Standard Summary Project Fiche for the Transition Facility

1. Basic Information
   1.1 CRIS Number: 2007/019-303.03.04
   1.2 Twinning light contract BG/07/IB/AG/04 TL
   1.3 Title: Improvement of the Diagnostic and Laboratory System for Animal Health Control against Classical Swine Fever and High Pathogenic Avian Influenza in Bulgaria
   1.4 Sector: Agriculture
   1.5 Location: Exotic and Extremely Dangerous Diseases Section (EEDD) under National Diagnostic and Research Veterinary Medical Institute (NDRVMI) under National Veterinary Service (NVS) at Ministry of Agriculture and Food Supply in Bulgaria

2. Objectives
   2.1 Overall Objective(s):
   Improvement of the animal health status, effective protection against the penetration of exotic viruses on the territory of Bulgaria and other Member States, eradication process, with regard to the Classical Swine Fever (CSF) and the High Pathogenic Avian Influenza (HPAI)

   2.2 Project purpose:
   Implementation of effective control on Classical Swine Fever (CSF) and the High Pathogenic Avian Influenza (HPAI) diseases through improved diagnostic capacity of the laboratory system. Improvement the possibility of diagnostic capacity of the Classical Swine Fever labs according to the New programme for the Control and Eradication of CSF on the territory of Bulgaria.

   2.3 Justification

   The project aims at improving the diagnostic capacity of the laboratories for CSF and HPAI with the purpose to respond to the requirements of the EU and to achieve the standards necessary for these 2 laboratories to become accredited national reference laboratories.

   Moreover, currently Bulgaria can not export live animals and pork meat and products in EU due to the found cases of CFS in the country. The prohibition was imposed to Bulgaria with Commission Decision 805 from 24.11.2006.

   This problem has been mentioned in the Monitoring report on the state of preparedness for EU membership of Bulgaria and Romania, issued on 26 September 2006 (p. 3.3.3 Food Safety):

   "Bulgaria and Romania are currently prohibited to export live pigs, pig meat, and certain pig meat products to the EU due to the existence of classical swine fever in both countries. The situation as regards classical swine fever requires the adoption of certain decisions by the Commission by the date of accession. Bulgaria has submitted for formal approval a plan finalizing the eradication of classical swine fever in feral pigs. Approval of this plan would lead to the integration of Bulgaria in the community regime already set up for those Member States which are affected by classical swine fever. Romania has submitted for formal approval a plan for the eradication of classical swine fever in feral and domestic pigs. However, the current situation in both countries still require the prohibition to trade live pigs.

   FINAL
pig meat, and certain pig meat products to the EU after accession. The corresponding measures enter into force upon accession.”

As a result of the Peer Review 2006 for Evaluation Mission on Classical Swine fever conducted in January 2006, the experts made the following comments and recommendations (Draft Report, ref. Peer 21521) and Draft Report of a Mission Carried out in Bulgaria from 11 to 15 June 2007 in order to evaluate the protection measures in place relating to Classical Swine fever (DG(SANCO)2007-7483-MR Draft – FYO – 20/07/07-41592):

*The classical swine fever laboratory - comments*

The classical swine fever laboratory is in the position to conduct routine diagnosis of CSF within the framework of the CSF surveillance program for domestic pigs and wild boar.

No automated system is available to perform ELISA tests.

Confirmation tests like virus isolation, neutralization tests and PCR are not conducted routinely. This situation might delay the diagnostic work in case those samples react positive in routine tests (ELISA, IFT). The confirmation or not of a suspect CSF case might last relatively long and cause problems under those circumstances. This might especially be the case for pigs vaccinated with the subunit vaccine and which do react positively in the marker ELISA test.

The virus isolation test is considered as reliable by the Head of the Department in charge of the NRL, but is not used as confirmatory test.

The evaluation of the results of virological tests does not take into account the epidemiological or clinical background, and requires three positive virological tests for the confirmation of CSF (the PCR test being used as a confirmatory test).

The limited daily diagnostic capacity due to the basic equipment and the number of staff might lead to a bottle neck situation in case of crisis situation (CSF outbreaks).

The communication of results is rather an interpretation than a report on the results of performed tests.

*Actions proposed*

In general it is recommended to increase the diagnostic capacity and improve the all diagnostic methods of the CSF laboratory.

This has to be done with regard to the equipment, as well as regards the staff (pathologist, molecular diagnostician, and technicians).

Provisions should be made and a contingency plan should be drafted regarding additional required staff and consumables in case of a crisis situation (outbreaks of CSF).

It is recommended to establish on routine basis as second diagnostic line of confirmation tests based on PCR, virus isolation and neutralization assays. Therefore a cell culture unit and molecular diagnostic unit should be built up at the institute.

The transparency of result communication should be improved.

Currently the activities of the laboratory for CSF comprise: screening and diagnostic investigation of swine samples – heparinised blood, suspension of internal organs (spleens, tonsil's, lymphonodes), collection of samples of suspected and vaccinated animals of different categories. The intensive trade contacts and movement of live animals are the reasons for exchange of geographical border for this disease.

The epizootological situation imposes the need of permanently screening investigation of antibodies detection. A 10% /105 000 samples/ of the different swine categories are investigated from the whole country territory.
Even though the NRL is in the process of accreditation, the documentation system presently applied, from submission to traceability to reporting of the analysis, fails to provide the necessary level of confidence that all samples received have been adequately analyzed.

Whereas the NRL demonstrated its ability to deliver quality results on CSF analysis, the criteria for interpretation of the results do not completely follow the requirements of the Diagnostic Manual, with in particular the possibility that under some conditions, outbreaks or cases are left unidentified.

According the standard diagnostic procedures of OIE, the ELISA tests, direct immunofluorescence test and PCR test have to be introduced in daily laboratory work. The laboratory diagnostic capacity has to be adequate in order to respond to the contemporary requirements and strategies of OIE and European legislation.(Article 4.2 c of Regulation (EC) No 882/2004)

To put in place a quality control scheme ensuring that sampling, testing and interpretation of results are performed according to Good Laboratory Practices, quality and traceability standards described in Article 12, 2 of Regulation (EC) No 882/2004.

As a result of the Peer Review 2006 for Evaluation Mission on Avian Influenza in Bulgaria, conducted in February 2006, the experts made the following comments and recommendations (Draft Report, ref. Peer 140106):

HPAI laboratory - comments

A separate branch of the NDRVMI located in a building at some distance from the NDRVMI’s headquarters acts as the National Reference Laboratory (NRL) for AI.

The team also received information regarding plans for opening a second laboratory dealing with HPAI. It should be located in the east of the country, thus facilitating the submission of samples and increasing the capacity substantially. However, no clear timetable for these plans was provided and the necessary funding still needs to be obtained.

