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Project Fiche for Phare / Pre-accession instrument 2006

1. Basic Information

1.1 CRIS Number (Year 1): 2006/018-343.03.05

Title: Improvement of the Control on the Feed and Food Additives, contaminants and of the Diagnostic and Laboratory System for Animal Health Control in Bulgaria

1.2 Sector: Agriculture

1.3 Location: Bulgaria

1.4 Duration: 16 months

2. Objectives

2.1 Overall Objective(s):

Improvement of the control of feed and food additives and contaminants in fields of feed safety, food safety chain, environmental pollution and protection of customer's interests and improvement of veterinary public health and animal health status.

2.2 Project purpose:

Sub-project 1:

NGFS is able to practically implement the control (inspections and chemical analyses) of animal feeds in accordance with Regulation 882/2004, Regulation 1831/2003 and Regulation 183/2005.

Sub-project 2:

Increasing the diagnostic capacity of the Laboratory System for control of the feed and food safety in order to ensure the farm animal health status, protection against environmental pollution and veterinary public health safety.

2.3 Accession Partnership (AP) and NPAA priority (and implementing measures envisaged by the Action Plan for AP priorities related to strengthening administrative and judicial capacity)

Accession Partnership priority:

- Complete alignment of veterinary and phytosanitary legislation in order to enforce internal market control systems and imports from third countries fully and effectively; continue to implement veterinary, phytosanitary and food safety legislation, including animal disease control measures.
- Resource the NVS adequately and establish a programme of the National Veterinary Service for establishments to meet fully the EU requirements.

2005 Comprehensive Monitoring Report:

“Legislation in the area of **animal disease control** has been transposed as regards the EU rules for combating individual diseases. However, general control measures (vaccination ban, certain eradication measures) still need to be transposed (see also Veterinary Framework Law). Bulgaria has joined the Animal Disease Notification System. The contingency plans for Classical Swine Fever, Foot and Mouth Disease, Newcastle Disease and Avian Influenza have been provided. Surveillance programmes for Foot and Mouth Disease, Blue tongue, Classical Swine Fever, TSE and fish diseases will be implemented in the course of 2005. Particular

attention needs to be paid to the control of Classical Swine Fever and the review of Bulgaria's strategy to manage the evolution of the disease situation in the field."

All the basic *acquis* on **animal nutrition** has been transposed. The National Grain Service and the National Veterinary Service share the competence for the implementation and enforcement of the *acquis* in this sub-sector and are continuing to establish rules for their cooperation and communication. Furthermore, implementation of a risk-based inspection and sampling programme covering all stages of the feed chain still need to be implemented. Bulgaria has to ensure that international veterinary and phytosanitary agreements are brought into line with the EU *acquis* by accession.

Monitoring Report May 2006

Implementation and enforcement of the **animal welfare** rules at farm level during transport and slaughter have started, accompanied by training on application of the new legislation. The EU norms and standards on animal welfare are not yet fully enforced. Preparations need to be stepped up.

National Veterinary Service Strategy

The NVS has prepared its *Strategy for development* and the relevant timetable up to 2006 (Annex 3), which is approved by the Collegium of MAF. The document was included in the Position Paper of Bulgaria in the Veterinary sub-sector.

In the **Review of the Veterinary system of Bulgaria** (DG SANCO /7635/2005, /8306/2006 and /1401/2006) it is recommended that the equipment and facilities in the laboratories for Veterinary hygiene expertise of feed and animal origin food stuffs need to be upgraded in order to meet the EU standards.

Also, the Draft Report /ref. Peer 21728/ from the Peer Review 2006 Evaluation Mission on Residues and Pesticides stipulates that: "Priority should be given to some training for the analysts in charge of the new instruments not only with short courses proposed by the instruments providers, but also, and preferably with well-trained analysts of other monitoring laboratories in the same field of competence and with the same equipment to speed up the transfer of technology".

2.4 Contribution to National Development Plan (and/or Structural Funds Development Plan/SDP)

Not applicable.

2.5 Cross Border Impact

Not applicable.

3. Description

3.1 Background and justification:

Sub-project 1:

National Grain and Feed Service is the official authority which executes the control of the animal feeds in Bulgaria by inspections (taking of samples) and chemical analyses (of the taken samples) in accordance with the Feed Law. Animal feed producers and/or traders who had met all requirements are entered in the "Public Register of the producers and/or traders with animal feeds". This Register is available at NGFS internet site. Chief Directorate "Feed Control" was established in accordance with Feed Law, Gazette issue 82/17 September 1999 issue 101/ 12 December 2000 and it's a part of National Grain and Feed Service at Ministry of Agriculture and Forestry. Activity of CDCF is settled by the Feeds Law. In accordance with Feed Law CDCF controls:

1. Execution of the requirements given by Ordinance laying down the conditions and order of approving and registration of the producers and traders of animal feeds;
2. Circulation of animal feeds;
3. Conditions for using and circulation of feeding-stuff additives;

4. Control of the trade with the animal feeds;
5. Correspondence and quality of the animal feeds for particular purposes;
6. Observance of the animal feeding-stuffs legislation.

CDFC executes elaboration and implementation of annual Inspection plan, checks of the documents accompanying product, checks of the product identity, sampling and chemical analyses of taken samples. Sampling and testing are carried out in compliance with validated methods of analyses. Laboratories of the National Grain and Feed Service perform those analyses. After analyses are completed the control body issues a certificate.

In case that the feeding-stuffs do not meet the requirements the CDFC prescribes some of the following measures to be undertaken:

- Bringing of feeding-stuffs in compliance with the safety requirements;
- Decontamination of feeding-stuffs where it is possible;
- Redirecting of feeding-stuffs to other purposes or
- Destruction.

In the event of non-fulfillment of the prescribed measures sanctions are imposed according to the Feed Law. Preparation of annual lists of approved products and substances for feeding is the main function. Because of the specificity of the analyses at the moment in the system of MAF there is no one laboratory which could execute the whole range of necessary analyses of feeding-stuffs, premixtures and feed additives. As the one and only control authority in the field of animal feed control NGFS and particularly CDFC aims with further equipment of the Central laboratory in Sofia to meet the requirements of the EU rules with a view to perform more efficient feed control in accordance with the EU standards.

According to this project Central laboratory and laboratory in Varna will be equipped as follows: 2 HPLC apparatuses (for determination of vitamins, amino acids, coccidiostats etc.), 2 AAS apparatuses (for analyses of micro and macro elements); 1 microwave system for extraction; 1 microwave system for digestion; 2 water purification systems for ultra pure water. Because of the absence of the above mentioned equipment now NGFS is unable to execute full control of feeds as it is required by the legislation. With purchasing of this equipment NGFS will be able to implement all the acquis concerning samples analyses in feed control sector.

