, BT, Fish Diseases, SVD and CSF.

Over the years Interbull Centre has built up a credible reputation in the EU and worldwide and is internationally recognised as a politically neutral and professional body. Since its appointment as CRL (Reference Evaluation Centre) more traits and breeds have progressively been introduced in the international genetic evaluations, and the number of countries participating has increased (although not all MS are currently participating). The challenge has been to update the methods for the evaluations; and in this sense substantial

efforts are being put into the development and implementation of genomic based international evaluations.

#### **4.4. Competition between public laboratories and private companies**

Currently there is a lack of harmonization of registration of diagnostic products and methods for animal health in the EU. In some countries registration is mandatory and well organized, in others registration is in its infancy or even absent. The different administrative procedures and considerable differences in the costs limit effective and equal marketing of animal health diagnostics throughout Europe. The animal health diagnostics sector is characterized by a high number of relatively small companies who cannot afford to finance the separate procedures in different EU countries.

Many countries use a tender system to purchase diagnostic tests, and companies are sometimes in competition with government institutions that sometimes also market their own “home brew” diagnostic tests. In addition, the tender process is not always fully transparent to the market players. In some countries, public laboratories can be the evaluator, producer and marketer of animal health diagnostic tests, which leads to a situation in which objectivity cannot always be guaranteed. .

For the development and commercialization of animal health diagnostics, diagnostics companies rely in many cases on the collaboration with research institutions, universities and knowledge centres especially in the first stages of development of new tests, from discovery to proof of principle. The collaboration is also critical in accessing field samples in sufficient numbers and other reference material. Scale-up, registration and marketing/sales activities are carried out by the companies that commercialize the product. The collaboration with public laboratories is important and necessary for the development of new tests.

For diagnosis of notifiable diseases, the situation varies greatly depending on the member state (MS). In some countries, government institutions produce diagnostics and at the same time play a role in the approval and/or licensing process of commercial diagnostics. It may be difficult to guarantee fair competition on the basis of transparent quality criteria such as registration, accredited GLP processes and robust and controlled production processes.

An exception is the mechanism that has been followed for TSE tests. Private companies could submit their test for validation, and when meeting the criteria, the particular test was authorized for the market. In this case, the initial testing was performed at public laboratories but was transferred to private laboratories when the testing expanded in such a way that the public laboratories could not cope with the number of tests required and was also partly triggered by the pressure from the meat industry to reduce costs of testing. Thus, in particular cases market access has been provided.

Most CRLs are part of larger institutional settings, and do not constitute of separate laboratories with staff fully assignable to CRL activities. Many times diagnostics reagents

are also produced, or diagnostic services are commercialized by those research organizations. This creates a possible conflict of interest between the independent scientific CRL duties and the commercial interest of other parts of those organizations.

In the past, requests from commercial companies to CRLs for strains and/or reference sera did not always get the required attention and prompt response. Of course CRLs are not assigned to serve commercial companies as such, but on the other hand this situation should not limit the development and availability of cost-effective diagnostic tests for animal diseases. Most reference laboratories have solved this situation constructing reference panels or sera that are available at a reasonable fee.

The current situation is not harmonized within the EU and hampers open competition for development of diagnostic tests for notifiable diseases. This situation is harmful for the sector and is impeding the development of new tools in animal disease management. There are many options for safeguarding the commercial interest of research institutes based on their intellectual property, such as licensing and payment of royalties, but today these must be developed and agreed case by case.

A clear and unambiguous separation from public and commercial activities of the governmental institutions hosting the CRLs is needed. CRLs should advise on requirements of diagnostics based on scientific grounds, whereas the industry can meet regulatory and quality standards related to (mass) production under appropriate Good Manufacturing Practice (GMP) conditions and registration requirements.

For diagnostic tests such as ELISA and PCR, strains and materials should be made available upon request at a reasonable fee and time by CRLs to the industry. .

For hazardous infectious agents, CRLs should supply with strains and materials, to commercial companies upon request, provided that company is compliant with EU biosafety regulations. Guidelines on this issue could be developed.

#### **4.5. Appropriateness of diagnostic methods and techniques**

To answer if diagnostic methods and techniques developed by the CRLs are appropriate we need to specify the meaning of ‘developing’ in this context as the primary task of CRLs is not research. Development is here understood as making a new test suitable for use as standard test for NRLs in EU MS. From the visits to the CRL, and the CVO and NRL survey, there is general consensus and evidence demonstrating that CRLs have developed tests suitable for use as standard tests. Examples include new PCR tests and the FAVN tests for rabies (serology).

For developing new tests, CRLs rely on the research capabilities of their hosting laboratory institution. Examples are lateral flow tests for on-side diagnosis of FMD and CSF.

All the CRLs are at the top scientific level or at least up to date. For some CRLs (AI, CSF, SVD) there are NRLs that are considered to be at the same top scientific level. Due to the success of the CRL activities the professional and technical level of many NRLs, particularly in new EU MS, has greatly improved. The difficulty for the CRL for fish diseases is that it has to cover many different species and many different pathogens and not all laboratories are at the top scientific level for all these species and pathogens. It should be noted that apart from being up to date with the diagnostic tests, CRLs should also be equipped to deliver the required services such as organisation of PT, annual meetings, and trainings.

For the CRL for Zootechnics, the current mathematical methods are considered to be adequate, but there is debate about if the mathematical calculations used for comparison should not be revised to be in accordance with USA mathematical methodology, due to pressure from market parties.

An interesting remark from the CVO survey was whether validation of diagnostic tests should be done with reference to diagnostic specificity and sensitivity or to analytical specificity and sensitivity<sup>29</sup>. Such new approaches are interesting to discuss at annual meetings.

*To what extent are the diagnostic methods and techniques developed by the CRLs sustainable in the long term?*

The regular CRL and NRL meetings are the best fora to evaluate new diagnostic techniques proposed by CRLs. The audience is composed of NRL specialists and hence no diagnostic tests that would only be used for a short period of time are adopted.

Some new techniques may be too costly for smaller NRLs (e.g. CSF luminex) and in that case the adoption of such techniques has to be evaluated in terms of their costs and benefits and added value (e.g. increase in sensitivity, accuracy, rapidity etc. compared to the conventional or older techniques).

For the CRL for Rabies (serology) a particular situation has arisen because the testing protocol itself is under discussion. The Commission has adopted a proposal on 16 June 2009<sup>30</sup> aiming at prolonging the abovementioned transitional measure until 31 December 2011. It is currently discussed in Council and European Parliament (EP). If the proposal were adopted by Council and EP, the antibody titration would only be a requirement for movement into the whole Community from third countries not listed in part C of Annex II to Regulation (EC) No 998/2003. This might lead to a decrease in the number of samples received by those approved laboratories although activities in relation to non-listed third countries ought to compensate for those losses. This might also have an indirect impact for the CRL for Rabies (serology).

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<sup>29</sup> Analytical sensitivity and specificity apply at laboratory level, while diagnostic sensitivity and specificity relate to testing of individual animals or a herd (including false positive and false negative results).

<sup>30</sup> COM(2009)268 Final



In general, the Team was favourably impressed with the standard of the diagnostic tests used by the CRLs. Determinants of long term sustainability will include: the provision of sufficient funding by the Commission; the political will of MS; the enthusiasm and hosting CRLs the willingness of competent authorities in the Member States finance CRLs/NRLs.

#### **4.6. Relevance of the CRLs for the diseases for which they are established**

In general, evidence suggests that the designation of CRLs has contributed to fight against animal diseases. It is still important to have CRLs for some diseases that continue to pose a significant threat (e.g. AI, BT, CSF) and also for emerging diseases but less so for diseases where risks are currently lower (e.g. ND, SVD, ASF, AHS, rabies serology). However, it should be noted that for some of these diseases new sources of risk are emerging (e.g. ASF from Europe's eastern borders). For fish diseases/molluscs the situation is mixed, as a large number of diseases are covered and there are always emerging risks.

Some of the issues to be considered for continuing the designation of the 12 CRLs under evaluation are:

- avian influenza has become a much bigger threat than Newcastle disease;
- bluetongue virus spread with unprecedented speed across EU countries in 2006 causing significant economical damage, and prompt diagnosis was of eminent importance;
- African swine fever and African horse sickness both pose a risk for EU MS (particularly in the Caucasus region for ASF), and CRLS should be maintained;
- swine vesicular disease occurs mainly in Italy, and the NRL there is at least of equal scientific level as the CRL. Moreover, SVD occurs mostly subclinically, which makes it less important but differential diagnosis from FMD in case of clinical disease is still important;
- for rabies, 54 approved laboratories are designated, which seems to be a sufficient number, but still laboratories are found to deviate from the proficiency test. Also, rabies present in wildlife poses a threat to the EU in central Europe, and threats from bat lyssa viruses have prompted the need to evaluate protection levels after oral vaccination. Conversely, discussion about replacing antibody testing in pets by double vaccination may reduce the need for the CRL for Rabies (serology).
- for fish, the number of diseases has expanded from three in 1994, to six in 2009, clearly demonstrating the need for a CRL;
- classical swine fever regained importance with the continuing occurrence of the disease in new EU MS;
- TSEs have successfully been controlled, and the incidence is falling. This means that the need for a CRL for TSE gradually decreases.