Actions proposed

Bulgaria should provide the NRL with the necessary resources to ensure swift testing of samples submitted and to allow it to work in accordance with Quality Assurance standards. In particular, the traceability of samples within the NRL should be improved.

Currently the activities of the HPAI laboratory comprise: screening and diagnostic investigation of poultry samples – blood, suspension of internal organs (spleens, lymphonodes and etc.), collection samples of suspected and vaccinated wild and domestic bird of different categories. The intensive trade contacts and movement of live animals are the reasons for exchange of geographical border for this disease.

The epizootological situation imposes the need of permanently screening investigation of antibodies detection.

According the standard diagnostic procedures of OIE the ELISA tests, Hemmaglutination Inhibition Test, AGID, direct immunofluorescence test and PCR test need to be introduced in daily laboratory work. The technical level of laboratory is responding of contemporary requirements and strategies of OIE and European legislation, but additional equipment and consumables are needed in order to improve the implementation of GLP.

3. Description

3.1 Background and justification:

The project aims at improving the animal health with regard to the Classical Swine Fever (CSF) and the High Pathogenic Avian Influenza (HPAI). This improvement is intended to be reached through the increase of the diagnostic capacity of the Laboratory System for
monitoring and eradication of the Classical Swine Fever (CSF) and the High Pathogenic Avian Influenza (HPAI) diseases. The project will also contribute to the prevention of the appearance and the dissemination of the 2 diseases on the country territory. According to this project National references labs for CSF and HPAI will be equipped as follows: 1 PCR thermal Cycler, 1 Mini chemical chamber for PCR, 1 Laboratory freeze-dryer with Stopping chamber; 1 Multi-Detection Microplate Reader, 1 Virus washer system for laboratory with accessories electrolyzed filter system for disinfection and suppression of air born viruses, 1 ELISA system with software and 1 Medical freezer to – 40 °C. With purchasing of this equipment reference labs will be able to implement all the acquis concerning samples analyses and sending them to EU reference labs according to EU legislation requirements.

The improvement of diagnostic and control systems for CSF is needed for:

- Alignment of the Bulgarian diagnostics system of CSF with the EU one;
  Quality control scheme ensuring that sampling, testing and interpretation of results are performed according to Good Laboratory Practices, quality and traceability standards described in Article 12, 2 of Regulation (EC) No 882/2004.

- Improvement of the CSF control system through:
  - Regular update of Contingency plans for CSF, according to the EU veterinary legislation, in order to unify the disease control measures between the member states;
  - Update of surveillance and monitoring programs for CSF disease control, which shall be harmonized with the programs of the other member countries, for the purposes of the intercommunity trade.
  - New programme for the Control and Eradication of CSF on the territory of Bulgaria.
  - Update the lab methods for virus isolation and VNT
  - Update the some equipment in the reference lab for CSF according to the project technical fiche

The improvement of diagnostic and control systems for HPAI is needed for:

- Implementation of EU Directive 93/36/ for HPAI, transposed in Bulgarian legislation with Ordinance No 10/26.03.1998;
- Alignment of the Bulgarian diagnostics system of HPAI with the EU one;
- Improvement of the HPAI control system through:
  - Regular update of Contingency plan for HPAI, according to the EU veterinary legislation, in order to unify the disease control measures between the member states;
  - Update of surveillance and monitoring program for HPAI disease control, which shall be harmonized with the programs of the other member countries, for the purposes of the intercommunity trade.
  - Update the some equipment in the reference lab for CSF according to the project technical fiche

3.2 Linked activities:

The project is linked to the following previous Phare activities, none of which will be overlapped:

- Twinning project BG-2002/IB/AG-03 with Greek Ministry of Agriculture

As a result of the project experts from National Diagnostic and Research Veterinary Institute
were trained in Reference laboratories in Athens and Thessaloniki in the field of laboratory diagnosis of Brucellosis, Salmonellas, Parasitozoonesoses, AHS, Myco and toxicology. Experts from Greek Ministry of Agriculture carried out training workshops in Sofia for prevention and eradication of zoonoses. Workshops for training on Good Laboratory Practice were also conducted in Sofia.

- BG - 0201.04 - Supply of laboratory equipment

Through the project the necessary laboratory equipment was supplied for:

- Laboratory diagnosis of Brucellosis, Salmonellas, Parasitozoonesoses, AHS, Myco and toxicology. The equipment is installed and functioning in the respective National Reference Laboratories, located in the National Diagnostic and Research Veterinary Institute – Sofia.
- Laboratory diagnosis of TSE. The equipment is installed and functioning in the respective National Reference Lab, located in the National Diagnostic and Research Veterinary Institute – Sofia and in 2 Regional Labs – in Stara Zagora and Veliko Tarnovo.
- Twinning project BG 2002/IB/AG-04 with German Federal Ministry of Agriculture

As a result of the project experts from National Diagnostic and Research Veterinary Institute were trained in Reference laboratories in Germany in the field of laboratory diagnosis of TSE. Experts from German Ministry of Agriculture carried out training workshops in Sofia for prevention and eradication of TSE. Workshops for training on Good Laboratory Practice were also conducted in Sofia.

- Under USAid in HPAI were supplied diagnostic kits, ELISA system, 2 refrigerators and an incubator which are situated in Regional reference lab for HPAI in Varna

3.3 Results:

- Two National Reference Laboratories for CSF and HPAI equipped and able to implement diagnostic and control activities with regards to CSF and HPAI, according to Monitoring & Surveillance programmes;
- 5 laboratory experts from NRL on CSF, 4 laboratory experts from NRL on HPAI and 1 from Regional Laboratory on HPAI and NDV trained in new diagnostic methods, preparation of monitoring and surveillance programmes;
- The NRLs for CSF and HPAI accredited;
- Improved quality of the reports on the current situation in Bulgaria with regards to CSF (domestic, wild, backyards and semi-wild boar pigs) and HPAI in terms of broader information for the tests carried out, improved quality of the data and diagnostic methods;
- Improved NVS Annual Monitoring plan on CSF and HPAI in terms of provision of broader information as basis for amendment of the strategy and approach for taking samples for the different bird and swine categories;
- Improved quality of the special laboratory methods – virus isolation and VNT on the diagnostic purposes of CSF (Regulation (EC) No 882/2004.)
- Laboratory quality standards introduced for diagnostic routine of the NRLs for CSF and HPAI and the Regional laboratory on HPAI and NDV in Varna.

3.4 Activities:

The EU expertise and assistance, necessary for achievement of the above results will be covered by a Twinning light contract and a Supply contract.