To achieve complete compliance with the EU legislation in feeding-stuffs sector is prepared a project draft of a Feed Law, which introduces Regulation 178/2002, Regulations 183/2005, Regulation 882/2004, and Regulation 1831/2003. This draft is prepared by a work group consists of experts from the Ministry of Agriculture and Forestry (Directorate 'Control of foods and their safety'), National Grain and Feed Service (NGFS), National Veterinary Service (NVS) and representatives of the Union of feeding-stuffs producers (UFP) from the country. The draft of the Feed Law was discussed at first reading at the committee of agriculture in the Bulgarian Parliament. Forthcoming introduction of the new Feed Law is fixed for 1 July 2006. Regulation 183/2005 is introduced in a secondary legislation in a draft of Ordinance for hygiene of the feeding-stuffs. This Ordinance will be published in the State Gazette together with the Feed Law. Ordinance for feeding-stuffs hygiene will abrogate the Ordinance laying down the conditions and arrangements for approving and registering of animal feed producers and traders (based on Directive 95/69). Draft of Ordinance about the feed additives is elaborated. This Ordinance introduces Regulation 1831/2003 in the Bulgarian legislation. This draft of Ordinance about the feed additives is going to be considered at the MAF council in June 2006. This ordinance will be published in the State Gazette together with the new Feed Law. Ordinance about the feed additives will abrogate present Ordinance No 3 based on Directive 70/524.

In order to fulfil all European requirements in the field of animal feed control CDFC aims to equip (by launching of this PHARE project) its laboratories in Sofia and Varna with very sophisticated and expensive apparatuses for determination of amino acids, vitamins, coccidiostats, high fatty acids, micro and macro elements. First step in the process of answering of all European requirements was made by adopting of European norms in Bulgarian legislation (annex 5). Second step is to complete the process of establishing of control authority in accordance with the EU rules by equipping laboratories of NGFS with necessary apparatuses.

Sub-project 2:

The project aims at improving the feed and food safety with regard to the veterinary public health. This improvement is intended to be reached through the increase of the diagnostic capacity of the feed and food

safety laboratory system. The project will also contribute to the prevention of the appearance and the dissemination of the non-infection animal diseases on the country territory.

The improvement of diagnostic and control systems for feed and food safety is needed for:

- Implementation of EU Directives 29/1999, 102/2001, 32/2002, 126/2003 for mycotoxicology and ecotoxicology, transposed in Bulgarian legislation with MAF Ordinances No 6/18.03.2003, 24/05.06.2003 and 44/07.11.2004;
- Implementation of EU Directives 91/493 amended by 2886/89 - transposed with MAF Ordinance No 10/2000; 89/107 - transposed with MAF Ordinance from 2005 for amendment of MAF Ordinance No 8/2002, concerning the health conditions for the production and placing on the market of fishery products and food additives authorized for use in food stuffs intended for human consumption;
- Implementation of R/EC/ 853/2004 and 854/2004 - transposed with MAF Ordinance 36/2006 concerning maximum levels and method of analysis of certain marine biotoxins in bivalve molluscs, etc. and Commission Regulation 466/2001 - transposed with MAF Ordinance No 31/2004 setting maximum levels for certain contaminants for foodstuffs;
- Alignment of the Bulgarian diagnostics system of feed and food safety with the EU one;
- Improvement of the feed and food safety control system through:
 - Researches on feeding stuffs, components and carcass material with regard to feed safety control and diagnostic of poisoning;
 - Laboratory analysis of: mycotoxins /Aflatoxine, Fuzariotoxine, Fumonizine, Zearalenon, etc./ - through HPLC methods; heavy metals /lead, cadmium, mercury, copper, zinc/ and arsenic – ICP methods; pesticides /organochlorine, organophosphorus and carbamates/ - GC/MS system; veterinary drugs - through HPLC methods and GC/MS system;
 - Laboratory analysis of: biogenic amines and volatile nitrogen components in fish; additives and colorants in foodstuffs by HPLC methods; certain marine biotoxins /saxitoxins, domoic acid, ocaidaic acid, dinophysis toxin, etc./; low levels heavy metals /lead, cadmium, mercury, copper, zinc/ and arsenic – through AAS method in graphite cuvette;

3.2 Sectoral rationale

Not applicable

3.3 Results

Sub-project 1:

The NGFS laboratories in Sofia and Varna are equipped for carrying out the tests, as per EU regulations.

Sub-project 2:

- The NRL for Mycotoxicology and Ecotoxicology and the Physico-Chemical Food Analysis Laboratory are equipped and able to implement diagnostic and control activities with regards to feed and food safety and poisoning diagnosis, as per EU regulations;
- 3 laboratory experts from NRL for Mycotoxicology and Ecotoxicology and 3 laboratory experts from Physico-Chemical Food Analysis Laboratory trained in new diagnostic methods.

3.4 Activities

Sub-project 1:

Supply of equipment for analyses of feeds in accordance with EU regulations in the field of food safety as is follows:

- 2 HPLC apparatuses (for determination of vitamins, amino acids, coccidiostats etc.)
- 2 AAS apparatuses (for analyses of micro and macro elements)
- 1 microwave system for extraction;
- 1 microwave system for digestion;
- 2 water purification systems for ultra pure water.

Sub-project 2:

- **Twinning Light**

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

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:

A. 1 Preparation for accreditation of the NRL for Mycotoxicology and Ecotoxicology 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 laboratory and the technical assistance will only support the advanced preparation;

(Short-term mission of 2 MS experts for 10 days).

A. 2 Preparation for accreditation upgrading of the Physico-Chemical Food Analysis Laboratory for new methods which will be applied in using the new equipment, supplied under the project;

(Short-term mission of 1 MS expert for 10 days).

A. 3 Organization of collecting, keeping and transportation of biological samples (materials and infectious strains) in the territory of the country;

(Short-term mission of 1 MS expert for 5 days).

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

(Short-term mission of 1 MS experts for 5 days).

A. 5 Training on implementation of the requirements and conformity conditions, necessary for the accreditation of NRL for Mycotoxicology and Ecotoxicology and the Physico-Chemical Food Analysis Laboratory, working under the EU rules;

(Two short-term missions of 2 MS experts for 5 days each).

A. 6 Training of 3 BG experts from NRL for Mycotoxicology and Ecotoxicology for 5 days in a MS country on laboratory diagnostic system for feedstuffs analysis of undesirable and forbidden substances. The Bulgarian experts need to receive practical knowledge on applying the ICP, HPLC and GC/MS methods in relevant reference laboratories in a MS. They have to be trained on the spot on the above-mentioned diagnostic and analytical methods;

(Study visit to MS of 3 BG experts for 5days).

A. 7 Training of 3 BG experts from Physico-Chemical Food Analysis Laboratory for 5 days in a MS country on laboratory diagnostic system for food analysis concerning biogenic amines, volatile nitrogen components, marine biotoxins as well as heavy metals like mercury, arsenic, etc. The Bulgarian experts need to receive practical knowledge on applying the AAS and HPLC methods in relevant reference laboratories in a MS. They have to be trained on the spot on the above-mentioned diagnostic and analytical methods, especially for those that are not implemented in the country yet;

(Study visit to MS of 3 BG experts for 5days).