The present CRLs are very relevant to the diseases for which they are established. However, in a couple of instances there is considerable overlap in the nature of the diagnostic tests and in the staff and equipment employed to carry out the activities. This is

the case with the CRLs for AI and ND and CRLs for FMD and SVD. It is recommended that the CRLs for AI and ND and the CRLs for FMD and SVD are combined. Under this arrangement it should be possible to obtain the same outputs without compromising the activities. This issue is discussed further under section 5 in the report.

CRL	RELEVANCE		
	Low/Decreasing	Relevant	Increasing
AI			X
ND	X		
BT		X	
CSF		X	
ASF		X	
SVD	X		
AHS		X	
Rabies (serology)	X		
Fish Diseases		X	
Mollusc Diseases		X	
Zootechnics		X	
TSEs	X		

Note: Epidemiological evolution of diseases has significant influence on relevance

By clustering CRLs, economies of scale are expected in organising meetings, and organisation of proficiency testing programmes

From the evaluation results there is no reason to recommend ceasing of particular CRLs from functioning, but it is advised to adjust inputs based on risks. The lessons from the recent past have shown that disease threats are unpredictable.

#### **4.7. Appropriateness of CRL tasks and duties for the achievement of the objectives of the CAHP**

It is considered that the tasks and duties of the CRLs are appropriate to meet the objectives of the CAHP. This is evidenced by the critical role which CRLs have played in responding to animal disease emergencies in the EU in recent years and in supporting animal disease control and eradication programmes within the EU. It is not only within the EU that the CRLs have achieved success, as centres of excellence they have had global influence through training and technology transfer with a significant proportion of their staff being recognised as world experts in their field.

In the context of the new strategy we have identified additional tasks and duties as well as potentially the need for addressing animal identification in a separate CRL. These issues are explored further under the options for the future in section 5.

## **4.8. Effectiveness and efficiency of the financial aid granted to the CRLs, and the EU financial rules and procedures**

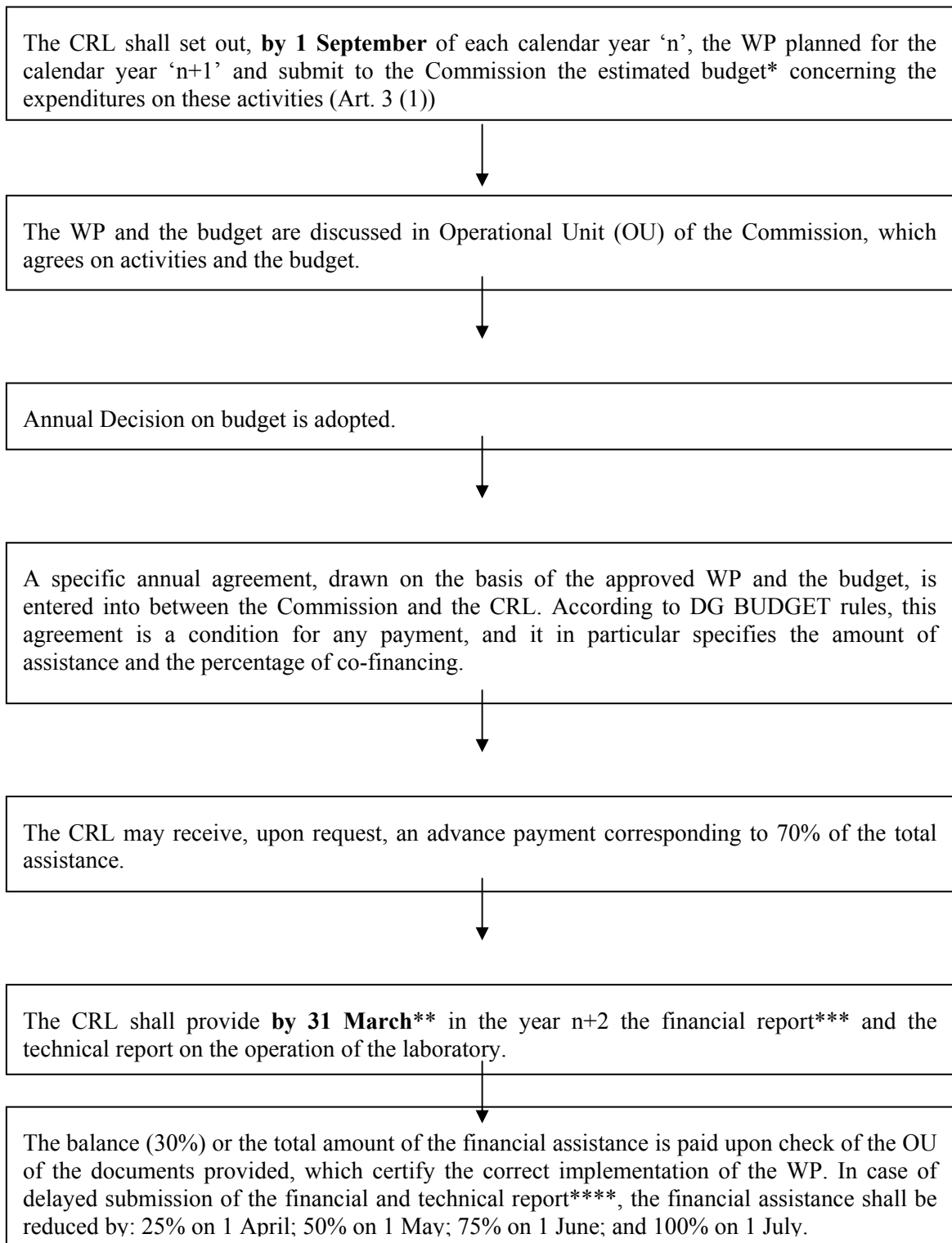
### **4.8.1. The EU rules and procedures for granting assistance**

The Community provides financial assistance to CRLs, pursuant to Article 28 (1) of Council Decision 90/424/EEC on expenditure in the veterinary field. The arrangements for granting the aid, the conditions to which it may be subject and the amount shall be determined in accordance with the Standing Committee on the Food Chain and Animal Health procedure (Art. 28 (2), art. 41). According to Art. 28 (3), appropriations are decided upon each year as part of the budgetary procedure; the financial assistance is provided to the CRLs in the form of a grant decided every year through a Commission decision.

The Community financial assistance relates to specific CRL tasks, within the functions and duties established generally for all CRLs by Regulation (EC) 882/2004, and the specific functions and duties established for each CRL by the Directive or Decision that designated the CRL and additional responsibilities decided through Comitology.

The grant contributes towards the financing of “eligible” costs. Commission Regulation (EC) No 1754/2006 of 28 November 2006 lays down detailed rules for the granting of Community financial assistance to CRLs for food, feed and the animal health sector, and establishes eligible costs corresponding to eligible activities defined in the work programmes (WPs) of the CRLs. In particular, Reg. 1754/2006 establishes that the relationship between the Commission and each CRL is laid down in a partnership agreement of the duration of five years and supported by a multi-annual working programme (Art. 2). All the CRLs covered by this evaluation currently have such a multi-annual agreement.

The procedure to be followed in order to receive financial assistance is as follows:



\* The estimated budget is provided in computerized form in accordance with Annex I of the Regulation.

\*\* In case of expenditures related to workshops, the financial report and the technical report shall be submitted no later than two months after the workshop was held.

\*\*\* The certified financial report shall be provided in accordance with the form contained in Annex III of the Regulation.

\*\*\*\* In case of expenditures related to workshops, the listed rates are applied for delays of, respectively, one month, two months, three months and four months.

The grant provides up to 100% of the amount necessary to cover “eligible” costs. According to the Regulation, the following categories of costs are eligible:

- Staff<sup>31</sup>;
- Subcontracting;
- Capital equipment<sup>32</sup>;
- Consumables;
- Comparative tests (costs for the shipment of samples);
- Missions; and
- Workshops.

A contribution for the overheads is also provided, and this is calculated at a flat rate of 7% of the direct costs as indicated in the budget; these cover all the administration, business travel (other than missions) and secretarial services.

The appropriateness, effectiveness and efficiency of the EU financial rules and procedures were examined under the present evaluation, both in the context of the CRL field visits and internally within the Commission (DG SANCO in particular). The conclusion has been that the rules are closely adhered to and generally accepted. Although the CRLs have over the years faced a certain learning curve in getting familiarised with the various rules and procedures, they have now reached a point where they are generally comfortable with the rules in place. Nonetheless, three issues in particular were highlighted where further improvements could be made:

- The need for further flexibility, over and above that currently allowed by Regulation 1754/2006, particularly to deal with unforeseen or emergency situations (this issue is further discussed in section 4.9);
- The need for some simplification, in terms in particular of the necessity and added value of the multiannual framework agreements.
- The need to train CRL staff on administrative and financial procedures to be followed and on the availability of EU funds from other sources.

Options to overcome these issues are discussed further under section 5.

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<sup>31</sup> Staff costs (whatever the staff’s status) are limited to actual wage costs (remuneration, wages, social charges and retirement pension costs) for staff specifically allocated entirely or in part to the Community tasks, as set out in the approved work programme, Annex II (1), Commission Regulation (EC) No 1754/2006.