**Twinning Light**

The quality of veterinary diagnostic activities and hence the reliability of certification of animals and animal products, depends mainly on the ability of the laboratories to provide
results of proven reliability. Therefore, the staff of both laboratories shall be acquainted and trained in the following fields:

1. Preparation for accreditation of the Laboratory for CSF and the Laboratory for HPAI against EN ISO 17025:2000 standard and Good Laboratory Practice (GLP) standard requirements in order to guarantee the quality of the laboratories’ activities and the related training on elaboration of quality manuals, procedures and control/auditing according to the standards. NVS has already started the preparation for accreditation of the laboratories and the twinning assistance will only support the advanced preparation;
   (1 Short-term mission of 2 MS experts for 10 days).

2. Organization of collecting, keeping and transportation of biological samples (materials and infectious strains) in the territory of the country;
   (1 Short-term mission of 2 MS experts for 5 days).

3. Training of 6 BG laboratory experts for 5 days in a MS country on laboratory diagnostic system for CSF and HPAI. The Bulgarian laboratory experts need to receive practical knowledge of preparing the Real Time PCR, ELISA and AGID protocols in reference laboratories of CSF and HPAI in a MS. They have to be trained on the spot on the diagnostic methods on CSF and HPAI.
   (1 Study visit to MS of 6 BG experts for 5 days)

4. Training on the application of Animal Diseases Notification System, notably the registration and documentation of certain important infectious animal diseases;
   (2 Short-term missions of 2 MS experts for 5 days each).

5. Training on implementation of the requirements and conformity conditions, necessary for the accreditation of the 2 labs, to work under the EU rules;
   (2 short-term missions of 2 MS experts for 5 days each).

6. Organization of 2 seminars and 1 workshops, for dissemination of EU Methodology for Good Laboratory Practice (GLP), the Good Experimental Practice (GEP) in the NRLs on CSF and HPAI.
   (3 short-term missions of 2 MS experts for 5 days each).

The trained experts will write detailed reports on the trainings passed, including description of know-how achieved and will disseminate the gained knowledge to all laboratory staff through on the job trainings and presentations.

**Supply of equipment**
The needed laboratory equipment is as follows:

- 1 PCR thermal Cycler
- 1 Mini chemical chamber for PCR
- 1 Laboratory freeze-dryer with Stoppering chamber
- 1 Multi-Detection Microplate Reader
- 1 Virus washer system for laboratory with accessories electrolyzed filter system for disinfection and suppression of air born viruses
- 1 ELISA systems with software
- 1 Medical freezer to - 40 °C

3.5 Lessons learned:
In the final report of the project BG-2002/IB/AG-03, which has finished in 2005, a recommendation is given, that minimum two of the laboratories of the EEDD have to be improved and equipped with new specialized equipment for applying of the modern laboratory diagnostic methods. We have to develop the routine laboratory methods for diagnostic of CSF especially – Virus isolation, Virus Neutralisation test, PCR and Real-Time PCR. Also we need to built the cell culture laboratories in “Exotic Department” and special rooms for PCR and Real-Time PCR diagnostics. Further to this it is recommended that the staff in the labs for CSF and ASF and HPAI and NDV have to be trained for use and interpretation the results of the same methods of diagnosis, which are used by the reference lab in the EU. It is very important because the situation in Bulgaria against CSF now is the problem disease and from its eradication is depends the swine meat and meat products export from Bulgaria to other European members countries.

4. Institutional Framework

The legal basis of the system of laboratory and diagnostic control in the National Veterinary Service (NVS) is provided by the Law on Veterinary Activity (LVA) and the Rules for application of the LVA (the detailed list of relevant legislation is provided in Annex 5).

The National Diagnostic and Research Veterinary Medical Institute (NDRVMI) was established in Sofia in 1901. In 2001, it became an integral part of the structure of the National Veterinary Service (NVS), specialized for science-and-research and diagnostic activities performed in the areas of animal health, veterinary public health, control on food safety and products of animal origin, animal feeds, feed components, medicated feedstuffs and prevention of environmental pollution (contamination).

The NDRVMI in Sofia is been structurally and operationally divided into seven main departments (sections), as follows:

- ‘Virology and Viral Diseases’ Section;
- ‘Bacteriology and Bacterial Diseases’ Section;
- ‘Exotic and Extremely Dangerous Diseases’ Section;
- ‘Public Health’ Section;
- ‘Parasitology and Disinfection, Disinfection and Deratisation’ Section;
- ‘Diseases in Fish, Bees and Silkworms’ Section;
- ‘Non-infectious Diseases’ Section.

The NDRVMI in Sofia is managed by a Director that is directly subordinated and accountable to the Director General of the NVS. The Institute employs highly qualified specialists involving veterinarians, biologists, chemists and others. Its staff totals 135 persons, 4 of which are Professors, 35 are Senior Researchers of Second Grade and another 21 are also Scientific Researchers.

The NDRVMI science-and-research activities are focused in applied science - finding practical solutions of problems related with the etiology, epizootology, diagnostics, prophylaxis and combat against (control of) certain, currently significant for the country, animal diseases, and also problems related to food safety of foods of animal origin. The Institute is participating in development of internationally operated scientific projects. Substantial share of its activities is occupied by diagnostic and expertise activities laid down in the State Prophylactic Programme and the surveillance programmes, run by the NVS to monitor the epidemiological situation with certain extremely dangerous and exotic diseases in animals.

The Institute hosts the 17 National Reference Laboratories (NRL) in animal health and control of products and foods of animal origin. These NRLs operate the appropriate system.
for receiving, registering and dealing with the samples received for diagnostic testing and for registering the results of all such tests.

Under preparation for accrediting are the NRL dealing with exotic and extremely dangerous infections (FMD, bluetongue, avian influenza, Newcastle disease, African horse sickness, classical swine fever and African swine fever), the NRL in TSE diagnostics, the NRL in fish diseases.

The NDRVMI is an arbitrage structure in the NVS system of laboratory control, with reference to its level of competence, regarding the life-stock health care and public health care.

The "Exotic and Extremely Dangerous Diseases" Section (EEDD) under NDRVMI employs 22 qualified laboratory experts, of which 8 are senior researchers, 4 are veterinary doctors, and 10 are laboratory technicians. There are 5 different national reference labs (NRL) for former List A of OIE diseases – FMD and vesicular diseases; CSF and ASF; HPAI and NDV; AHS and viral diseases of Horses and Blue Tongue. All labs perform a scientific, applied and diagnostic work in the veterinary area and play the main role in the whole Bulgarian diagnostic systems.

The tasks of laboratory diagnostic control are related to:

- The Annual State Prophylactic Program;
- The former list A of OIE of life-stock contagious diseases;
- Plans for laboratory analysis in the regions of diagnostic units of the laboratories;
- Development of new scientific researches about these diseases
- Fodder control, including drug fodder and mixtures, raw materials and components for them in case of importation, exportation, production and realization.

With relation to the necessity for investigation of bigger number of samples for CSF and HPAI, included into the Monitoring programmes and the dangerous epizootological situation in Europe with regards to HPAI, NVS has planned to establish a Regional Laboratory in the Northern-East part of Bulgaria (on Vila Pontica), which will be located in Varna.