A. 8 Organization of 2 seminars and 2 workshops, for dissemination of EU Methodology for Good Laboratory Practice (GLP), the Good Experimental Practice (GEP) in the NRL for Mycotoxicology and Ecotoxicology and the Physico-Chemical Food Analysis Laboratory and exchange of information related to the veterinary public health field .

(Two short-term missions of 2 MS experts for 5 days each).

- **Supply of Equipment**

The equipment will be delivered for NRL for Mycotoxicology and Ecotoxicology and the Physico-Chemical Food Analysis Laboratory. Supply of equipment for analyses of feeds and foods in accordance with EU regulations in the field of food safety as is follows:

- 4 HPLC apparatuses (for determination of mycotoxins, veterinary drugs, food additives and marine biotoxins, etc.);
- ICP for determination of heavy metals and arsenic;
- 1 AAS apparatus (for analyses of micro and macro elements);
- 2 microwave system for digestion;
- 2 UV/VIS spectrophotometers for alkaloids, glycosides and coumarins;
- 1 GC/MS with library for pesticides;
- 2 Digital microscope for determination of proteins of animal origin;
- 2 Mercury Analyzer System for Hg determination in feeds and foods;
- 1 Kjeldahl apparatus for protein determination;
- 2 Ultrasonic baths for cleaning and degasification;
- 2 Moisture balance;
- 2 Analytical balance;
- 1 Water distillation glass system;
- 1 Polarimeter
- 8 Air conditioning units;
- 4 PC.

A list of equipment is provided in Annex 7 and the detailed needs assessment - in Annex 8.

3.5 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

Sub-project 1:

According to the Twinning Covenant BG2002/IB/BG/AG-03 NGFS experts were trained in implementation of EU requirements by Dutch and Greek experts in Bulgaria and in the Netherlands. The activities under this project were to provide assistance for the establishment of a modern system of control on feeding stuffs and feed additives, to strengthen the control system with this of the EU standards by improving the professional qualification of inspectors and chemistry specialists in relation to the new administrative methods and methods of analyses.

EU member states experts found that NGFS experts are well trained and well acquainted with the EU legislation and requirements. Training helped them to upgrade their knowledge and to improve quality of their work. First training week in Bulgaria was focused on “Harmonisation of EU feeding-stuffs legislation in Bulgaria”, second week – on “Introduction of new administrative methods for operation in compliance with the EU rules” and the third week on “Training and implementation of the analytical methods for antioxidants, colorants including pigments, acidity regulators, microelements, organic fat acids, sucrose, carbohydrates, amino acids, vitamins as well as Cobalt or Manganese determination for the control of homogeneity testing of the feeding-stuffs”. On these topics was carried out two-weeks training in the Netherlands. After the completion of the project the conclusion was that the training was fruitful for both sides – trainers and trainees. The main result of the twinning was achieving of compliance in work of Bulgarian experts (inspectors and chemists) with the European requirements (introduced in Bulgarian legislation). Greek and Dutch experts also obtained detailed information about the situation of animal feed sector in Bulgaria. Their conclusion was that NGFS specialists (inspectors and chemists) are capable to implement EU requirements and standards. Moreover EU experts found in their Bulgarian colleagues future (after the accession of Bulgaria in EU) partners in applying of the acquis. On the basis of successfully implemented training was started a new project with Dutch side in order to continue co-operation between Bulgaria and the Netherlands in animal feed sector and to train Bulgarian specialist in implementation (in practice) of European Regulations: No. 178 (food safety) and No. 183 (hygiene of feeding stuffs), organization of the control of feeding-stuffs, control of gene modified feeds, Dutch experience in cooperation between control authorities and producers and traders of feeding-stuffs, and carrying out of chemical analyses of feeding-stuffs.

Sub-project 2:

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, Parasitoozonoses, 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

Sub-project 1:

According to the project the equipment was separated into two lots. Lot 1 included sophisticated equipment for specific analyses (HPLC, GC, AAS, Microwave systems for digestion and extraction). Due to procedure problems the tender for lot 1 was cancelled and the equipment was lost. The Technical Specifications of lot 1 equipment were approved by the ECD and they are ready to be used in the Tender of this current project because the equipment is the same.

Lot 2 included general chemical equipment (Sieving shaking machine, Drying oven, Laboratory glassware washer, Analytical balance, Precision balance, etc.). The equipment under lot 2 was successfully contracted, delivered and put into operation.

In general the main purpose of the project wasn't achieved and the current project aims to ensure supply of the equipment from cancelled lot 1. As it was mentioned above without this equipment NGFS is unable to execute effective control of animal feed producers and traders in accordance with EU norms.

Sub-project 2:

Through the project the necessary laboratory equipment was supplied for:

- Laboratory diagnosis of Brucellosis, Salmonellas, Parasitoozonoses, 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.
- The NRL for Mycotoxins and Ecotoxins was supplied with Soxhlet apparatus and Kjeldahl system. The equipment is installed and functioning in the National Reference Laboratory, located in the National Diagnostic and Research Veterinary Institute – Sofia.

- Twinning project BG 2002/IB/AG-04 with German Federal Ministry of Agriculture

Sub-project 2:

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.

- BG 2003/004-937.02.04 – Strengthening Food Safety Policy

Sub-project 2:

- The Physico-Chemical Food Analysis Laboratory was supplied with Gamma-spectrometer for radionucleid content in food and Gas Chromatograph for fatty acids analysis in foods. The equipment is installed and functioning in the Physico-Chemical Food Analysis Laboratory, located in the National Diagnostic and Research Veterinary Institute – Sofia.

A Reference list of feasibility/pre-feasibility studies is attached as Annex 4 to the project fiche.

3.6 Lessons learned:

Sub-project 1:

A mission of SANCO experts has audited NGFS. Conclusion is that the EU legislation requirements are introduced and NGFS experts work in compliance with them. As a problem was considered absence of the

necessary equipment for carrying out of all chemical analyses, specified in the legislation. Coping with this problem was emphasized as a significant step towards in achieving of full compliance with the EU standards.

According to the Phare project BG0201.04 "Improvement of Veterinary Border Control, Improvement of the Diagnostic System for Animal Health Control and Improvement of Feeding-stuffs and Feed Additives Control" NGFS had to receive necessary for its functions equipment divided into lot 1 and lot 2. Tender for lot 1 was cancelled and supply of equipment failed. Tender for lot 2 was successfully finished and equipment was supplied.