<sup>32</sup> For equipment purchased, leased or rented, calculated according to the following formula (Annex II Reg. 1754/2006):  $(A \times C \times D)/B$  where: A = period in months for which the equipment is to be used for the project, from the date of delivery; B = depreciation period of 60 months (36 months in the case of computer equipment costing less than EUR 25 000); C = cost of equipment; D = percentage use of equipment on the project.

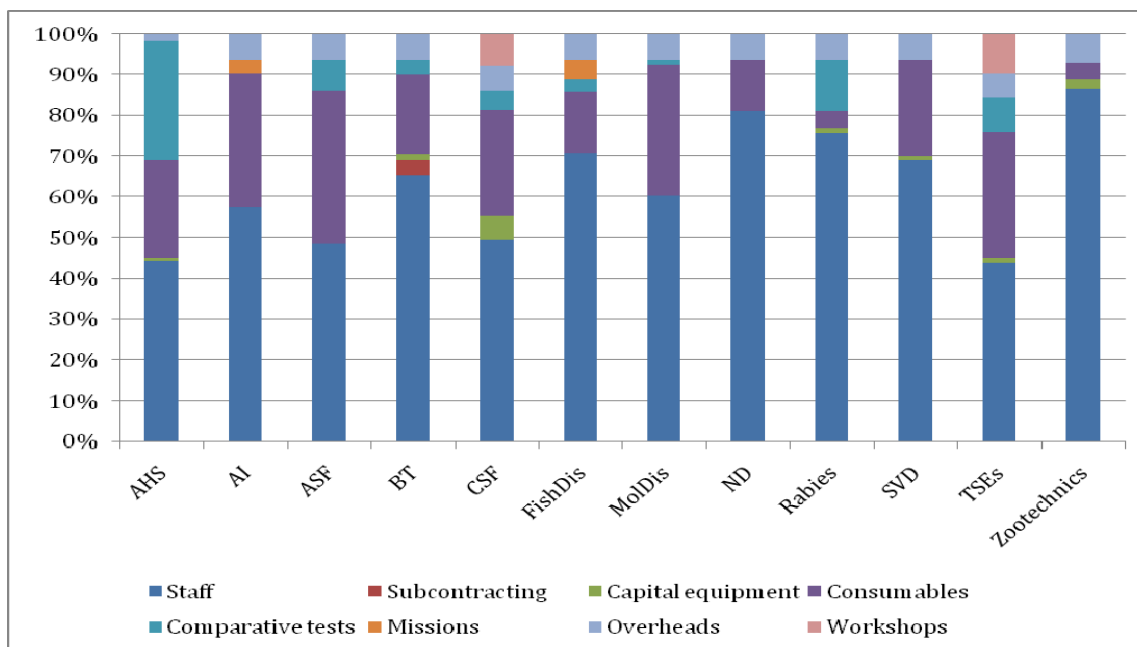
#### 4.8.2. Overview of Community financial assistance to the CRLs

An overview of the funds granted to the CRLs by the Community during the evaluation period is given in section 2.3. Further analysis is made here in terms of the allocation of the funding between the various categories of eligible expenditure.

The analysis of the financial reports of the CRL reveals that, in all cases, the categories of costs absorbing the largest share of Community grants is represented by staff costs (on average 63%), followed by consumables (on average 22%) (Figure 21).

On the other hand, costs for sending samples for inter-comparative tests represent (on average) a marginal expenditure for the CRLs<sup>33</sup> (2-5% on average, with higher figures for Rabies and AHS CRLs). Funding for capital equipment is seldom requested or represents a low share of the total funding, perhaps due to the difficulties of attributing the percentage to be used for the activities of the CRL. Funds for workshops appear to be requested systematically only by certain CRLs<sup>34</sup>. Funds are spent in missions also in a lower percentage. In this context it was noted by one CRL that while travel costs associated with Commission requests for missions (planned therefore in advance, when the budget is submitted) will be paid for by the Commission other travel deemed necessary may not be so readily accommodated within the budget framework and will therefore need to be supported by other sources of funding.

**Figure 21 Allocation of EU funds by cost category, 2008\***



Source: Agra CEAS elaboration based on financial reports, \*2007 for CRL for CSF

<sup>33</sup> Not applicable for Zootechnics.

<sup>34</sup> It is noted that workshops come under another financial regulation.

In terms of the staff costs, in general, the structure of the staff comprises several persons, devoting time to the CRLs activities to a different degree, in most of the cases a senior scientist is the Director of the CRL, in a supervising role and mostly involved in networking and assistance. Directors' involvement (in terms of time) varies from 10% to 25%; usually a junior scientist coordinates the activities of the CRL spending 70% to 100% to these functions, including administrative tasks. Other important contributions come from technical staff.

The financial reports examined reported the number of days/hours spent on the activities of the CRLs; it is noted, however, that the function of CRL is performed within "virtual units", which nevertheless carry on other activities on a daily basis; therefore the process of estimation of the time spent on CRLs' activities presents clearly some difficulties. These difficulties are illustrated by the example of one CRL<sup>35</sup>, for which the expenses for staff claimed to the EU progressively increased, reflecting an improved awareness by the CRL on the type of costs that could be claimed under the EU contribution, the real situation of staff needs and use of time, and the percentage of time that other people actually spend in CRL related work, which was not previously claimed through the CRL EU contribution. This progression has also been seen, although to a lesser extent, in the case of some other CRLs.

CRLs also use external staff contracted on an annual basis. One CRL (CSF) commented that moving to a multiannual partnership agreement has greatly improved its capacity to plan forward with a greater degree of certainty, which has impacted positively on staff retention. However, it is noted that the partnership agreement does not provide a guarantee of funding, and therefore a certain degree of instability still persists for certain CRLs. This is the case for the CRLs for ASF<sup>36</sup> and AHS<sup>37</sup>, for instance, who face difficulties in retaining expertise because contracts have to be renewed on an annual basis.

#### 4.8.3. Effectiveness and efficiency of the financial assistance

The **effectiveness** of the financial aid granted to the CRLs has to be evaluated considering the actual results achieved against the global and specific objectives and the originally expected outcomes. Effectiveness analysis compares what has been done with what was originally planned, *i.e.*, it compares actual with expected or estimated outputs, results, and/or impacts.

The analysis in the previous sections has demonstrated that the CRLs have, individually and as a system, fulfilled their tasks and duties as stated in the relevant legislation, and carried out their duties as outlined in the annual working plans.

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<sup>35</sup> CRL for ASF. In 2000, the budgeted costs for staff included time of one scientist.

<sup>36</sup> Two technicians, working 100% on CRLs' activities, are employed on a temporary basis, according to the Financial Report (2008). Also, according to information provided during the visit, since 2006, 4-5 people are subcontracted by INIA and they work 40-60% on the activities of the CRL.

<sup>37</sup> Two technicians, working 40% on CRLs' activities, are employed on a temporary basis.

In terms of the effectiveness of the CRLs as a system, by contributing to the harmonisation and improvement of diagnosis and providing confirmatory diagnosis in emergency situations, the CRLs are crucial for prevention and early detection of animal diseases. This function renders benefits which are not always possible to capture in monetary terms. However, in the context of the limited costs of prevention compared to the potential significant costs of animal disease outbreaks, as repeatedly demonstrated by the costs of outbreaks in the EU in the last 15 years, the allocated Community contribution is an effective way of dealing with animal health issues.

In terms of the effectiveness of the individual CRLs, the annuality of the funding as such is a mechanism that guarantees results and targets are met on a year to year basis. This is also demonstrated by the fact that where CRLs have not been as effective in a particular year, funding was adjusted in the following year.

As already discussed, the core duty of the CRLs has related to the activities for harmonising diagnostic tests and raise the quality of diagnosis across the EU. This objective appears to have been significantly achieved. It is generally agreed that the work of the CRLs during the evaluation period has contributed to the improvement of the quality of the diagnosis capacity at EU level, and thereby to the achievement of the overall objectives of EU legislation in the field of animal health. It is also noted that when the CRLs covered by this evaluation were designated, the EU comprised 15 MS. With the accession of the 10 NMS in 2004 and later Romania and Bulgaria, the CRLs had to extend their scope to cover the EU-25 and later the EU-27, a challenge to which they appear to have responded extremely well.

These general observations apply, nonetheless, to varying extents for the various CRLs, and some areas for improvement have been outlined in the previous sections.

Training activities, for instance, are not provided by all the CRLs to the same extent. Some CRLs organise and provide training on a regular basis, and for the benefit of the majority of the NRLs, while others charge a fee for training courses. The feedback of participants on the training provided has been very positive. However, generally not as many NRLs as would be expected have participated, and in certain cases they appear not to be aware of the possibility of taking part in these activities.

The **efficiency** of the financial aid granted to the CRLs has to be evaluated considering the resources (inputs) that have been committed to the CRLs against the actual outputs or results. Efficiency analysis looks at the ratio between the outputs, results, and/or impacts and the inputs (particularly financial resources) used to achieve them.

In terms of overall efficiency, the system of the CRLs has the primary advantage of streamlining multiple operations at a central level, therefore avoiding duplication of activities, while developing a common approach at EU level. This is expected to result in cost savings. However, it should be noted that standardisation and harmonisation of tests and procedures is a time consuming and labour-intensive task, which requires considerable resources and therefore such savings will take time to materialise. The amount of resources available at EU level is not equal among MS, and in some MS the number of researchers available (in total and for each disease) or the capacity in place may not be sufficient to address the scope of tasks and to reach the satisfactory results in a comparable timeframe.