The equipment supplied will be used by the Laboratories for CSF and HPAI.

5. Detailed Budget

<table>
<thead>
<tr>
<th>€M</th>
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<th>Co-financing</th>
<th>Total cost</th>
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<td>Contract 1 Twinning Light</td>
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</table>
(*) contributions from National, Regional, Local, Municipal authorities, FI loans to public entities, funds from public enterprises. All the co-financing is joint co-financing and will be provided from the state budget. In the case where the total cost is lower than foreseen in the project, the national public and Transition Facility co-financing shall be reduced proportionally so as to maintain the agreed rate of co-financing.

(**) private funds, FI loans to private entities

Contributions from the Bulgarian administration for effective implementation of the twinning (twinning light/TA) may be further detailed in the twinning contract/term of references.

To ensure smooth implementation of the project, the beneficiary will provide adequately equipped office space with telephone, PC (Internet) and fax. Photocopier and access to the necessary information as well as secretarial support will be ensured during the project life-time. In addition, the beneficiary will provide space and facilities for workshops (training), consultations and seminars. The national co-financing will be specified in the twinning contract.

(***) the national co-financing up to 10% will be ensured by the National Fund (Ministry of Finance)

6. Implementation Arrangements

6.1 Implementing Agency

The CFCU (Ministry of Finance) will be the Contracting Authority and in that capacity will issue and evaluate tenders, conclude contracts and authorize contractually related payments. The State Treasurer of Ministry of Finance will act as PAO of the project.

Contact details of PAO are:

Ms. Gergana Beremska
State Treasurer of Ministry of Finance and PAO
Address: 102 Rakovski Str.
1040 Sofia
Tel.: (+359 2) 9859 24 90
Fax: (+359 2) 980 68 63
E-mail: g.beremska@minfin.bg

The PIU at the Ministry of Agriculture and Food Supply will be responsible for monitoring of project implementation and coordination of the activities at all stages of the project cycle.

Contact details of the PIU:

Ms. Demina Bairaktarska
Director of “European programs and projects” Directorate
Ministry of Agriculture and Food Supply
Address: 55 Hristo Botev blvd.
Sofia
Tel: 359 2 981 6163
Fax: 359 2 981 75 42
E-mail: demina@phare-agr.orbitel.bg

Contact details of the SPO:

Mr. Dimitar Peychev
Deputy Minister of agriculture and food supply
Address: 55 Hristo Botev blvd.
Sofia
Tel: 359 2 98511 240
Fax: 359 2 980 87 06
E-mail: d.peychev@mzar.gov.bg
The Beneficiary of the project will be the EEDD under NVS, which will be responsible for the preparation of the Technical specifications and for the implementation of the project.

Project leader: Assoc. Prof. Dr. Ivaylo Chenchev, Deputy Head of EEDD; NVS-EEDD contact details:
Address: National Veterinary Service, 15A Pencho Slaveikov Blvd, 1606 Sofia, Bulgaria
Tel No: + 359 2 934 54 02
Fax No: + 359 2 834 10 04
E-mail: eclips@abv.bg

6.2 Twinning
The Twinning Manual shall apply.

6.2.1 Experts profile
A Twinning Light project is envisaged for exchange of experience and know-how with a MS with traditions and practice in this area. The twinning partner shall provide an adequate team of experts, meeting the following requirements:

*Project Leader Profile*
- Master's degree in veterinary medicine or chemistry;
- Professional experience in laboratory diagnostic methods of animal diseases at least 15 years;
- Good knowledge of EU animal health legislation and experience in its implementation in the laboratory work;
- Project management experience and good organizational skills;
- Ability to work in multidisciplinary and multilingual team;
- Fluency in both written and spoken English;
- Computer literate;
- Good reporting capabilities;
- Public servant.

*STEs profile*
- Education in veterinary medicine or chemistry;
- Public sector experts;
- Good knowledge of screening, ELISA and epidemiology;
- Good knowledge of EU animal health legislation and experience in its implementation in the laboratory work;
- At least 10 years practical experience in laboratory diagnostic methods of animal diseases;
- Excellent inter-personal communication skills;
- Proven experience in lecturing and drafting teaching aids;
- Excellent command in written/spoken English;
- Computer literate;
- Public servants.

The interested MS Institution shall include in their proposal the CVs for the proposed experts and the specific tasks to which they are related. The proposal shall contain the name of designated Project leader who will be responsible for the coordination of member state inputs.

6.2.2 Steering Committee
In order to control over the project the following Steering Committee meetings shall be held during the project implementation.

- Kick-off Meeting at the project’s start.
- Steering Committee during the 3rd month to discuss and approve the start-up report.
- Final Steering Committee to discuss and approve the final report.

The committee will include the SPO, the executive director of NDRVMI, the director of the PIU/MAFS and senior officials from the relevant department of MAFS, the project leaders of the twinning partners and the representative of NAC. Representative of CFCU will be invited as observer of the steering committee’s meetings.

The steering committee’s meetings will be the forum to discuss any unforeseen difficulties arising during the previous work period. Exceptional steering committees can be convoked, in case the situation dictates so.

6.2.3. REPORTING

6.2.3.1 Content, official language, format and number of reports

The twinning partners shall submit the following reports:

- A jointly drafted start-up report covering the first two months of the contract and submitted during the third month.
- A jointly drafted final report describing the project implementation, including detailed information on the results achieved, follow-up recommendations and any necessary corrective actions.

Reports will follow the templates of Annex C4 of the Common Twinning Manual

In addition to these formal reporting stages, the Contractor is obliged to inform the Beneficiary, the Contracting Authority and the Monitoring bodies - Phare Implementation Unit within MAFS, in writing of any critical aspects or conditions of project implementation, or any amendments/modifications necessary within the budget.

All reports must be produced both in the English and in Bulgarian languages in electronic format and in three (3) hard copies. These reports shall be signed by both project leaders and shall be endorsed and countersigned by the beneficiary and contain additional comments (if any).

Each report must be presented in electronic format one week prior to the Steering Committee and in hard copies in the following addresses:

<table>
<thead>
<tr>
<th>Contracting Authority</th>
<th>Phare Implementation Unit at MAFS</th>
<th>EEDD</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mr. Lubomir Tushanov</td>
<td>Ms. Demina Bairaktarska</td>
<td>Assoc. Prof. Dr. Ivaylo Chenchev, Deputy Head of EEDD;</td>
</tr>
<tr>
<td>CFCU Director,</td>
<td>Head of PIU at MAFS</td>
<td>Address: National Veterinary Service, 15A Pencho Slaveikov Blvd., 1606 Sofia, Bulgaria</td>
</tr>
<tr>
<td>Ministry of Finance</td>
<td>Address: #55, Christo Botev Blvd., 1040 Sofia, Bulgaria</td>
<td>Tel No: +359 2 934 54 02</td>
</tr>
<tr>
<td>Address: #102,</td>
<td>Email: demina@phare-</td>
<td></td>
</tr>
<tr>
<td>Rakovsky Str, 1040</td>
<td></td>
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<tr>
<td>Sofia, Bulgaria Email:</td>
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<tr>
<td><a href="mailto:cfcu@minfin.bg">cfcu@minfin.bg</a></td>
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The final versions of the reports should incorporate any comments and discussions during the Steering Committee meetings.