Sub-project 2:

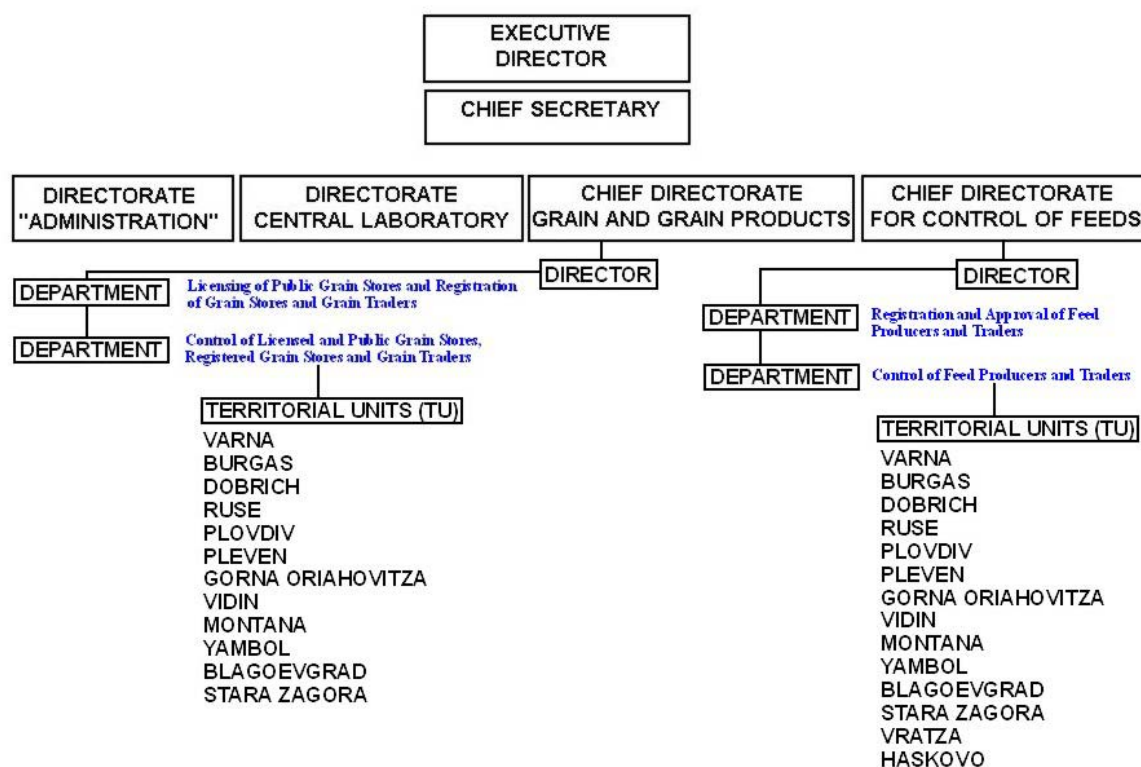
The Department of Public Health was beneficent of Phare Project BG2003/004-937.02.04 "Strengthening Food Safety Policy", under which a modern GC technique and apparatus for nuclide determination in food and feedstuffs was delivered. This new technique will help the experts to improve food safety analyses, concerning food composition and food contaminants in accordance Regulation (EC) 853/2004 (specific hygiene rules for food of animal origin) and CD 96/29 (protection the health against the dangers from ionizing radiation (EURATOM). A contemporary solution for determination of other harmful agents as biogenic amines, food preserves, marine biotoxins, etc., will be achieved by the new apparatuses in the new project. In that way the circle of investigations connected with food safety will be closed.

Under project BG - 0201.04 some laboratory equipment was supplied for the NRL for Mycotoxins and Ecotoxins. The delivered Soxhlet apparatus and Kjeldahl system support the National Reference Laboratory experts in caring out the analyses and researches on feeding stuffs, components and carcass material with regard to feed safety control.

4. Institutional Framework

Sub-project 1:

ADMINISTRATIVE STRUCTURE OF NATIONAL GRAIN AND FEED SERVICE



NGFS was established by the Grain Trade and Storage Law - Gazette issue 58/27.06.2003 and consists of Chief Directorate "Grain and Grain Products", Chief Directorate "Feed Control" (CDFC), Directorate Central Laboratory and Administration Directorate.

Chief Directorate "Feed Control" was established in accordance with Feed Law, Gazette issue 82/17 September 1999 issue 101/ 12 December 2000 and it's a part of National Grain and Feed Service at Ministry of Agriculture and Forestry. Activity of CDCF is settled by the Feeds Law.

CDFC consists of Department "Registration and Approval of Feed Producers and Traders" and Department "Control of Feed Producers and Traders" which has 14 Territorial units in the country. Territorial units are situated in Varna, Burgas, Dobrich, Ruse, Plovdiv, Pleven, Gorna Oriahovitza, Vidin, Montana, Yambol, Blagoevgrad, Stara Zagora, Vratza and Haskovo.

Total NGFS staff is 84 experts. 28 of them are working in CDFC.

Sub-project 2:

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**) 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 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 and veterinary hygienic expertise of feedstuffs and diagnostic of non-infectious animal diseases /inc. animal poisonings/. 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.

From the beginning of 2006, the Department on Public Health (DPH) at the Institute, dealing with control of foods, is in process of accreditation under ISO No 17025:2000 by the 'Bulgarian Accreditation Service' Executive Agency. The DPH includes 3 NRLs – on *Listeria*, on *Salmonella spp.*, on Milk (at the Sofia Directorate on Public Health) and 1 on marine biotoxins which will be soon established. Under preparation for such 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 and NRL for mycotoxicology and ecotoxicology.

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 'Non-infectious Diseases' Section (NID) under NDRVMI employs 13 qualified laboratory experts, of which 1 is Professor, 7 are senior researchers, 3 are junior researchers and 2 chemists. There are 5 different labs (1 of which is NRL) for mycology and mycotoxicology, pharmacology and toxicology, non-infection pathology, zoo hygiene and animal ecology and pathology on animal reproduction. 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:

- Chemical toxicological laboratory diagnostic of toxic agents and their metabolites in animal tissues, feedstuffs and environmental materials;
- Fodder quality control, including drug fodder and mixtures, raw materials and components for them in case of importation, exportation, production and realization;
- Prophylactic of non-infectious animal diseases;
- Implementation of Annual State Prophylactic Program;
- Development of new scientific researches about non-infectious diseases.

The 'Public Health' Section (PH) under NDRVMI employs 22 qualified laboratory experts, of which 1 is Professor, 5 are senior researchers, 4 are junior researchers, 7 veterinary doctors and chemists and 5 technicians. There are 4 different labs - 3 of which are NRL: for *Listeria*, *Salmonella* spp and Microbiological food safety and 1 for physico-chemical analysis which will form the NRL for marine biotoxins. All labs perform a scientific, applied and diagnostic work in the food safety control and public health area.

The tasks of laboratory diagnostic control are to ensure:

- Health safety of animal origin foodstuffs with regard to the pathogenic and dangerous parasites;
- High quality and safe to consumer's health diet foods with balanced chemical composition, high nutritive and biological value;
- Toxicological safety of animal foods with regard to biogenic amines, supplements, synthetic colouring agents, non-permitted preservatives, marine biotoxins, residues of harmful compounds as heavy metals, pesticides and pharmaceuticals;
- Harmonisation of Bulgarian legislation with EU one in the field of laboratory control of animal origin foods by introducing the principles of GLP.