This is particularly important for those diseases for which the majority of MS do not have experience and where the use of protocols developed by the CRL is therefore crucial.

Conducting research on infectious diseases requires having in place expensive high-containment facilities, which is the case for the majority of the CRLs visited in the context of this study. The same capacity is also present in other NRLs, but not all NRLs can afford this high level standard. There are therefore benefits in terms of NRLs being able to have indirect access and benefit from the high level infrastructure and resources of the CRL. There are also benefits of knowledge diffusion and exchange related to belonging to the CRL network.

An alternative to this system could - in principle - be the establishment of an "EU Central Laboratory" on the diseases under review. However, this would imply huge costs, of a scale not comparable with those currently provided to the CRLs. The huge collection of samples and strains of highly contagious pathogens would cost tremendous amounts to transfer to a new location, if at all possible, and would create a serious risk by having it all in one place. The use of a network, instead, is cost saving since it capitalises on the resources already available at EU level and generates multiplier effects, for an extended number of beneficiaries.

There are also important complementarity, synergy and leverage effects. The CRLs capitalise on the existence of an available infrastructure to attract resources from various sources, all of which contribute to common objectives. The Community assistance to a CRL typically builds on the budgetary contributions made by the MS to the basic infrastructure of the laboratory in which the CRL is based. Although the Community assistance specifically targets CRL duties and activities as such, the CRL benefits from the wider laboratory facilities and resources both directly and indirectly. This point is discussed further in the following section.

The individual CRLs are also repositories of a great number of strains, which allows the conduct of genetic studies and epidemiological tracing, and generates important cost savings.

#### 4.9. Adequacy of financial aid granted to the CRLs

According to the legal base, the Community financial assistance to CRLs can reach up to 100%. The actual relative contribution of DG SANCO funding to the activities performed by the designated laboratories in their role as CRLs has been explored in the context of this evaluation. Most of the laboratories have provided the financial reports related to their activity as CRL in the reference period or for at least the most recent years; however, it was not possible to retrieve this information for the entire period considered<sup>38</sup>.

**Figure 22** summarises the actual contribution of Community funding to the CRL operational expenses against other sources of contribution, in percentage terms. According to these figures, the share of contribution varies according to the CRL and it ranges from 24% (African swine fever) to 90% (Fish diseases). With the exception of the CRL for

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<sup>38</sup> For a full list of the documents examined, please refer to Annex 2.

Zootechnics (Interbull), in most cases national governments cover the additional shares of expenses. In the case of Interbull, the fees paid by the members to participate in the international evaluations represent the greatest source of income. Also, in most cases the CRLs have a considerable source of funding for research activities from projects funded by DG RTD.

The discrepancy, as shown in **Figure 22**, among the current financial assistance and the expenses incurred by the CRLs for the performance of the activities appear to be due to the following:

- The level of the annual financial assistance is determined every year by specific Decisions. It is noted that for some CRLs, the expenses reported in the annual budgets submitted to the EC are lower than the actual ones, having been balanced according to the maximum contribution foreseen by DG SANCO for running the CRL function.
- The assessment of some costs (e.g. costs related to cell cultivation facilities and of the share of resources used for CRL activities) is a difficult process, which therefore leads to some underestimation of the actual expenses supported by the laboratory to perform its function as a CRL. This also applies to the estimation of staff time and overall to the allocation of the overheads to the different projects or activities. It is noted that in some institutes there is not a systematic procedure in place for registering and attributing these expenses to the various projects/activities in place.
- In some cases, the model applied by the laboratory to calculate cost rates may differ from the one adopted by the Commission (i.e. actual salary costs), therefore generating a difference, which has to be covered by national governments. It is also noted that in general the level of overheads amounts to 20%-40% of direct costs, whereas only 7% is covered by DG SANCO funding.

The total expenditure figures submitted by the CRLs should be treated with caution. The difficulty for example of estimating the time spent by staff on CRL duties may overestimate the overall scale of the CRL operational expenses. Also, the lack of a harmonised approach in the way CRLs make these estimates may account for some of the difference between the CRLs. However, even after allowing for these factors, it is generally accepted that in many cases there is a significant contribution from sources other than Community funding towards the operational expenses of a CRL.

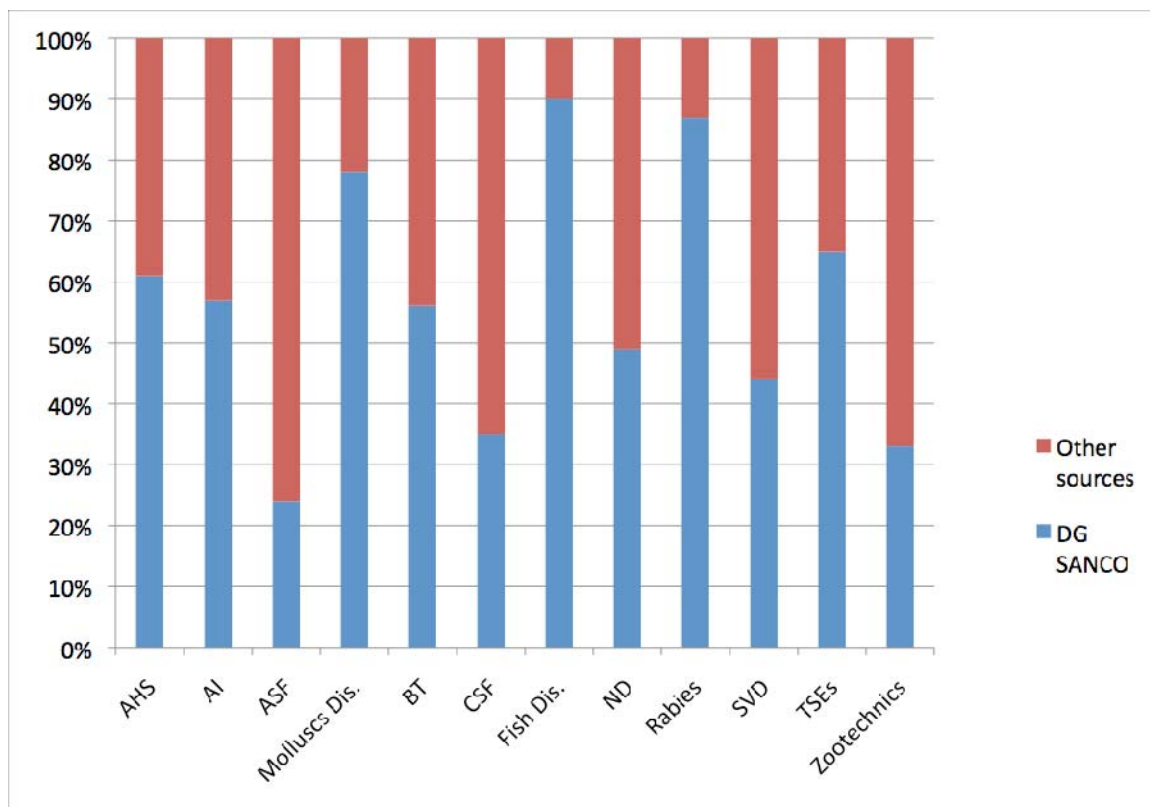
Reliance on other sources of funding is not the issue here *per se*. This is indeed a positive feature of the system: the co-financing principle is in any case underlying the legal basis of this Community assistance.

However, the apparently significant dependence on other sources of funding to run the activities of the CRLs could raise concerns on the sustainability of the support received by public national funds, as in some cases national resources are decreasing or have reached the maximum ceiling. In most cases this was identified as a potential threat for the future operation of the CRLs. There is also concern that institutes which may receive more

funding from their national authorities could become competitors to those receiving less funding, thus undermining the position of the latter to maintain designation as a CRL.

In some cases, CRLs are making efforts to diversify their sources of income, for example in getting involved in more research work, which not only attracts additional RTD funding but also raises their scientific profile.

**Figure 22 Contribution to CRL operational expenses: Community versus other sources**



*Note: Percentage contribution by each source. Data are included for available years only, as follows. CRLs for Fish Diseases and Zootechnics: Average data for the years 1999-2008; Mollusc Diseases: Average data for the years 2000-2008; AHS: Average data for the years 2001-2008; AI, ND, TSEs: Average data for the years 2002-2008; ASF: Average data for the years 2003-2008; CSF: Average data for the years 2002-2007; Rabies: Average data for the years 2006-2008; BT and SVD: data for the year 2008.*

Source: Agra CEAS elaborations on the basis of data provided by the CRLs

In terms of the adequacy of the funding for the individual cost items, and the likely impact this may have on CRL activities, the following issues are raised.

In the majority of the cases funds from the Community do not fully cover the costs related to the staff involved in the activities of the CRL<sup>39</sup>. A fuller coverage appears to be advocated to avoid problems of instability and ultimately to ensure the possibility of retaining staff for these activities. In particular, many inputs are needed from the staff in the organization and implementation of the proficiency tests (preparation of the panels,

<sup>39</sup> These in some instances carry an actual overhead of salary x 2.5

sending operations, follow up activities), from a technical point of view, but also in terms of administrative tasks.