6.2.3.2 Translation & interpretation needs

The working language will be English.

The interested Member State institution shall include in their proposal the necessary budget for translation of the relevant documentation and interpretation needed.

Interpretation will be provided for Bulgarian experts during their visit to the Member State(s), as well as for the twinning experts during their visits to Bulgaria to secure optimal communication.

6.2.3.3 Date of submission

The start-up report will be submitted in the third month after the signing of the contract.

The final report shall be submitted within one month after the completion of the project.

6.3 Non-standard aspects

N.A.

6.4 Contracts

<table>
<thead>
<tr>
<th>Contract 1</th>
<th>Twinning Light</th>
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<tbody>
<tr>
<td>Contract 2</td>
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7. Implementation Schedule (please adjust schedules)

7.1 Start of tendering/call for proposals

Twinning Light: **November 2007**
Laboratory Equipment Supplies: **November 2007**

The technical specifications for the supplies under the project are ready.

7.2 Start of project activity

Start of project activities:
Twinning Light: **February 2008**
Laboratory Equipment supply: **April 2008**

Duration of Twinning Light: **6 months**
Duration of Supply Contract: **4 months**

7.3 Project Completion

Twinning Light: **July 2008**
Laboratory Equipment Delivery: **July 2008**
7.4 Schedule and number of units (man-days) for the assignment (twinning light):

The indicative estimation of the experts’ man-days needed for the implementation of the foreseen activities is the following:

<table>
<thead>
<tr>
<th>Activities</th>
<th>Type</th>
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</thead>
<tbody>
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<td>A.3.</td>
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<td>A.5.</td>
<td>STE missions</td>
<td>20</td>
</tr>
<tr>
<td>A.6.</td>
<td>STE missions</td>
<td>30</td>
</tr>
<tr>
<td><strong>Total:</strong></td>
<td></td>
<td><strong>100</strong></td>
</tr>
</tbody>
</table>

Proposed indicative time-schedule

<table>
<thead>
<tr>
<th>Activities</th>
<th>Months/man-days</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>1</td>
</tr>
<tr>
<td>A.1.</td>
<td></td>
</tr>
<tr>
<td>A.2.</td>
<td></td>
</tr>
<tr>
<td>A.3.</td>
<td></td>
</tr>
<tr>
<td>A.4.</td>
<td></td>
</tr>
<tr>
<td>A.5.</td>
<td></td>
</tr>
<tr>
<td>A.6.</td>
<td></td>
</tr>
<tr>
<td><strong>Total man/days in BG:</strong></td>
<td>20</td>
</tr>
</tbody>
</table>

8. Sustainability

The legal basis of the system of laboratory and diagnostic control in the National Veterinary Service (NVS) is provided by the Law on Veterinary Activity (LVA) and the Rules for application of the LVA.

The National Diagnostic and Research Veterinary Medical Institute (NDRVMI) is established in Sofia in 1901. In 2001, it became an integral part of the structure of the National Veterinary Service (NVS), specialized for science-and-research and diagnostic activities performed in the areas of animal health, veterinary public health, control on food safety and products of animal origin, animal feeds, feed components, medicated feedstuffs and prevention of environmental pollution (contamination). The experts that will be trained under the project will disseminate
the acquired knowledge and skills to all laboratory staff through preparation of manulas, on the job trainings and regular methodological guidance. The accreditation of the laboratory will ensure long-term sustainability of project results.

9. Conditionality and sequencing

Conditionality:
- Laboratories have available premises to receive the requested equipment. The premises where the equipment will be placed are newly refurbished in order to meet all EU requirements and standards.
- NVS will prepare financial justification before the procurement of the equipment to demonstrate that the resources for accreditation of CSF and HPAI labs and O & M costs of the equipment (consumables, reagents, running, maintenance and operations costs) are included in MAFS/NVS yearly budget.
- In some cases, supplies have been included in past projects (under Phare Programme) for the same beneficiary. Should this equipment procured in the past not have been used (e.g. still packed), or should past commitments taken by the NVS related to past supplies or programmes not been fulfilled, the Commission reserves itself the right not to finance the contracts listed in this fiche.
ANNEXES TO PROJECT FICHE

1. Logical framework matrix in standard format (compulsory)
2. Detailed implementation chart (compulsory)
3. Contracting and disbursement schedule by quarter for full duration of programme (including disbursement period) (compulsory)
4. List of relevant Laws and Regulations (optional)
5. Indicative List of Equipment and indicative budget breakdown for the twinning
6. Technical Specifications for the Equipment to be Supplied
ANNEXES TO PROJECT FICHE

1. Logical framework matrix in standard format (compulsory)

<table>
<thead>
<tr>
<th>Project Logframe</th>
<th>Project name and number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Improvement of the Diagnostic and Laboratory System for Animal Health Control against Classical Swine Fever and High Pathogenic Avian Influenza in Bulgaria</td>
<td>Contracting period expires 15 December 2009</td>
</tr>
<tr>
<td>Total Budget 0.279 MEUR</td>
<td>Execution of contracts period expires 15 December 2010</td>
</tr>
<tr>
<td>TF budget 0.259 MEUR</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Overall objective</th>
<th>Objectively verifiable indicators</th>
<th>Sources of Verification</th>
</tr>
</thead>
</table>
| Improvement of the animal health status, effective protection against the penetration of exotic viruses in the territory of Bulgaria and other Member States, eradication process with regard to the Classical Swine Fever (CSF) and the High Pathogenic Avian Influenza (HPAI) | - Decrease of outbreaks of CSF and HPAI  
- Working laboratories for HPAI and CSF according EU legislation  
- Recognition of Bulgarian certification for HPAI and CSF in EU countries and tests' results by the Laboratories of OIE and WHO. | - Official statistic documentation concerning infectious diseases and zoonoses in the country  
- Official reports of relevant DGs of the European Commission  
- DG SANCO evaluation reports  
- Annual reports |

<table>
<thead>
<tr>
<th>Project purpose</th>
<th>Objectively verifiable indicators</th>
<th>Sources of Verification</th>
<th>Assumptions</th>
</tr>
</thead>
</table>
| Implementation of effective control on Classical Swine Fever (CSF) and the High Pathogenic Avian Influenza (HPAI) diseases through improved diagnostic capacity of the laboratory system. Improvement | - Number of tests carried out increased by 50%  
- Monitoring programme for eradication of CSF and implementation of the requirements of EU Directive 93/36/ for CSF till eradication of the disease and obtaining of | - Annual progress reports to the European Commission  
- Laboratory diaries of CSF and HPAI Labs  
- Reports for implementation of the Programs for surveillance | Enough trained personnel ensured and at the disposal of NRLs |
the possibility of diagnostic capacity of the Classical Swine Fever labs according to the New programme for the Control and Eradication of CSF on the territory of Bulgaria.