5. Detailed Budget

	Phare/Pre-Accession Instrument support	Co-financing				Total Cost
€M		National Funds (*)	Public	Other Sources (**)	Total Co-financing of Project	
Year 2006 - Investment support jointly co funded						

<i>Sub-project 1:</i> Supply of laboratory equipment	0,345	0,115		0,115	0,460
<i>Sub-project 2:</i> Supply of equipment for NRL for Mycotoxicology and Ecotoxicology and the Physico-Chemical Food Analysis Laboratory	0,555	0,185		0,185	0,740
Investment support – sub-total	0,900	0,300		0,300	1,200
% of total public funds	max 75 %	min 25 %			

Institution Building support					
<i>Sub-project 2:</i> Twinning Light	0,200	***			0,200
IB support	0,200	***			0,200

Total project 2006	1.100	0,300		0,300	1,400
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(*) contributions form National, Regional, Local, Municipal authorities, FIs loans to public entities, funds from public enterprises

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

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

“The PHARE contribution for investment costs will be no more than 75% of eligible public expenditure, the balance having to be covered by the national co-financing. The national co-financing will be provided by the National Fund Directorate at the Ministry of Finance. All operational and running costs and the maintenance of the equipment will be provided by the final Beneficiaries.”

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 the treasury to make contractually related payments. The State Treasurer of Ministry of Finance will act as PAO of the project.

Contact details of PAO are:

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 Forestry 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:
Head of Phare Department
Ministry of Agriculture and Forestry
Address: 55 Hristo Botev blvd.
Sofia
Tel: 359 2 981 6163
Fax: 359 2 981 75 42
E-mail: demina@phare-agr.orbitel.bg

The beneficiary for Sub-project 1 will be the National Grain and Feed Service (NGFS) at the Ministry of Agriculture and Forestry

Contact details of the NGFS:
Executive director of NGFS
15 Vitosha blvd
Sofia
Tel: 359 2 9805831, 359 2 9555 301
Fax 359 2 9805832, 359 2 9555 301
E-mail: nszf@nszf.bg, s.spasov@nszf.bg

The Beneficiaries for Sub-project 2 will be the NID and PH under NVS:

NVS-NID contact details:

Name: Assoc. Prof. Dr. Lidia Borisova, Head of NID;
Address: National Veterinary Service, 15A Pencho Slaveikov Blvd, 1606 Sofia, Bulgaria
Tel No: + 359 2 952 39 03, ext. 348 or 250
Fax No: + 359 2 954 95 93
E-mail: ndrvmi-s@vetinst-bg.com; drlboriss@yahoo.com

NVS-PH contact details:

Name: Assoc. Prof. Dr. Vesela Peneva, Head of Physico-chemical Food Analysis Laboratory;
Address: National Veterinary Service, 15A Pencho Slaveikov Blvd, 1606 Sofia, Bulgaria
Tel No: + 359 2 952 39 03, ext. 209 or 392
Fax No: + 359 2 954 95 93
E-mail: ndrvmi-s@vetinst-bg.com; v.peneva@yahoo.com

6.2 Twinning

The Beneficiaries of the twinning project will be the NID and PH under NVS:

NVS-NID contact details:

Name: Assoc. Prof. Dr. Lidia Borisova, Head of NID;
Address: National Veterinary Service, 15A Pencho Slaveikov Blvd, 1606 Sofia, Bulgaria
Tel No: + 359 2 952 39 03, ext. 348 or 250
Fax No: + 359 2 954 95 93
E-mail: ndrvmi-s@vetinst-bg.com; drlboriss@yahoo.com

NVS-PH contact details:

Name: Assoc. Prof. Dr. Vesela Peneva, Head of Physico-chemical Food Analysis Laboratory;
Address: National Veterinary Service, 15A Pencho Slaveikov Blvd, 1606 Sofia, Bulgaria
Tel No: + 359 2 952 39 03, ext. 209 or 392
Fax No: + 359 2 954 95 93
E-mail: ndrvmi-s@vetinst-bg.com; v.peneva@yahoo.com

The Steering Committee, overseeing the project will have representatives of the following institutions:

The Contracting authority,
The EC Delegation,
MAF - Project Implementation Unit,

The Beneficiary
The Contractor

6.3 Non-standard aspects

Practical Guide to Contract Procedures for EC External Actions will be followed strictly during the project implementation.

6.4 Contracts

Sub-project 1:

Contract 1	Supply contract for laboratory equipment	€460 000
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Sub-project 2:

Contract 1	Twinning Light	€200 000
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Contract(s) 2	Supply Contract(s) [depending on the awarded Lots]	€740 000
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All laboratory equipment will be tendered in 1 tender procedure.

7. Implementation Schedule

7.1 Start of tendering/call for proposals

Sub-project 1:

Supplies: November 2006

Sub-project 2:

Twinning Light: September 2006

Laboratory Equipment Supplies: February 2007

7.2 Start of project activity

Sub-project 1:

Supplies: May 2007

Sub-project 2:

Twinning Light: February 2007

Laboratory Equipment Supplies: September 2007

7.3 Project completion

Sub-project 1:

Supplies: August 2007

Sub-project 2:

Twinning Light: July 2007

Laboratory Equipment Supplies: December 2007

8. Equal Opportunity

There will be an equal approach toward women and men in the project.
No discrimination of whatever nature will be applied.

9. Environment

The project does not have negative impact on the environment.

10. Rates of return

Not applicable.

11. Investment criteria (applicable to all investments)

11.1 Catalytic effect

Not applicable.

11.2 Co-financing

National co-financing of the supplies under the project is 25 % of the total budget. The national co-financing for the Twinning contract up to 10% will be ensured by the National Fund (Ministry of Finance).

11.3 Additionality

Not applicable.

11.4 Project readiness and size

Sub-project 1:

The Technical Specifications are ready and they are approved by the ECD.

Sub-project 2:

The technical specifications will be ready by the date of the start of the tendering procedures.

11.5 Sustainability

Sub-project 1:

NGFS is an official control authority with responsibilities for control of grain, grain products and feeding-stuffs. Control functions of NGFS are given by the Feed Law and by the Grain Storage and Trade Law. Control functions of NGFS are in full compliance with the acquis and with the completion of this project NGFS will become fully equipped in accordance with the EU requirements and will be able to implement EU norms and standards at 100 %. All this is a proof that NGFS will be the official control authority in the future and will work in co-operation with similar authorities in other EU member-states after the accession.

Sub-project 2:

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) 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).

11.6 Compliance with state aids provisions

Not applicable.

12. Conditionality and sequencing

Sub-project 1:

- In the implementation of the project are included all experts who are working in the animal feed control sector.