It is also noted that training activities take up a considerable amount of time of the personnel, and that the scarcity of time or funding may reduce the availability of such activities. From the survey of the NRLs, it is suggested that an increase of funding for the organization of training and workshops would be welcome. As mentioned earlier, the requests for training have increased in the last years and some of the CRLs have increased their offer, some charge fees and some others are introducing a similar system.

Some of the CRLs charge fees for the supply of diagnostic reagents or reference material. This appears to be occurring mostly in situations where such material is requested in high quantities beyond what would be the scope of the normal level of assistance provided by the CRL to NRL diagnostic activities. Also, some CVOs refer to the difficulty of obtaining reference reagents from the CRL for TSEs. Nonetheless, this appears to be an issue of continuing criticism from a few CVOs, and so it needs to be ensured that where fees are charged this is only to justify the costs of increased (above normal) requests from some NRLs. In this case, some threshold levels could be established, in relation to what would constitute a 'normal' request.

**Table 7 Fees charged by the CRLs for the supply of diagnostic material**

CRL	MATERIAL	FEE
<b>TSEs</b>	Frozen brainstem	£150/g for bovine £75/g for ovine
	VLA anti-PrP MAb R145	Gifted as a sample in the first instance, if a laboratory wishes to use it routinely, further aliquots can be purchased for approx £150/ml
<b>AI and ND</b>	Reference reagents  Antigen Antiserum	Small amount: free of charge. If the countries need reagents for the diagnostic testing carried out in their country: 50.4 Euros 56 Euros
<b>BT</b>	Specific isolates Reference antiserum	€125 for 2 x 1ml vials €65/ml All laboratories are invoiced for shipment.
<b>SVD</b>	Non-concentrated, non purified antigen Concentrated, purified antigen  Rabbit and Guinea Pig antisera (purified virus)  Six control reference sera for SVD serology including negative Positive pig serum Negative pig serum <u>Reagents for the 5B7 SVD</u>	£ 42.00/ml £395.00/100µg  £210.00/ml  (6 x 0.5ml) £ 85.00/serum £ 58.00/ml £ 48.00/ml  £42.00/ml £105.00/ml £32.00/ml

CRL	MATERIAL	FEE
	<u>antibody competition ELISA:</u> 5B7 Purified IgG (as capture antibody) 5B7 HRP-conjugated detector antibody SVD Virus Inactivated antigen	

Some of the CRLs claim that the procedure of budget approval limits the activities as it does not ensure enough flexibility throughout the year, which would be needed to adapt to emergencies or contingency situations which require additional funding, or to move from one category of cost to the other. According to Commission Regulation 1754/2006, Art. 9 (3), any modification of an item which exceeds 10 % of its amount shall require the written prior consent of the Commission. Changes are allowed within the same category of costs and between categories, provided this is occurring within the 10% of the amount of the category of the costs from which the transfer is to be made.

## 5. Options for the future

This analysis corresponds to Task 6.4 of the ToR. Following a brief discussion of the main problems, challenges and areas for improvement based on the evaluation results, this section proposes options to overcome current and future challenges and shortcomings.

The aim is to exploit more fully the potential of the CRLs individually and as a whole for achieving the strategic goals set in the Commission Communication on a New Animal Health Strategy, and the ultimate objective of improving the animal health situation in the EU, while ensuring that the Community financing remains adequate, effective, and efficient.

In the following sections the future challenges and CRL strengths, weaknesses, opportunities and threats are briefly discussed; consequently, options for the future to respond to these gaps and challenges are presented and analysed.

### 5.1. Future challenges

Changes taking place, at both global and at EU levels, are likely to impact in forthcoming years on the activities of the individual CRLs and to bring new challenges for the EU and for the system of CRLs as a whole:

- The increase in global trade and the shift to the East of the EU borders represent a risk of introduction of exotic diseases, or reintroduction of eradicated diseases.
- Climate change and global warming are likely to influence the evolution of pathogens and their geographical distribution. All these factors are likely to shape in the future the work of the CRLs, and, as a whole, represent challenges for the

EU, in terms of being adequately prepared and tailoring its intervention to the changing context.

- The development of new technologies requires continuous effort for the laboratories to keep up to date and it will increase the possibility to have quicker and cheaper tests, which should be made available to the majority of the laboratories.

In the following sections the challenges are analysed and the options for the future for the CRLs discussed.

## **5.2. Identification of strengths, weaknesses, opportunities and threats (SWOT)**

Individual SWOT analyses have been prepared for each CRL and are presented in the Technical Annexes. The following SWOT analysis identifies strengths, weaknesses, opportunities and threats relevant to the overall system of CRLs:

<b>Table 8 SWOT Analysis of the system of CRLs</b>	
<p><b>Strengths</b></p> <ul style="list-style-type: none"> <li>▪ All 12 CRLs currently fulfil their contractual obligations.</li> <li>▪ All CRLs have contributed to harmonisation of diagnosis over the past 15 years.</li> <li>▪ CRLs benefit from the scientific expertise and technical advances of the host institutions.</li> <li>▪ They act as a bridge between research and disease management and enhance the disease management role of the Commission and Member States.</li> <li>▪ The current system of ‘virtual’ laboratories embedded in larger institutions is very cost-effective.</li> <li>▪ Collectively the CRLs have compiled a large databank and extensive collections of biological reference materials.</li> <li>▪ CRLs provide valuable assistance to candidate countries and new Member States, which are still in the process of strengthening their veterinary control systems.</li> <li>▪ CRLs provide valuable assistance to third countries.</li> <li>▪ The CRL for Zootechnics provides reliable independent support in a sector dominated by commercial interests.</li> </ul>	<p><b>Weaknesses</b></p> <ul style="list-style-type: none"> <li>▪ The CRLs do not yet operate as a system and fail to benefit from inter-CRL collaboration and best practice.</li> <li>▪ The collaborative nature of communication can cause delays in addressing underperformance.</li> <li>▪ Annual work plans tend to be drafted as a formal procedure rather than a real exercise, and this has frequently resulted in CRLs adopting different priorities (e.g. for training) than actual needs, with a lack of overall structure and consistency.</li> <li>▪ Informal networking links may be less effective with the increased number of Member States in the EU-27.</li> <li>▪ Many CRLs have only an informal network of contacts and there is no centrally coordinated network of NRLs and national contacts (or even updated lists made available).</li> </ul>
<p><b>Opportunities</b></p> <ul style="list-style-type: none"> <li>▪ The threat of emerging animal and human diseases together with the EU ‘Prevention is better than cure’ policy principle requires increased involvement of CRLs.</li> <li>▪ Clustering of similar CRLs could provide economies whilst improving effectiveness.</li> <li>▪ CRLs should review their priorities with less emphasis on diagnosis as NRLs become increasingly competent at diagnosis.</li> <li>▪ The Commission could set up a CRL Coordination Centre leading to a more professional and structured management of the network of CRLs.</li> <li>▪ More communication needed between the Commission and Competent Authorities to address underperformance.</li> <li>▪ The Commission could set up a web page with contact details of Competent Authorities, which in turn designate NRLs for different diseases.</li> <li>▪ CRLs should emphasise their independence and public duty by maintaining staff that only work on public tasks and clearly separate their work from any commercial activities of the host laboratory.</li> <li>▪ Combine CRLs for AI/ND, FMD/SVD, and Rabies serology/Rabies diagnosis.</li> <li>▪ Designate a CRL for West Nile virus (one possibility would be within existing CRL for horse diseases).</li> <li>▪ Redesignate the CRL for zootechnics as a Community Reference Centre (CRC).</li> <li>▪ Create a CRC for animal identification and registration to support an integrated animal and veterinary database network.</li> <li>▪ CRLs could participate in more training and technical activities in third countries with funding from DG SANCO or other training programmes</li> </ul>	<p><b>Threats</b></p> <ul style="list-style-type: none"> <li>▪ Commercial activities of the host institute could be a potential conflict of interest and compromise the work of the CRL unless the roles are functionally separated.</li> <li>▪ Private companies are ahead in genomics and this may undermine the role of the CRL for Zootechnics in international evaluations.</li> <li>▪ CRLs are slow to respond to changing patterns of animal disease and increased risks from a larger EU with greater trade links.</li> <li>▪ New vaccination practices may diminish the need for Rabies serology tests.</li> <li>▪ The incidence of TSEs is declining; therefore there may be a decreasing need for the CRL function.</li> <li>▪ Decreasing roles for SVD and ND CRLs due to lower risk of the diseases.</li> </ul>

### 5.3. Overview of options

The analysis of sections 3 and 4 has demonstrated that overall the current system of CRLs on animal health is working reasonably well. Nonetheless, some gaps and shortcomings have been identified, while the EU CAHP is evolving with an increasing emphasis towards prevention and new risks and challenges are emerging for the future. To address the current shortcomings and future challenges, options for improvements are made in this section. It is noted that the development of these options takes also into account any best practices that have been identified by the evaluation, so that they could be transferred to the other CRLs.

*A priori*, the range of future options that can be examined in this context stretches from status-quo (do-nothing) to deregulation. This evaluation considers the most pragmatic options within this range.

Clearly, the **status quo maintenance** or do-nothing (continue as usual) option is not discussed, as the evaluation has found that there are reasons to make improvements.