<table>
<thead>
<tr>
<th>Results</th>
<th>Objectively verifiable indicators</th>
<th>Sources of Verification</th>
<th>Assumptions</th>
</tr>
</thead>
<tbody>
<tr>
<td>- Two National Reference Laboratories for CSF and HPAI equipped and able to implement diagnostic and control activities with regards to CSF and HPAI, according to Monitoring &amp; Surveillance programmes;</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
| - 5 laboratory experts from NRL on CSF, 4 laboratory experts from NRL on HPAI and 1 from Regional Laboratory on HPAI and NDV trained in new diagnostic methods, preparation of monitoring and surveillance programmes; | - National Reference Laboratories for CSF and HPAI accredited by December 2008  
- Diagnostic and control activities with regards to CSF and HPAI compliant to "ring trials" of the EU reference laboratories  
- Equipment supplied to the NRLs for CSF and HPAI by November 2008  
- GLP and GEP applied by December 2008 by laboratories’ staff and confirmed by labs accreditation | - Documents for accreditation of Labs  
- Annual operation plans of the Labs  
- Monitoring plan of NVS  
- NVS Monitoring reports on laboratories’ activities  
- Reports to the Steering Committee on the project | - Good level of cooperation between involved institutions  
- High quality project management ensured throughout  
- No significant changes in EU standards |
- The NRLs for CSF and HPAI accredited;
- Improved quality of the reports on the current situation in Bulgaria with regards to CSF (domestic, wild, backyards and semi-wild boar pigs) and HPAI in terms of broader information for the tests carried out, improved quality of the data and diagnostic methods;
- Improved NVS Annual Monitoring plan on CSF and HPAI in terms of provision of broader information as basis for amendment of the strategy and approach for taking samples for the different bird and swine categories;
- Improved quality of the special laboratory methods – virus isolation and VNT on the diagnostic purposes of CSF (Regulation (EC) No 882/2004);
- Laboratory quality standards introduced for diagnostic routine of the NRLs for CSF and HPAI and the Regional laboratory on HPAI and NDV in Varna.

<table>
<thead>
<tr>
<th>Activities</th>
<th>Means</th>
<th>Assumptions</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
**Supply**
Supply of laboratory equipment for the NRL for CSF and the NRL for HPAI

**Twinning light**
1. Preparation for accreditation of the Laboratory for CSF and the Laboratory for HPAI against EN ISO 17025:2000 standard and Good Laboratory Practice (GLP) standard requirements in order to guarantee the quality of the laboratories’ activities and the related training on elaboration of quality manuals, procedures and control/auditing according to the standards. NVS has already started the preparation for accreditation of the laboratories and the twinning assistance will only support the advanced preparation;

2. Organization of collecting, keeping and transportation of biological samples (materials and infectious strains) in the territory of the country;

3. Training of 5 BG laboratory experts for 5 days in a MS country on laboratory diagnostic system for CSF. The Bulgarian laboratory experts need to receive practical

<table>
<thead>
<tr>
<th>Supply contract.</th>
<th>Twinning light contract</th>
</tr>
</thead>
</table>

- Successful tendering and contracting.
- Supply of the equipment in time.
- Time schedule of implementation is observed
knowledge of preparing the Real Time PCR and ELISA protocols in reference laboratories of CSF in a MS. They have to be trained on the spot on the diagnostic methods on CSF.

4. Training on the application of Animal Diseases Notification System, notably the registration and documentation of certain important infectious animal diseases;

5. Training on implementation of the requirements and conformity conditions, necessary for the accreditation of the 2 labs, to work under the EU rules;

6. Training of 5 BG laboratory experts for 5 days in a MS country on laboratory diagnostic system for HPAI. The Bulgarian laboratory experts need to receive practical knowledge of preparing the Real Time PCR, ELISA and AGID protocols in reference laboratories of HPAI in a MS. They have to be trained on the spot on the diagnostic methods on HPAI;

7. Organization of 2 seminars and 1 workshops, for dissemination
Preconditions

Laboratories have available premises to receive the requested equipment. The premises where the equipment will be placed are newly refurbished in order to meet all EU requirements and standards.

NVS will prepare financial justification before the procurement of the equipment to demonstrate that the resources for accreditation of CSF and HPAI labs and O & M costs of the equipment (consumables, reagents, running, maintenance and operations costs) are included in MAFS/NVS yearly budget.

In some cases, supplies have been included in past projects (under Phare Programme) for the same beneficiary. Should this equipment procured in the past not have been used (e.g. still packed), or should past commitments taken by the NVS related to past supplies or programmes not been fulfilled, the Commission reserves itself the right not to finance the contracts listed in this fiche.
2. Detailed implementation chart (compulsory)

Project: Improvement of the Diagnostic and Laboratory System for Animal Health Control against Classical Swine Fever and High Pathogenic Avian Influenza in Bulgaria

<table>
<thead>
<tr>
<th>Components</th>
<th>2007</th>
<th>2008</th>
<th>2009</th>
</tr>
</thead>
<tbody>
<tr>
<td>Transition Facility</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Contract 1</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Twinning</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Contract 2</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Supply</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

P – Preparation
T – Tendering
C - Contracting
I – Implementing
3. Contracting and disbursement schedule by quarter for full duration of programme (including disbursement period) (compulsory)

**Project: Improvement of the Diagnostic and Laboratory System for Animal Health Control against Classical Swine Fever and High Pathogenic Avian Influenza in Bulgaria**

<table>
<thead>
<tr>
<th></th>
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<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Contract 1</td>
<td></td>
<td></td>
<td></td>
<td>0.200</td>
<td>0.200</td>
<td>0.200</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Contract 1</td>
<td></td>
<td></td>
<td></td>
<td>0.160</td>
<td>0.160</td>
<td>0.200</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Contract 2</td>
<td></td>
<td></td>
<td></td>
<td>0.079</td>
<td>0.079</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Contract 2</td>
<td></td>
<td></td>
<td></td>
<td>0.047</td>
<td>0.079</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
4. List of relevant Laws and Regulations (optional)

EU Legislation:

- EU Directive 2001/89/EC for CSF.
- EU Standard 45001
- WTO Standards Codex
- OECD Codex
- Good Laboratory Practice and European Union (EU)
- EU Directive 32/2002 on undesirable substances in feedingstuffs


Bulgarian Legislation:

Bulgarian Law on Veterinary Activities (LVA), published in State Gazette No 87/01.11.05
Ordinance No 10/26.03.1998
MAF Ordinance No 10/2000
Ordinance No 32/29.07.2002

MAF Ordinance No 8/2002

MAF Ordinance No 31/2004
MAF Ordinance No 36/2006
MAF Ordinance No 6/18.03.2003
MAF Ordinance 24/05.06.2003
MAF Ordinance 44/07.11.2004
5. Indicative List of Equipment

<table>
<thead>
<tr>
<th>SPECIFICATION</th>
<th>UNIT</th>
<th>PRICE EURO</th>
<th>TOTAL EURO</th>
</tr>
</thead>
<tbody>
<tr>
<td>PCR THERMAL CYCLER WITH ACCESSORIES</td>
<td>1</td>
<td>21 000</td>
<td>21 000</td>
</tr>
<tr>
<td>MINI CHEMICAL CHAMBER FOR PCR</td>
<td>1</td>
<td>4 500</td>
<td>4 500</td>
</tr>
<tr>
<td>LABORATORY FREEZE-DRYER WITH STOPPERING CHAMBER</td>
<td>1</td>
<td>13 500</td>
<td>13 500</td>
</tr>
<tr>
<td>MULTI-DETECTION MICROPLATE READER</td>
<td>1</td>
<td>31 000</td>
<td>31 000</td>
</tr>
<tr>
<td>MEDICAL FREEZER TO –40 °C 420 LITERS APPROX.</td>
<td>1</td>
<td>5 000</td>
<td>5 000</td>
</tr>
<tr>
<td>VIRUS WASHER SYSTEM FOR LABORATORY WITH ACCESSORIES ELECTROLYZED FILTER SYSTEM FOR DISINFECTION AND SUPPRESSION OF AIR BORN VIRUSES</td>
<td>1</td>
<td>4 000</td>
<td>4 000</td>
</tr>
<tr>
<td>TOTAL:</td>
<td></td>
<td></td>
<td>79 000</td>
</tr>
</tbody>
</table>
6. Technical Specifications for the Equipment to be Supplied

<table>
<thead>
<tr>
<th>Item</th>
<th>Number</th>
<th>Type of Analyses required</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Conventional PCR equipment</strong>&lt;br&gt;PCR thermal cycler&lt;br&gt;- block formats: 60x0.5 ml; 96x0.2ml; 384-well block; In-situ block&lt;br&gt;- block temperature: maximum ramp rate: 2.6°C/sec; block uniformity: ±0.3°C; temperature range: 4°C to 99°C; temperature set; point precision: 0.1°C&lt;br&gt;- heated lid: selectable heated lid temperature: 100°C-115°C; Heated lid enable/disable; over-temperature cut-out; Regulated lid pressure&lt;br&gt;- programming: number of programs-80; password protection; 4-line alphanumeric programming; incremental/ decremental temperature; incremental/decremental hold time; max.hold time-18hrs; min.hold time-1 sec; variable programmable ramp rate-0.1°C/sec steps; run end time calculation; pause and stop facility; end of program alarm; auto restart on power failure&lt;br&gt;- serial port: RS232&lt;br&gt;<strong>Including PC software</strong>&lt;br&gt;- temperature sensor: thermistor&lt;br&gt;- elements/block:8&lt;br&gt;- dimensions: 420x220x260mm&lt;br&gt;- connection to PC control program&lt;br&gt;- power consumption: 620Watts&lt;br&gt;- voltage: 230/115V&lt;br&gt;<strong>Photo - System including</strong>&lt;br&gt;- CCD camera 5.24 million pixels&lt;br&gt;- A/D conversion 12 bit&lt;br&gt;- Exposure time: 1/1000 to 60 sec. LCD monitor with integrated software without computer.&lt;br&gt;- Exposure control: Program AE, Shutter priority AE, Focus AE&lt;br&gt;- Exposure correction: ± 2.0 EV; Step 1/3 EV&lt;br&gt;- Digital zoom: 16x in 8 steps</td>
<td>1</td>
<td>For used in special diagnostic reaction PCR.</td>
</tr>
</tbody>
</table>
- Interval shooting: 10 sec – 6 hr
- Exposure metering range: 3 selectable size
- White balance: Set method, Color balance adjustment.
- Compensation: Gamma compensation 9 types, Shading compensation (Auto – 5 steps), color/modechrome, color enhancement, Hue rotation, Vertical and horizontal rotation
- Image size: 2560x1920 pixels; 1280x960 pixels; 640x480 pixels
- Storage format: BMP, JPEG
- Live display mode: 4 selectable modes
- Interface: USB 1.1 host port; USB 1.1/2.0 device port.
- LCD monitor 6,3 inch TFT colour
- Memory card
- Functions – distance measurement, count marking function, two-screen split display, XY scale display, Automatic detection of imaging status

Instruction manual translated on Bulgarian language
ISO certificate requested

<table>
<thead>
<tr>
<th>2</th>
<th>Mini chemical chamber for PCR</th>
<th>1</th>
<th>For keeping and preparing the samples, different kits, reagents and reactives, etc., which shall be stored in 4°C.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>With 1 prefilter</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>With 1 inlet HEPA filter</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>With U.V. sterile lamp (15 W)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Floor support without wheels</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Front closing panel</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>U.V. sterile lamp</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Gas and water service connections</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Electrical sockets</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Prefilters</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>C100 charcoal filters</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>HEPA filters</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Instruction manual translated in Bulgarian language</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>ISO certificate requested</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>3</th>
<th>ELISA-Computerized systems – Full equipment</th>
<th>1</th>
<th>Application of the difference ELISA – techniques for antigen and antibody tests.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>ELISA reader</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>- Reading system 8 independent channels, mono or bichromatic readings.</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>- Light source: tungsten lamp</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>- Optical filters: min (340, 405, 450, 492, 620, 650 nm)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>- Detectors: 8 silicone photodiodes</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>- Inaccuracy: ±1% from 0.000 to 1.500 OD; ±2% from 1.500 to 3.000 OD</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
- Reading time: 16 sec. to perform a monochromatic reading on a full plate, 31 sec. for bichromatic reading.
- Cuvettes: 96 well plate or 12x8 or 8x12 well strips
- Shaking plate
- Built-in printer: 40 columns on thermal paper
- RS 232
- Curves: curve direct plotting, point to point, linear regression and 4 parameters
- Memory: 170 tests
- Calendar/timer
ELISA Washer for 96 well plate and strips.
- Memory: 100 washing configurations
- Residual volume: <3 µl
- Dispensation volume: 200-400 µl with 50 µl increasing
- Dispensation inaccuracy: < 5% with 300 µl
- RS 232
Management Software and Computer
CPU Pentium 4, 2.4 Ghz 512M or equivalent
RAM 512 MB DDR, 400 MHz
HDD 40 GB, FDD 1,44 MB
VDC GF4 MX440 74 DDR
CD-DVD-RW 48x24x48X+16X
SB Intergrated Stereo
TFT MON 19” Flat
Scanner 2400x4800 48 bit USB2
Laser printer
Keyboard
Optical mouse
Microphoto-Camera - Fully compatible with the microscope described above.
Resolution - Min. 2.3 M pixels
Image size - Min. 1900 x 1200 pixels
Memory - Min. 512 MB (integrated on flash card)
Connection cables, accessories included.
JPEG and/or TIF format image acquisition system,
image capture and processing software compatible to the operational system of the PC
Instruction manual translated in Bulgarian language
ISO certificate requested