- In accordance with the Twinning Covenant BG2002/IB/BG/AG-03 NGFS Inspectors were trained on implementation of adopted in Bulgarian legislation EU norms.
- NGFS chemists were trained in analytical methods for testing of feeding-stuffs in accordance with EU standards.
- 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.

Sub-project 2:

- Good level of cooperation between involved institutions has to be ensured.

ANNEXES TO PROJECT FICHE

1. Logframe in standard format (compulsory) for each project
2. Detailed implementation chart (compulsory for year 1, optional for future years)
3. Contracting and execution of contracts schedule, by quarter, for full duration of project (including execution of contracts period) (compulsory for year 1)
4. Reference list of feasibility/pre-feasibility studies, in depth ex ante evaluations or other forms of preparatory work.
5. Reference list of relevant laws and regulations (compulsory)
6. Indicative Lists of Equipment
7. Needs assessment for *sub-project 2* Contract 2
8. List of acronyms

ANNEX 1

Project Logframe		Project name and number	
Improvement of the Control on the Feed and Food Additives, contaminants and of the Diagnostic and Laboratory System for Animal Health Control in Bulgaria		Contracting period expires November 2008	Execution of contracts period expires November 2009
		Total Budget 1.400 MEUR	Phare / pre-accession budget 1.100 MEUR
Overall objective	Objectively verifiable indicators	Sources of Verification	
Improvement of the control of feed and food additives and contaminants in fields of feed safety, food safety chain, environmental pollution and protection of customer's interests and improvement of veterinary public health and animal health status.	<p><i>Sub-project 1:</i> NGFS meets the requirements of the EU legislation on 100%.</p> <p><i>Sub-project 2:</i> The NRL for Mycotoxicology and Ecotoxicology and the Physico-Chemical Food Analysis Laboratory meet the requirements of the EU legislation on 100%.</p>	<p><i>Sub-project 1:</i></p> <ul style="list-style-type: none"> • SANCO evaluation reports • Annual reports <p><i>Sub-project 2:</i></p> <ul style="list-style-type: none"> • Official statistic documentation concerning non-infectious diseases and zoonoses in the country • Official reports of relevant DGs of the European Commission • DG SANCO evaluation reports • Annual reports 	
Project purpose	Objectively verifiable indicators	Sources of Verification	Assumptions
<i>Sub-project 1:</i> NGFS is able to practically implement the control (inspections and chemical analyses) of animal feeds in	<i>Sub-project 1:</i> NGFS as a competent authority ensures efficient and effective testing and control by march 2007	<i>Sub-project 1:</i> Certificates of laboratory accreditation.	<i>Sub-project 1:</i> Obtaining of certificates for accreditation in time.

<p>accordance with the acquis. Relevant legislation in animal feed sector is presented in annex 5. Following Commission Regulations are under introduction in Bulgarian legislation and will be published in July 2006:</p> <ul style="list-style-type: none"> • 882/2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules; • 1831/2003 on additives for use in animal nutrition; • 183/2005 laying down requirements for feed hygiene <p>The whole range of analyses of feeds is carried out on compliance with the European requirements in food safety field.</p> <p><i>Sub-project 2:</i> Increasing the diagnostic capacity of the Laboratory System for control of the feed and food safety in order to ensure the farm animal health status, protection against environmental pollution and veterinary public health safety.</p>		<p>Registrations and approvals of feed business operators.</p>	<p>Adoption of the new Feed Law and supporting Ordinances in time.</p>
	<p><i>Sub-project 2:</i></p> <ul style="list-style-type: none"> • Number of tests carried out increased by 50 % • Accreditation of the NRL for Mycotoxicology and Ecotoxicology by June 2008 • Accreditation of the Physico-Chemical Food Analysis Laboratory by June 2008 • The NRL for Mycotoxicology and Ecotoxicology and the Physico-Chemical Food Analysis Laboratory as competent authorities ensure efficient and effective testing and control by December 2007 	<p><i>Sub-project 2:</i></p> <ul style="list-style-type: none"> • Annual progress reports to the European Commission • Laboratory diaries of NRL for Mycotoxicology and Ecotoxicology and Physico-Chemical Food Analysis Laboratory • NVS monitoring reports • Certificates of laboratories' accreditation 	<p><i>Sub-project 2:</i> Enough trained personnel ensured and at the disposal of NRLs</p>

Results	Objectively verifiable indicators	Sources of Verification	Assumptions
<p><i>Sub-project 1:</i> The NGFS laboratories in Sofia and Varna are equipped for carrying out the tests, as per EU regulations.</p> <p><i>Sub-project 2:</i></p> <ul style="list-style-type: none"> The NRL for Mycotoxicology and Ecotoxicology and the Physico-Chemical Food Analysis Laboratory are equipped and able to implement diagnostic and control activities with regards to feed and food safety and poisoning diagnosis, as per EU regulations. 3 laboratory experts from NRL for Mycotoxicology and Ecotoxicology and 3 laboratory experts from Physico-Chemical Food Analysis Laboratory trained in new diagnostic methods. 	<p><i>Sub-project 1:</i> Equipment is delivered and installed 100% coverage of the feed producers in Bulgaria. 70% increase in number of analysed samples. 100% Guaranteed: 1. quality feedingstuffs production; 2. safe feedingstuffs production; 3. increase of customers confidence; 4. prevention of the environment from pollution.</p> <p><i>Sub-project 2:</i></p> <ul style="list-style-type: none"> The NRL for Mycotoxicology and Ecotoxicology and the Physico-Chemical Food Analysis Laboratory accredited by June 2008 Diagnostic and control activities with regards to feed and food safety implemented in compliance with EU requirements Equipment supplied to the NRL for Mycotoxicology and Ecotoxicology and the Physico-Chemical Food Analysis Laboratory by December 2007 GLP and GEP applied by December 2007 by laboratories' staff 	<p><i>Sub-project 1:</i></p> <ul style="list-style-type: none"> Protocols for chemical analyses. Prescriptions for corrections in cases of non compliance. Acts for administrative infringement. <p><i>Sub-project 2:</i></p> <ul style="list-style-type: none"> 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 	<p><i>Sub-project 1:</i> Legal requirements are unchanged.</p> <p><i>Sub-project 2:</i></p> <ul style="list-style-type: none"> Good level of cooperation between involved institutions High quality project management ensured throughout Changes in EU standards
Activities	Means		Assumptions
<p><i>Sub-project 1:</i> Supply of equipment for analyses of feeds in accordance with EU regulations in the field of food safety as is follows:</p> <ul style="list-style-type: none"> 2 HPLC apparatuses (for 	<p><i>Sub-project 1:</i> Laboratory equipment supply contract.</p>		<p><i>Sub-project 1:</i></p> <ul style="list-style-type: none"> Successful tendering and contracting. Supply of the equipment in time.