**Deregulation** is not discussed as it represents an extreme position, which has no grounds to be pursued under current circumstances. The evaluation has found that the CRLs under review continue to have an important beneficial role to play in the implementation of the CAHP, and this is reinforced under the new animal health strategy for 2007-13. Within this system, CRLs are an important link in assisting MS with diagnosis and providing early confirmatory diagnosis, which is crucial to the adoption of effective control measures. Savings from this option would therefore be minor compared to the potential losses from the dismantling of this system. The annual budget dedicated to the CRLs currently represents just over €2 million (€2.1 million in 2007). The losses from pursuing such an option would by contrast be considerable in terms of the loss of the network and effective waste of resources committed to the CRL system so far by the EU: Community contributions have amounted to some €11.7 million during the evaluation period towards the development of these structures and these EU funding flows have been much amplified by Member State contributions. Furthermore, there will be losses in terms of the important leverage of these national government contributions to the CRLs themselves and the wider structures in which the CRLs are based: it is estimated that national governments and other sources have contributed some €1-1.5 million a year, in recent years, to the operation of the CRLs.

The options that are therefore developed by the evaluation team as the most pragmatic to pursue are the following:

1. **Status quo improvements.** This option maintains current CRLs, but introduces a number of improvements which are presented in a menu of sub-options, and can be pursued in conjunction or separately. These are in particular:

1.1. Modify the scope (tasks and duties) of existing CRLs (including through outsourcing);



- 1.2. Reinforce network (create synergies): create an umbrella organisation, other improvements (communication, links to SANCO, third countries etc.);
- 1.3. Improve EU financial rules and procedures.

**2. Modifications to the CRLs.** This option examines modifications to the individual CRLs and to the system of CRLs as such. Again, these are presented in a menu of sub-options, and can be pursued in conjunction or separately. These are in particular:

- 2.1. Scope to add new CRLs;
- 2.2. Consolidation of CRLs (including the scope for closing down some CRLs).

It is also possible to pursue a combination of the above options and sub-options.

## **5.4. Status-quo improvements**

### **5.4.1. Modify the scope of existing CRLs**

An overview of the current functions and duties of the CRLs under review, as defined in the legal base (Regulation 882/2004 and legislation designating the individual CRLs), is provided in Table 2.

The evaluation has examined the option to modify the current scope, both in terms of reducing the tasks and duties and in terms of adding new ones.

#### **a) Reducing tasks and duties**

The evaluation has concluded that there is no need to reduce the tasks and duties deriving from the current legal base<sup>40</sup>. The current set provides a sufficiently wide range of tasks and duties that allow CRLs to adjust their annual WPs to the identified needs and gaps. However, within the defined set, there is scope to encourage outsourcing some tasks and duties for a more cost-effective approach to performing these tasks, as discussed below.

#### **b) Adding new tasks and duties**

On the other hand, the potential to add new tasks and duties was identified during the evaluation of the individual CRLs. From the survey among the CVOs, some additional tasks and duties that should be performed by the CRLs were suggested. These suggestions included both general tasks (i.e. common to all CRLs) and specific tasks for individual CRLs.

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<sup>40</sup> It was noted, however, that “*acquiring a thorough knowledge of the preparation and use of the products of veterinary immunology used to eradicate and control the disease*”, with reference to AI, ND, CSF and ASF is considered to be an outdated task.

The general tasks and duties that were suggested can be summarised as follows:

1. Active participation in emergency preparedness, for example by providing assistance for the development and simulation of MS emergency preparedness plans during peacetime periods.
2. Active support in monitoring the epidemiological situation, for example by adding a section during the Annual Meetings specifically dedicated to providing more information on the epidemiological situation.
3. Control of the quality of the diagnostic kits, for example through their comparative evaluation.

Specific activities by disease are also suggested in the CVO survey:

**Table 9 Potential additional tasks for some CRLs**

<b>CRL</b>	<b>Additional tasks</b>
<b>AI</b>	Epidemiology and risk analysis: support NRLs/EU MS.  Validation/Evaluation of commercial assays as an aid of licensing kits for use in official diagnosis of AIV infections. This would ensure a high and uniform level of diagnostic techniques. On a fee charging basis
<b>ND</b>	Epidemiology and risk analysis: support NRLs/EU MS.  Validation/Evaluation of commercial assays as an aid of licensing kits for use in the official diagnosis of AIV infections. This would ensure a high and uniform level of diagnostic techniques. On a fee charging basis
<b>BT</b>	Epidemiology and risk analysis: support NRLs/EU MS.
<b>ASF</b>	Assistance in emergency preparedness: e.g. to develop scenarios and simulation exercises in order to improve preparedness when a country has not experienced outbreaks recently
<b>AHS</b>	Assistance in emergency preparedness: e.g. to develop scenarios and simulation exercises in order to improve preparedness when a country has not experienced outbreaks recently
<b>CSF</b>	Assistance in emergency preparedness: e.g. to develop scenarios and simulation exercises in order to improve preparedness when a country has not experienced outbreaks recently
<b>Fish diseases</b>	To assist in understanding the role of fish farm management (ponds, indoor farms and recirculation systems with fresh water and marine water), pathogenesis of fish diseases, measurement in avoiding diseases, their spread to other wild fish (and vice versa) and epidemiology of fish diseases (Workshops on management, epidemiology and diagnostic methods)
<b>Molluscs diseases</b>	To learn more on mollusc farm management, pathogenesis of mollusc diseases, measurements on avoiding of diseases, their spread to other also

	wild molluscs and epidemiology of mollusc diseases.
<b>Rabies</b>	Testing of protective antibodies in foxes and bats.

Source: CVO survey

Some additional duties/services may involve fee charging, to cover the additional costs that would be incurred. In this case a common protocol would need to be developed, detailing which services should be free of charge and which should be provided on a fee-charging basis. There is a need for some sharing of responsibilities and costs with other laboratories in undertaking some of the tasks, in view of the burden already affecting the CRLs (which inevitably also leads to a lengthy time to respond to requests).

For example the third general suggestion above, organising comparative evaluation of the diagnostic kits, could be an activity undertaken on a fee charging basis with some responsibility and cost sharing amongst the laboratories involved. The controls could be realised by the CRL or by the NRLs in a harmonized way (for example, procedures and guidelines elaborated and validated by the CRL/NRLs network); this would ensure more reliable diagnosis and monitoring.

#### **c) Outsourcing tasks and duties**

This option could be considered in cases where the execution of some aspects of CRL activities, such as certain administrative tasks or tasks requiring advanced and costly technology can be subcontracted to obtain cost savings, instead of fully executing those in-house. The transfer of such tasks to an outside provider, assuming competitive market conditions and accredited quality operators are in place to provide these services, could generate cost savings both in expert staff time and in administrative costs and overhead.

For example, this option could be considered for the execution of certain administrative aspects of the proficiency testing. This activity involves certain routine tasks and administrative procedures (e.g. preparation of packages, mailing, sending out samples, recording), which currently take a significant part of the time of the CRL staff. Some CRLs are considering this possibility (e.g. CRL for BT although this is a special case as it groups several RLs in the same facilities). Other examples where this option could be considered would be for sequencing work (e.g. as currently done by the CRL for CSF), or other support services (e.g. software maintenance, improvements to the facility etc.) as currently practiced/considered by several CRLs visited.

An alternative to outsourcing such tasks could be the grouping of CRLs which is further examined below; on the other hand, it would still be possible to combine outsourcing with CRL consolidation to maximise cost savings.

#### **d) Exploring synergies**

Synergies with other EU financial assistance could also be explored. For example, training activities for Third Countries can be funded, via Better Training for Safer Food programme or TAIEX to expand financial capabilities.

#### **5.4.2. Reinforce network**

Many factors suggest that, although the CRLs work effectively individually and as a whole, they do not currently seem to constitute more than a ‘virtual’ system, as in practice the network is not yet fully operating as a real network in the sense of exchange of experiences between CRLs. Particular synergies exist for certain CRLs, mostly due to similarities of the diseases, but a more systematic and structured way of collaboration is proposed in order to increase the value added through sharing of best practices.

Options to improve this network include a higher degree of involvement of DG SANCO in terms of coordination of the various CRLs, and for a better communication of their work to interested stakeholders and the wider public. In particular, actions which would be recommended include:

- The organisation of a meeting of the CRLs with a yearly frequency (or once every two years);
- The update of the current webpage of the CRLs on DG SANCO’s website with links to the individual websites of the CRLs;
- Providing to the CRL an updated list of contacts for the official NRLs, as it appears that some of the CRLs do not hold this information.

It is also noted that the reports of the Annual Meetings provide a very high level of information on the diseases. Some CRLs, for instance, request to the NRLs to provide answers to a questionnaire on the epidemiology of the disease in their country, or data on the surveillance or eradication activities. This valuable outcome of the work of the CRLs and of the NRLs could be better exploited than at present, as these documents are currently largely intended for internal use. Their analysis could provide useful information, for the benefit of interested stakeholders and the wider public, on the geographical diffusion and status by country of the disease, the policies adopted by the MS and the outcomes of the actions taken.

#### **5.4.3. EU rules and procedures**

A number of areas were identified where improvements can be made to the current implementation of the EU rules and procedures for granting financial assistance to the CRLs. These are outlined below as follows:

##### **a) Development of harmonised reporting**

The procedure for granting financial assistance, as explained in section 4.8.1, foresees the submission of a budget and a working plan (WP), and of a technical and a financial report. These documents enable the relevant services of the Commission (DG SANCO) to monitor the correct and full implementation of the CRLs' contractual obligations. From the analysis of the documents submitted by the CRLs, it was noted that a degree of variability exists in terms of format and contents of the reports presented to the EC<sup>41</sup>.