<p>| 4 | Laboratory freeze-dryer with | 1 | For preparation of the special |</p>
<table>
<thead>
<tr>
<th>Stoppering chamber</th>
<th>source and samples to transport.</th>
</tr>
</thead>
<tbody>
<tr>
<td>- Designed and built according GLP</td>
<td></td>
</tr>
<tr>
<td>- Condenser capacity kg (of ice) - 4 (4kg/24h)</td>
<td></td>
</tr>
<tr>
<td>- Final temperature in condenser &lt;= 50°C</td>
<td></td>
</tr>
<tr>
<td>- Number of compressors - 1</td>
<td></td>
</tr>
<tr>
<td>- Nominal vacuum pump flow – 6 m³/h</td>
<td></td>
</tr>
<tr>
<td>- Base unit weight - 70kg</td>
<td></td>
</tr>
<tr>
<td>- Voltage (single phase) V-Hz-220-50/60</td>
<td></td>
</tr>
<tr>
<td>- Total power -1kW</td>
<td></td>
</tr>
<tr>
<td>- Bench mounted table-top unit</td>
<td></td>
</tr>
<tr>
<td>- Two stage vacuum pump</td>
<td></td>
</tr>
<tr>
<td>- Air-cooled refrigeration system</td>
<td></td>
</tr>
<tr>
<td>- Condenser: consisting of co-axial coil inside a drum type manifold.</td>
<td></td>
</tr>
<tr>
<td>- Microprocessor controlled system</td>
<td></td>
</tr>
<tr>
<td>- Stoppering chamber: Glass cylindrical chamber with 3 shelves and manual closing device</td>
<td></td>
</tr>
<tr>
<td>- Dimensions: 660x620x700mm</td>
<td></td>
</tr>
<tr>
<td>- Dimensions of cylindrical chamber (ØxH) - 200x250mm</td>
<td></td>
</tr>
<tr>
<td>- Distance between shelves - 75mm</td>
<td></td>
</tr>
<tr>
<td>Instruction manual translated in Bulgarian language</td>
<td></td>
</tr>
<tr>
<td>ISO certificate requested</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Multi-Detection Microplate Reader</th>
<th>For preparing and used in special test for HPAI.</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Detection method</strong></td>
<td></td>
</tr>
<tr>
<td>Fluorescence,</td>
<td></td>
</tr>
<tr>
<td>Fluorescence Polarization,</td>
<td></td>
</tr>
<tr>
<td>Luminescence, UV- Visible</td>
<td></td>
</tr>
<tr>
<td>Absorbance</td>
<td></td>
</tr>
<tr>
<td><strong>Microplate types</strong></td>
<td></td>
</tr>
<tr>
<td>Temperature control: 4°C above ambient to 50°C</td>
<td></td>
</tr>
<tr>
<td>Shaking</td>
<td></td>
</tr>
<tr>
<td>Automation</td>
<td></td>
</tr>
<tr>
<td>Software Included Control through USB or serial port</td>
<td></td>
</tr>
<tr>
<td>Light source - Xenon Flash</td>
<td></td>
</tr>
<tr>
<td>Wavelength range 200 - 999 nm,</td>
<td></td>
</tr>
<tr>
<td>Bandpass min. 2.4 nm</td>
<td></td>
</tr>
<tr>
<td>Dynamic range 0 - 4.0 OD</td>
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<tr>
<td>Resolution 0.001 OD</td>
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<tr>
<td>Pathlength correction</td>
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<tr>
<td>wavelength accuracy +/- 2 nm</td>
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<td>wavelength repeatability +/- 0.2nm</td>
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<tr>
<td>OD accuracy</td>
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<tr>
<td>&lt; 1% at 2 OD typical</td>
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<tr>
<td>&lt; 3% at 3.0 OD typical</td>
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<tr>
<td>OD linearity</td>
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<td>6</td>
<td>Medical freezer to $-40^\circ\text{C}$ 420 Liters approx.</td>
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<tr>
<td>Temperature control range $-15$ to $-40^\circ\text{C}$</td>
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<tr>
<td>Forced air circulation with auto defrost</td>
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<tr>
<td>Microprocessor digital temperature display</td>
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<tr>
<td>Alarms for – high temperature, power failure, remote alarm contact</td>
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<tr>
<td>Interior dimesions min. 640 x 615 x 1090</td>
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<tr>
<td>Instruction manual translated in Bulgarian language</td>
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<td>ISO certificate requested</td>
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<thead>
<tr>
<th>7</th>
<th>Virus washer system for laboratory with accessories Electrolyzed filter system for disinfection and suppression of air born viruses</th>
<th>1</th>
<th>For viral work in sterile conditions, for cell culture infection and performing of viral neutralization test and others manipulation.</th>
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<tbody>
<tr>
<td>Instruction manual translated in Bulgarian language</td>
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Annually the HPAI and CSF NRLs will investigate resp. approximately 20000 - 25000 blood samples for antibodies against HPAI and NDV and more 110 000 samples against CSF, by means of which the most of the domestic animals in these regions will be covered.

The equipment of the NRLs laboratories have to respond to the NVS strategy and laboratory diagnostic needs and activities. In summary the necessary equipment to be purchased is as follows:

- Multi-Detection Microplate Reader - for need of special diagnostic methods especially ELISA in HPAI lab.
- PCR thermal cycler - for preparing the conventional PCR method
- Medical freezer to $-40^\circ\text{C}$ 420 Liters approx. –necessary for keeping of pathological materials and samples, kits etc.
- Laboratory freeze-dryer with Stoppering chamber - for storing, drying and keeping of new coming materials and samples and also to drying the viral strain which are isolated in the labs

- Elisa-computerized systems - full equipment – for needs of laboratory diagnosis of CSF
- Virus washer system for laboratory with accessories Electrolyzed filter system for disinfection and suppression of air born viruses – for sterilization of laboratory glassware and decontamination of contaminated material; the presence of such an autoclave will prevent the transfer of the tested samples from the laboratory and will reduce the risk of infection of the environment.
- Mini chemical chamber for PCR - for protecting workers during performance of samples and environment and isolation and typing of bacterial isolates.