<p>determination of vitamins, amino acids, coccidiostats etc.)</p> <ul style="list-style-type: none"> • 2 AAS apparatuses (for analyses of micro and macro elements) • 1 microwave system for extraction; • 1 microwave system for digestion; <p>2 water purification systems for ultra pure water.</p> <p><i>Sub-project 2:</i></p> <ul style="list-style-type: none"> • Trainings for laboratories' staff and organization of two seminars and two workshops, for dissemination of EU Methodology for Good Laboratory Practice (GLP) and Good Experimental Practice (GEP) in the NRL for, Mycotoxicology and Ecotoxicology and the Physico-Chemical Food Analysis Laboratory. • Supply of equipment for the NRL for Mycotoxicology and Ecotoxicology and the Physico-Chemical Food Analysis Laboratory for applying the laboratory diagnostic methods, used by the reference labs in EU. 	<p><i>Sub-project 2:</i> Twinning assistance for trainings and seminars</p> <p>Supply contract</p>		<p><i>Sub-project 2:</i> Time schedule of implementation is observed</p>
Preconditions			
<p><i>Sub-project 1:</i></p> <ul style="list-style-type: none"> • Experts (chemists and inspectors) are basically trained in implementation of the legislation. 			

- Laboratories have available premises to receive the requested equipment.
- The premises where the equipment will be placed are refurbished.

ANNEX 2 Detailed implementation chart

Project: Improvement of the Control on the Feed and Food Additives, contaminants and of the Diagnostic and Laboratory System for Animal Health Control in Bulgaria

Components	2006						2007												2008												2009												
	J	A	S	O	N	D	J	F	M	A	M	J	J	A	S	O	N	D	J	F	M	A	M	J	J	A	S	O	N	D	J	F	M	A	M	J	J	A	S	O	N	D	
Year 1/Phare 2006																																											
Sub-project 1: Contract 1 Supply					T	T	T	T	T	T	C	I	I	I																													
Sub-project 2: Contract 1 Twinning light					T	T	T	I	I	I	I	I	I																														
Sub-project 2: Contract 2 Supply					P	P	P	T	T	T	T	T	T	T	I	I	I	I																									

P – Preparation

T – Tendering

I – Implementing

ANNEX 3 Contracting and Execution of Contracts Schedule

Project: Improvement of the Control on the Feed and Food Additives, contaminants and of the Diagnostic and Laboratory System for Animal Health Control in Bulgaria

	I 2007	II 2007	III 2007	IV 2007	I 2008	II 2008	III 2008	IV 2008	I 2009	II 2009	III 2009
<i>Sub-project 1:</i> Contract 1 Contracted		0.460	0.460								
<i>Sub-project 1:</i> Contract 1 Disbursed		0.276	0.460								
<i>Sub-project 2:</i> Contract 1 Contracted	0.200	0.200	0.200								
<i>Sub-project 2:</i> Contract 1 Disbursed	0.160	0.160	0.200								
<i>Sub-project 2:</i> Contract 2 Contracted			0.740	0.740							
<i>Sub-project 2:</i> Contract 2 Disbursed			0.444	0.740							

ANNEX 4 Reference list of feasibility studies

Sub-project 2:

BG 9001-01-08 A - Master Plan for Technical Support for NVS

BG 9507-02-06 - Supply of equipment for FMD laboratory

BG 95070201/L002 - Technical assistance to the National Inspectorate for Grain and Fodder Control.

SPAC 97-0534.00 Project B5-96-001 – Multi-country Veterinary Diagnosis and Control Programme

BG 98/AG/IB/01 - Twinning project with the Italian Veterinary Service

BG 9806-01-01 and BG9913-01-01 - Software development for bovine

BG 9913-01-01 - Supply of ear-tags

BG 2003/004-937.02.04 – Strengthening Food Safety Policy

Peer Review 2006 concerning Veterinary Public Health with particular focus on the zoonoses control and control of contaminants pesticides and residues and the corresponding laboratory capacity, Bulgaria, Draft Report (ref. Peer 21728)

ANNEX 5 Reference lists of relevant laws and regulations

Sub-project 1:

1. Feed Law Gazette issue 82/17 September 1999, issue 101/ 12 December 2000.
2. Ordinance N24 (Gazette, issue 106/1999) “Conditions and arrangements for approving and registering of producers and traders of animal feeds” – according to Council Directive 95/69/EC of 22 December 1995 laying down the conditions and arrangements for approving and registering certain establishments and intermediaries operating in the animal feed sector and amending Directives 70/524/EEC, 74/63/EEC, 79/373/EEC and 82/471/EEC;
3. Ordinance N4 (Gazette, issue 11/2001) “Circulation of the feed raw materials” – according to Council Directive 96/25/EC of 29 April 1996 on the circulation of feed materials, amending Directives 70/524/EEC, 74/63/EEC, 82/471/EEC and 93/74/EEC and repealing Directive 77/101/EEC;
4. Ordinance N3 (Gazette, issue 8/2001) “Feeding-stuffs additives” – according to Directive 70/524 concerning additives in feeding-stuffs;
5. Ordinance N44 (Gazette, issue 106/2001) “Compound feeding-stuffs trade” – according to Directive 79/373 on the marketing of compound feeding-stuffs;
6. Ordinance N30 (Gazette, 67/2001) “Control of the products intended for animal nutrition” according Council Directive 95/53/EC of 25 October 1995 fixing the principles governing the organization of official inspections in the field of animal nutrition;
7. Ordinance N44 (Gazette, issue 109/2002) “Sampling and methods of analyses of feeding-stuffs” – according to Commission Directives 71/250; 71/393; 72/199 /amended by 93/28/; 73/46; 74/203; 75/84, 76/371; 76/372; 78/633; Commission Directive 81/715/EEC of 31 July 1981 establishing Community methods of analysis for the official control of feeding-stuffs; Commission Directive 84/425/EEC of 25 July 1984; Commission Directive 93/70/EEC of 28 July 1993 establishing Community analysis methods for official control of feeding-stuffs; 93/117;
8. Ordinance N10 (Gazette, issue 20/2003) “Feeding-stuffs with special purpose” according to Council Directive 93/74/EEC of 13 September 1993 on feeding-stuffs intended for particular nutritional purposes and Commission Directive 94/39/EC of 25 July 1994 establishing a list of intended uses of animal feeding-stuffs for particular nutritional purposes.

Sub-project 2:

List of Relevant EU Regulations:

EU Standard 45001

DG SANCO/8306/2006/1401/2006

Council Regulation (EEC) No 3906/89 of 18 December 1989 on economic aid to the Republic of Hungary and the Polish People's Republic and Council Regulation (EC) No 1266/1999 of 21 June 1999 on coordinating aid to the applicant countries in the framework of the pre-accession strategy and amending Regulation (EEC) No 3906/89.

WTO Standards Codex

OECD Codex

Good Laboratory Practice and European Union (EU)

Council Directive 89/107/EEC concerning food additives authorized for use in foodstuffs intended for human consumption.