The WPs present the plan of the activities for the following year, and have to be approved by the operational unit within the Commission. Generally, the WPs are presented to the NRLs during the annual meetings, and are elaborated taking into account the anticipated needs for the following year. However, as remarked by one CRL, this is done generally at the margin of the meeting and therefore it is not based on in-depth discussion. Perhaps a separate forum or another mechanism should be identified in order to ensure that NRLs provide their inputs and approval for the WP. This would also lead to a higher elaboration and tailoring of the activities to be carried out, as in some cases WPs appear to be repetitions of previous years.

#### **b) Appraisal of the multiannual framework agreements**

The relationship between the Commission and each CRL is laid down in a partnership agreement for the duration of five years, supported by a multi-annual working programme, as explained in paragraph 4.8.1. Multiannual framework agreements currently exist for all 12 CRLs, but are coming to an end soon. This presents an opportunity to evaluate whether this requirement has an added value to the functioning of the CRLs or whether it would be appropriate to remove it from the current rules and procedures.

The majority of the CRLs visited are in favour of instruments which guarantee longer term certainty, in particular because these have a positive impact on planning ahead and therefore on retention of staff. However, it is not clear whether this agreement represents such a guarantee *per se*, or whether it simply enables the CRLs to be in a stronger position to attract funding from national/other sources. The multiannual agreement does not imply certainty of funding in the following years, as the budget is annually submitted and approved, and a specific agreement to this effect has to be signed every year between the EC and the CRL. A multiannual funding, which would perhaps provide a higher degree of certainty, but also potentially decrease flexibility to adjust funding according to annual needs, does not appear to be possible under the current EU financial rules. On the other hand, the designation of the CRLs is laid down in legislative acts, and therefore CRLs do not appear to be at risk of losing their mandate as such from one year to another.

It is also not clear whether the procedure of renewal of the multiannual partnership agreement implies a process of evaluation at the end of the five years: this would represent a positive element, which will enable a periodical assessment of the work carried out, which is currently not undertaken on a systematic basis.

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<sup>41</sup> For the budget and the financial report, the format is established in Reg. 1754/2006

In the view of DG SANCO, the current obligation to conclude multiannual framework agreements had little added value and was mostly seen a routine procedure that only added administrative burden to the process.

### **c) Use of indicators to monitor performance of tasks and duties**

In the context of harmonising the CRL reporting, but also developing a more systematic way to monitor CRL activities and performance between CRLs and over time, it is also suggested that a selected set of the indicators developed and used in this evaluation form the basis of future monitoring of the work of the CRLs. The use could be twofold:

- A set of “internal” indicators may be used by DG SANCO in order to assess the effective implementation of the WP and the efficacy of funding. The use of these indicators will also allow comparability among different CRLs, which at the moment is not possible given the differences applying.
- A set of “external” indicators could be introduced in the reporting and used by the CRLs themselves to evaluate their work. In particular, reference is made here to the achievement of higher level objectives, such as in terms of animal health, to which the CRLs contribute.

A list of proposed indicators, drawn on the basis of the indicators developed and used in this evaluation is attached in section 5.5.1.1. It is noted that this is a set of potential indicators, from which the Commission – in consultation with the CRLs – could draw those that would be most appropriate to use in regular reporting and monitoring, both internally (within DG SANCO) and externally (within CRLs).

### **d) Improvements in financial monitoring and efficiency**

To ensure efficiency in the use of the resources, as staff time is the largest component of the Community financial assistance, an estimation of the time of staff / category of staff needed to perform each activity could be included in the WP and approved by DG SANCO. Currently, an indication of the share of the overall resources allocated to each planned task is provided by some CRLs, but, as the staff time is the most important component of the budgets, its use could be shown in a more explicit way<sup>42</sup>.

With regard to the financial procedures within DG SANCO, a more systematic assessment than is currently the case of the resources - in particular the ratio of payments over commitments - could be undertaken in order to assess the execution of the tasks, and where this is low, to investigate and take action to resolve the underlying issues.

The option of introducing a contingency fund was examined, to allow more flexible responses to unanticipated training and support requirements, but the report is inconclusive on this. According to the Commission, there does not appear to be any need for this, as the current rules are thought to address sufficiently any extraordinary demands not foreseen within the WP. However, several CRLs have requested additional flexibility on this, as emergency situations do occur fairly frequently, and using the existing budget to draw resources appears to interfere and set back the normal progress of the WP of the CRLs.

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<sup>42</sup> An example of this approach is the financial plan of the CRL for TSEs.

## 5.5. Modify the CRLs as such

### 5.5.1. Need for additional CRLs

Based on the findings of the evaluation, there is evidence of the need for new CRLs in some cases. In particular the need to consider the designation of the following four new ‘CRLs’ was identified:

1. **CRL for West Nile Virus.** In terms of emerging diseases, West Nile Virus is considered a particular threat to the EU. The disease is already present on its territory, and may cause significant outbreaks in the future, with consequences on animal health and on trade. To ensure adequate preparedness for the future, the diagnosis should be harmonised. There is a need to specify for what species this new CRL would be necessary. As in the case of horses there is already currently a CRL in charge, it was noted that one possibility would be to integrate the tasks related to West Nile Virus within the existing CRL for horse diseases.
2. **Community Reference Centre (CRC)** in the field of animal identification and traceability. The identification and traceability of animals is of crucial importance for the control of infectious diseases and an intrinsic part of the Community Animal Health Policy. It is also related to food safety and livestock management going far beyond pure animal health. Increased intra-Community and global trade might require more harmonized standards in relation to means of identification and also data transfer. Therefore, the designation of a CRC in this area deserves further consideration.
3. **CRL for Bee and Bumble bee diseases.** Since a few years there is significant mortality of bee and bumble bee colonies. For this a CRL might be supportive to harmonise disease control strategies, and exchange best practise between MS.

Based on the above, and on the results of the CVO survey, there are many needs for harmonised control and prevention.

On the basis of the indicators developed for the evaluation of existing CRLs, and taking into account the various caveats discussed in the previous sections on the use of indicators, the evaluators have investigated possible indicators to be used as criteria for the selection of future CRLs. The following table comments on a list of potential indicators and highlights those that are proposed for selection of future CRLs:

**Table 10 Assessment of potential indicators for selection of CRLs**

		<b>Context: information collected from CRL visits, NRL survey and CVO survey, and background information</b>	<b>Usefulness as indicator for future CRL designation</b>
<b>Nr.</b>	<b>Diagnosis</b>		
1	Other points of call for NRLs	For AI, NCD, AHS, SVD, ASF, Molluscs, zootechnics, and fish diseases there are other points of call for NRLs instead of CRL. This means that for these diseases there is more than one laboratory with technical capability to perform certain CRL tasks.	YES. If a laboratory can demonstrate that it is used by other NRLs as point of call this could be an indication of relative excellence.
2	Diagnostic procedure in use	All CRLs use diagnostic procedures according to OIE or EU regulations. This is a minimum quality hallmark and requirement for a CRL, and indicator should be rephrased.	YES, if rephrased to: Diagnostic procedures in use according to EU or OIE standards
3	Serological tests in use	All CRLs use serological procedures according to OIE or EU regulations. This is a minimum quality hallmark and requirement for a CRL	Redundant when nr 2 is used
4	Ratio supply of strains/requests of strains	There are no accurate records of the number of requests and supply of strains available from all CRLs. Moreover, they are difficult to evaluate on accuracy.	NO
5	Ratio supply of reagents/requests of reagents	As above	NO
6	Time (speed of response) for supplying strains	The speed of response for supplying depends not only on the CRL, but also on the biosafety standards of a receiving laboratory, and obtaining a license from the CA which is beyond the control of a CRL.	NO
7	Time (speed of response) for supplying sera and other reference reagents	As above.	NO
8	Time to type strains	The time to type strains is important for confirmation of diagnosis, and is important for NRLs. It allows to compare between different laboratories when applying for CRL designation. However, for each pathogen it must precisely being described what kind of typing is required (i.e. sequence information of particular parts of the genome of the	YES



		<b>Context: information collected from CRL visits, NRL survey and CVO survey, and background information</b>	<b>Usefulness as indicator for future CRL designation</b>
		pathogen or serotyping for instance)	
<b>9</b>	Strains received/retained by year. Change over time	There are no accurate records of the change over time of the number of strains received/retained available from all CRLs. However, most laboratories do have an up to date list of their strain collection. That is an important tool for typing and characterization of strains, and for proficiency testing programmes, epidemiological study etc.	YES, when rephrased to: Strains available in the collection
<b>10</b>	No. of samples investigated	There are great differences between the number of samples investigated due to the incidence of the disease itself, i.e. Bluetongue and AI samples were numerous the last years due to the outbreaks. Thus, it cannot prospectively be used as quality indicator.	NO
<b>11</b>	No. of isolates received for characterization	As above	NO
<b>12</b>	Time to characterize isolate	See under 8	See under 8
<b>13</b>	Collecting/collating data on diagnostic methods and test results	CRLs are collecting/collating data on diagnostic methods in different ways, and this is presented in various forms, such as by the presentation of talks as invited speakers, participation in scientific seminars or publication of scientific papers. The important point is with whom papers are published, for instance, jointly with colleagues from other NRLs or TCs, or OIE experts, as this provides evidence of networking. These forms can be used for comparison of CRL activity in this field.	YES, if rephrased to: Number of invitations as speaker for CRL staff, presentations on seminars and conferences, and publications in peer-reviewed journals for the disease in question, mentioning possible co-authors from NRLs, TCs, or OIE.
<b>14</b>	Assistance with conducting epidemiological surveys	See above	Contained in the phrase above
<b>15</b>	Keeping abreast of developments in diagnostic methods and techniques	See above	Contained in the phrase above
<b>16</b>	Follow-up activities	This reflects action taken by CRLs already functioning, and cannot be used for CRL to be designated.	NO