Commission Decision 2002/225/EC laying down detailed rules for the implementation of CD 91/492/EEC as regards the maximum levels and the methods of analysis of certain marine biotoxins in bivalve molluscs, echinoderms, tunicates and marine gastropods

Council Regulation (EEC) 2377/90 laying down a Community procedure for the establishment of maximum residue limits of veterinary medicinal products in foodstuffs of animal origin.

Council Directive 91/493 EEC laying down the health conditions for the production and the placing on the market of fishery products amended by No EEC 2886/89

CR/EC/ 853/2004 and 854/2004 concerning maximum levels and method of analysis of certain marine biotoxins in bivalve molluscs

Commission Regulation 466/2001 setting maximum levels for certain contaminants in foodstuffs

EU Directives 29/1999 and 102/2001 on undesirable substances and products in animal nutrition

EU Directive 32/2002 on undesirable substances in feedingstuffs

EU Directive 126/2003 on the analytical method for the determination of constituents of animal origin for the official control of feedingstuffs

Relevant 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;

ANNEX 6 Indicative Lists of Equipment

Sub-project 1:

LIST OF EQUIPMENT FOR NGFS FEED CONTROL LABORATORIES

Number	ITEM	Distribution	Pieces	Price	Total
				Euro	Euro
Item 1	Atomic Absorption Spectrometer (AAS)	Sofia, Varna	2	90 000	180 000
Item 2	Microwave System for Digestion	Varna	1	45 000	45 000
Item 3	Liquid Chromatograph (HPLC)	Sofia	2	90 000	180 000
Item 4	Microwave System for Extraction	Sofia	1	42 000	45 000
Item 5	Water Purification System for ultra pure water	Sofia, Varna	2	5 000	10 000
				Total	460 000

Sub-project 2:

LIST OF EQUIPMENT FOR NVS LABORATORIES

Lot 1 General laboratory equipment

SPECIFICATION	UNIT	PRICE	TOTAL
REFRIGERATORS WITH DIGITAL CONTROL – (4°C)	2	1500	3000
WATER DISTILLATION GLASS SYSTEM	1	3000	3000
WATER BATH	1	2000	2000
ULTRASONIC BATH	2	1000	2000
THERMOSTAT, 60 L	1	3000	3000
ANALYTICAL BALANCE 0,0001 G	1	5000	5000
MOISTURE DETERMINATION BALANCE	2	4000	8000
DIGITAL MICROSCOPE	2	10000	20000
KJELDAHL SYSTEM	1	15000	15000
POLARIMETER	1	5000	5000
AIR CONDITIONING UNITS	8	500	4000
PERSONAL COMPUTERS WITH SYSTEM SOFTWARE	6	1500	9000
TOTAL LOT 1:			79000

Lot 2 Specific Laboratory Equipment

SPECIFICATION	UNIT	PRICE	TOTAL
ELISA-COMPUTERIZED SYSTEMS – FULL EQUIPMENT	1	16000	16000
ICP	1	80000	80000
AAS	1	50000	50000
MICROWAVE SYSTEM FOR DIGESTION	2	30000	60000
HPLC	3	40000	120000

<i>HPLC/MS</i>	1	200000	200000
<i>GC/MS WITH PESTICIDE LIBRARY</i>	1	85000	85000
<i>UV-VIS SPECTROPHOTOMETER</i>	2	10000	20000
<i>MERCURY ANALYSER SYSTEM</i>	2	15000	30000
TOTAL LOT 2:			661000
TOTAL LOT 1 + LOT 2:			740000

ANNEX 7 – Needs Assessment for *Sub-project 2 Contract(s) 2*

The necessity of equipment is as follows:

Item		Number		Type of Analyses required
		NRL for Mycotoxicology and Ecotoxicology	Physico-Chemical Food Analysis Laboratory	
1	Digital microscope	2	-	For determination of animal origin proteins in the fodders
2	Kjeldahl system	-	1	For determination of total nitrogen in foods
3	Ultrasonic bath	1	1	For sample preparation and degasation of liquids
4	Analytical balance 0,0001 g	-	1	For sample preparation
5	Moisture determination balance	1	1	For moisture determination inf feeds and foods samples
6	Thermostat, 60 l	1	-	Enzyme determination in biological material
7	Water bath	-	1	Sample preparation
8	Water distillation glass system	-	1	Sample preparation
9	Polarimeter	-	1	Modified starch determination in foods
10	Air conditioning units	4	4	Needed for the functioning of the lab equipment
11	Refrigerators with digital control – (4oc)	1	1	For storage of standards and samples
12	PC	3	3	For operative work needs
13	ICP	1	-	For heavy metals determinationin carcass material and feedstuffs
14	AAS with graphic furnace	-	1	For low levels of lead, cadmium, arsenic, chromium, etc. determination in food samples
15	Microwave System For Digestion	1	1	For sample wet digestion
16	HPLC	2	1	For determination of mycotoxins, veterinary drugs, residues, biogenic amines, marine biotoxins, food preservatives
17	HPLC/MS	-	1	For determination of very low residual amounts veterinary drugs, residues, biogenic amines, marine biotoxins

18	GC/MS with pesticide library	1	-	For pesticides determination /organochlorine, organophosphorus and carbamates/
19	UV-VIS Spectrophotometer	1	1	For determination of alkaloids, glycosides, colorants, nitrates, nitrites, etc.
20	Mercury Analyzer System	1	1	For mercury determination in foods and fodders
21	ELISA-computerized systems – full equipment	1	-	For mycotoxin determination in feeds /aflatoxins, fumonizins, etc./

1. For NRL for Mycotoxicology and Ecotoxicology:

The equipment is needed in order to ensure the farm animal health status, protection against environmental pollution and veterinary public health safety. To reach these objectives a systematic laboratory control of feeds for xenobiotics and mycotoxins has to be performed. In supplying this equipment to the NRL, the Lab will fully respond to the requirements set out in CR 183/2005.

2. For Physico-Chemical Food Analysis Laboratory:

The equipment is needed in order to ensure toxicological safety of animal foods with regard to biogenic amines, supplements, synthetic colouring agents, non-permitted preservatives, marine biotoxins, residues of harmful compounds as heavy metals, pesticides and pharmaceuticals in accordance with R/EC/ 853/2004 and 854/2004 and EU Directives 91/493 and 89/107.

ANNEX 8 LIST OF ACRONYMS

AHS	African Horse Sickness
AP	Accession Partnership
CC	Candidate Country
CFCU	Central Financing and Contracting Unit
ELISA	Enzyme linked Sorbent Assay
EU	European Union
FMD	Foot and mouth disease
GLP	Good laboratory Practice
GEP	Good Experimental Practice
MAF	Ministry of Agriculture and Forestry
MS	Member State
NDRVMI	National Diagnostic and Research Veterinary Medical Institute
NDV	Newcastle Disease Virus
NID	Non-infection disease Section
NRL	National Reference Laboratory
NGFS	National Grain and Feed Service
NVS	National Veterinary Service
PCR	Polymerase Chain Reaction
PH	Public Health Section