		<b>Context: information collected from CRL visits, NRL survey and CVO survey, and background information</b>	<b>Usefulness as indicator for future CRL designation</b>
17	Frequency of proficiency tests over reference period	This is important for retrospective evaluation, but not for designation of new CRLs. The number of Proficiency Testing Programmes may vary, depending on the urgency of new test developments or the epidemiological situation. Thus, the ability to perform PTP is important, and not the frequency as such.	NO
18	Effectiveness of proficiency tests	This is important for retrospective evaluation, but not for designation of new CRLs.	NO
19	Raise competence of NRLs	This is important for retrospective evaluation, but not for designation of new CRLs.	NO
20	Harmonised diagnostic procedures at EU level	This is important for retrospective evaluation, but not for designation of new CRLs.	NO
21	<ul style="list-style-type: none"> <li>Existence of EU manual</li> </ul>	This is important for retrospective evaluation, but not for designation of new CRLs.	NO
22	<ul style="list-style-type: none"> <li>Contribution of CRL in development of manual</li> </ul>	This is important for retrospective evaluation, but not for designation of new CRLs.	NO
23	Active assistance during outbreaks (including availability of staff)	The ability to assist actively during outbreaks is important, and the number of missions and number of qualified staff able to travel to assist during outbreaks (i.e. Taiex mission or other) can be used as an indicator.	YES, if rephrased to: Number of missions and number of qualified staff able to travel to assist during outbreaks
24	Contribution to the improvement of the AH situation	This is a general statement that cannot be assessed as such	NO
25	Fees charged for reagents	Fees charged for reagents reflect they way laboratories currently handle the demands	NO
	<b>Training</b>		
26	Type of training offered	The training is currently provided in different forms by CRLs; as ad-hoc training, as a follow-up activity of ring-trials, a separate Workshops, and as fixed training weeks every year open to any applicant, and the training materials differ. The type of training, the availability of training materials and the capacity of laboratories are useful in designating new CRLs	YES, including the availability of training materials and training capacity

		<b>Context: information collected from CRL visits, NRL survey and CVO survey, and background information</b>	<b>Usefulness as indicator for future CRL designation</b>
27	No. of people trained/year	See above	See above
28	Provision of training material to the NRLs	See above	See above
29	Effectiveness	For effectiveness of training there is no established method available, and hence cannot be evaluated unambiguously. This could be developed in the future or added the labs themselves using evaluation methods	NO
30	Fees charged for training	Fees charged for training reflect the way laboratories currently handle the demands	NO
	<b>Networking</b>		
31	Website for the CRL	A website is an important tool for dissemination of information, and is useful for designation of new CRLs	YES
32	Website with restricted area for NRLs	A secured website with information only for members/NRLs has proven useful for several CRLs. For candidate CRLs the ability to develop these are important	YES
33	Organisation of annual meetings	The organization of meetings is an important CRL tasks. For CRL candidate the ability to organize annual meeting should be proved by organization of comparable international events	YES, rephrased to: Capacity to organise international meetings.
34	Collaboration with NRLs	The CRL need to collaborate with NRLs, but for candidate CRLs this can not be used an an indicator. Their international networking is already covered by items 13 and 23	NO, covered by nr. 13 and nr. 23
35	Communication of data from CRL activity/ openness	The communication of data from CRL is a qualitative indicator, but cannot be assessed for designation of new CRLs	NO
36	International reputation	The international reputation of a CRL is an essential criterion. It can be assessed by invitations as speaker, and presentations and publications, and hence is covered by nrs. 13 and 23	NO, covered by nr. 13 and nr. 23
37	<ul style="list-style-type: none"> <li>• staff listed in the OIE international experts</li> </ul>	The international reputation of a CRL is an essential criterion. It can be assessed by invitations as speaker, and presentations and publications, and hence is covered by nrs.	Yes, but covered by nr. 13 and nr. 23

		<b>Context: information collected from CRL visits, NRL survey and CVO survey, and background information</b>	<b>Usefulness as indicator for future CRL designation</b>
		13 and 23	
<b>38</b>	Cooperation with OIE/FAO/WHO (when applicable) laboratories	The international reputation of a CRL is an essential criterion. It can be assessed by invitations as speaker, and presentations and publications, and hence is covered by nrs. 13 and 23	Yes, but covered by nr. 13 and nr. 23
<b>39</b>	Collaboration with TCs	The international reputation of a CRL is an essential criterion. It can be assessed by invitations as speaker, and presentations and publications, and hence is covered by nrs. 13 and 23	Yes, but covered by nr. 13 and nr. 23
<b>40</b>	Participation to EU/international projects	Participation to EU/International projects is evidence for international scientific networking. It can also be used for selection of candidate CRLs	YES
	<b>Quality issues</b>		
<b>41</b>	Quality Manual	The presence of a Quality Manual, Quality manager, accreditation of the laboratory and tests is essential for a high quality laboratory and can be regarded as a minimum requirement. In addition, an accreditation for performance of proficiency testing programmes is an extra quality criterion, and should be used as indicator	YES, including Quality Manager, accreditation of the laboratory and tests, and accreditation for proficiency testing programmes.
<b>42</b>	Quality Manager	See above	See above
<b>43</b>	Accreditation status	See above	See above
<b>44</b>	Accreditation status of the tests in use	See above	See above
<b>45</b>	Quality of equipment	The quality of the equipment is impossible to assess unambiguously and would require the development of a specific methods for that. When the laboratory performs tests according to EU or OIE requirements and the test is accredited, this is sufficient proof of the quality of the laboratory	NO
<b>46</b>	Academic qualifications of the key staff	The scientific reputation of the CRL staff is very important, but is evidenced by the international networking and representations as invited speaker, international missions and publications, and as such covered by nr 13, and 23	NO

### 5.5.2. Consolidation of CRLs

The status quo could be improved by increasing the synergies existing already at the level of some CRLs for certain diseases, by merging roles for two diseases into a single CRL. In particular, this option could be considered for the following CRLs:

- CRL for Avian Influenza and Newcastle Diseases: many of the activities of the CRLs are very similar and currently performed in the same laboratory, VLA Weybridge, by the same staff. This suggestion was also supported by one CVO, adding furthermore that the majority of the MS are vaccinating against this disease and that therefore the CRL for ND is deemed less necessary.
- CRL for Swine Vesicular Disease and Foot and Mouth Disease: also in this case, the activities of the CRLs are located within the same laboratory and the same unit, IAH, Pirbright. Many activities, such as training, are run together for the two diseases. There are many factors which would suggest the option of a combination of the two diseases as optimal: currently, the disease is present only in limited areas of the Community (Italy) and the perception of the risk of the disease is low. The majority of the NRLs are able to perform diagnosis, and some of them have excellent capability in place. Furthermore, SVD and FMD are inter-dependent and SVD is mostly important in terms of differential diagnosis from FMD.
- CRL for African Horse Sickness and Bluetongue: the diseases are very similar, while in some aspects an element of “underperformance” was noted in past years in respect of this CRL. A comparable level of excellence is present at the OIE Reference Laboratory for AHS at IAH, Pirbright and for some years, some NRLs have sought reagents and assistance from this laboratory. There has therefore been the suggestion that the latter should take on this role. However, the evaluation concludes that the CRL for AHS has taken action to overcome previous difficulties and that the outlook for the future remains promising.

The reasons for the “underperformance” of this CRL in the past appear to have their origin on the status of facilities of the laboratory, but these issues have now been resolved. In particular, for many years the CRL was located in a series of small laboratories at LCV and there was not sufficient space to hold in-house workshops. As a substitute arrangement workshops for AHS were combined with those for BT and held jointly at the CRL for BT. A consequence was that there was less interaction between NRLs and the CRL for AHS than might otherwise have been the case. The building of a new, state of art laboratory at Algete, seen by the Team during their visit to the CRL for AHS, and expected to become operational this autumn, should solve this problem.

Given the above, and considering that the diagnostic and surveillance capability/capacity at LCV is satisfactory and that geographically and historically Spain is a front-line risk country for AHS, it is recommended that the current CRL for AHS should continue in this mandate.

- Rabies (serology) and Rabies. The CRL for rabies (serology) and the recently designated CRL for Rabies (diagnosis) are currently based in the same laboratory. Because the activities of the CRL for Rabies (serology) expands to assessment of oral vaccination in wild life and protective antibody titres in bats, and in view of the knowledge gained on assessing protection against rabies, there is a risk of overlapping activities. Therefore for efficiency and technical reasons it seems logical to combine the two CRLs into one.