STANDARD SUMMARY PROJECT FICHE

1. BASIC INFORMATION

1.1 CRIS Number: BG2004/016-711.03.02

1.2 Title:

Improving the internal market control via variety testing and seed control, improvement of the phytosanitary control and biological testing, and bringing the animal waste processing system in Bulgaria in line with the EU requirements

1.3 Sector:

Agriculture

1.4 Location:

Bulgaria

1.5 Duration:

Three years

2. OBJECTIVES

2.1. Overall Objective:

Strengthen the capacity of the Ministry of Agriculture and Forestry (MAF) and its services to undertake the priorities for EU alignment and implement the reforms identified in the current Accession Partnership and the National Program for the adoption of the Acquis (NPAA).

2.2. Project purpose:

Sub-project 1:

Reaching of the EU level in conducting of variety testing and seed control and seed certification procedures and improvement of the conditions and technical facilities at the structures of the Agency for Variety Testing, Field Inspection and Seed Control (EAVTFI&SC)

Sub-project 2:

Reinforcement of the National Service for Plant Protection (NSPP) through development of Quality assurance system by implementation of EN ISO 9001:2000, EN ISO 17025 or GLP and GEP requirements in order to guarantee the quality of NSPP control activities.

Sub-project 3:

To establish a EU-compliant processing plant for Category 1, Category 2 and Category 3 animal by-products not intended for human consumption in Bulgaria.

Sub-project 4:

Reinforcement of the use of the laboratory facilities by the MoAF.

2.3. Accession Partnership (AP) and NPAA priority

Sub-project 1:

Being the responsible institution and official controlling body of MAF the Agency for Variety Testing, Field Inspection and Seed Control (EAVTFI&SC) plays an important role in the

implementation of the EU legislation and procedures in the variety testing and seed control and certification of seed and propagating material. This requires sufficient and adequate conditions for conducting the Agency's activities.

The improvement of the technical conditions and facilities and strengthening of administrative capacity of the Agency through the proposed new project is an important follow up of the previous Phare projects in this sector and will be a step forward in closing of Chapter 7 "Agriculture" and speeding up the process of accession of R Bulgaria to EU as part of enlarged Europe.

Sub-project 2:

Accession Partnership

Short-term

• "Continue alignment of the veterinary and phytosanitary legislation and upgrade inspection arrangements, in particular at the future external borders".

NPAA priority:

- Continuation of the alignment of the phytosanitary legislation
- Up-grading of inspection arrangements
- Administrative capacity reinforcement
- Effective implementation of the EU acquis for carrying out phytosanitary control in mind of its future role as an external border of EU
- Building of stations for biological testing of plant protection products and adoption of the GEP in them in accordance with the proper implementation of the legislation
- Improvement of the phytosanitary protection

Sub-project 3 and 4:

Accession Partnership priority:

- Continue the upgrading of food processing establishments so that they are in a position to respect EC food safety standards.
- Continue the reinforcement of the food control administration.

Roadmap priority:

- Improve the situation regarding animal waste in particular in rendering plants. Ensure feed ban on processed animal proteins is in line with EC requirements to avoid cross contamination of ruminant feed with animal proteins for ruminants and cross feeding.
- Improve investigation of BSE epidemiology and use of approved diagnostic methods.
- Remove discrepancies in the field of TSE controls compared to the EC system.
- On food safety, implement and enforce legislation.

NPAA priority:

• Regulation 999/2001/EC with the amendments: 1248/2001/EC, 1326/2001/EC, 1494/2002/EC and Directive 90/667/EEC

2.4. Contribution to National Development Plan

Not applicable

2.5. Cross Border Impact

Not applicable

3. DESCRIPTION

3.1. Background and justification:

Sub-project 1:

The Agency for Variety Testing, Field Inspection and Seed control was established at the end of 1999 as a similar organisation in EU. It is the official controlling body of the Ministry of Agriculture and Forestry (MAF) in the seed sector responsible for the enforcement of the Law on Seed and Propagating Material (LSPM) and the Law on Protection of New Plant Varieties and Animal Breeds (LPNPVAB) and for the adoption and enforcement of the EU legislation in this field. The new project for strengthening and improvement of the activities and the procedures for variety testing and listing of plant varieties, for certification and control on seed and propagating material is necessary in order for the Agency to execute its functions and activities in conformity with EU requirements and practices. In particular, the Agency for Variety Testing, Field Inspection and Seed Control in the seed and propagation material sector faces a strong necessity for:

- Approximation of the level of technical conditions and facilities for conducting of variety testing and seed control with that of EU to conform with the EU standards and requirements;
- Unification of the standards for conducting DUS and VCU variety testing with the EU ones;
- Unification of the standards for evaluation of the quality of seed and propagating material with those of EU;
- Establishment of database for exchange of information.

The testing of plant varieties is carried out by 12 Regional Trial Stations all part of a testing network throughout Bulgaria, and 14 Regional Stations are involved in the seed testing and certification services, executing the control functions of the Agency pursuant to the Law on Seed and propagating Material (LSPM) and the Law on Protection of New Plant Varieties and Animal Breeds (LPNPVAB). The Agency is a UPOV member since 1998 with the ratification of the 1991 UPOV Convention. Being the official controlling body of MAF the Agency is the only state institution entitled to carry out DUS testing according to the UPOV Rules.

In order to conduct field trials for **DUS testing** (distinctness, uniformity and stability) and **VCU testing** (value for cultivation and use) in compliance with the UPOV Rules the Variety Testing Stations of the Agency need to have adequate equipment for setting of the field trials, for harvesting and precise reading out of the test results. The trial stations conducting the trials face a strong necessity of proper equipment and apparatuses for better precision of the measurements for the technological, chemical and phytopathological evaluation of the test results. The conducting of DUS tests requires precise measurements and documentation of the test results.

There is a strong necessity for equipping of a green house for the purposes of carrying out trials with early field vegetable crops and setting of varieties in Post Control trials with a view to speeding up of the seed certification process for seed lots to be placed on the market.

The Agency's Central Laboratory is the only ISTA accredited laboratory in Bulgaria. The seed control and certification procedures also require accurate seed testing and correct evaluation results for the seed moving in home and international trade. To achieve conformity with the

ISTA standards and upgrade the level of laboratory facilities there is need of new up-date equipment.

Under previous Phare projects basic laboratory equipment was supplied to the Central Laboratory (Central Seed Testing Station) and five (5) regional Labs for seed control were partially equipped but they do not fully meet the ISTA requirements and EU standards yet. In a number of the Agency's stations some of the lab equipment is missing which is needed for performing of seed analyses with better accuracy. The machines used for cultivation of the seed plots are either missing or over twenty years old and they need to be replaced by new and reliable ones for performing of the relevant agricultural activities for growing of the varieties tested. The equipment is strongly needed for the recognition by the EU countries of the DUS test results obtained at the Agency's Trial Stations.

In order to build up a well-equipped and efficient network of variety testing stations within the country for conducting the DUS and VCU tests in compliance with the UPOV Rules and EU standards and for more effective seed control following ISTA Rules, it is necessary to strengthen laboratories and facilities carrying out such controls. For achieving this, a number of regional Variety Testing Stations and the Labs in the Seed Control Stations should be equipped.

Achieving conformity with EU standards and reaching the level of EU in conducting the variety testing and seed control and certification procedures through application of a more precise equipment and measurement apparatuses will ensure:

- facilitating and speeding up of the evaluation processes in DUS testing (distinctness, uniformity and stability) and VCU testing (value for cultivation and use) and seed testing which will result in more accurate and reliable results;
- recognition of DUS test results from the trials conducted in the Bulgarian variety testing system by EU countries and listing of plant varieties in EU Common Catalogues;
- free movement of quality seed and propagating material on the EU internal market.

Sub-project 2:

As a future external border of the EU, Republic of Bulgaria should establish well structured and efficient border and internal control systems, including sufficient laboratory and testing capacity, and to enforce official control schemes with respect to plant health. The Bulgarian law designates the NSPP to the Ministry of Agriculture and Forestry as the official body responsible for the plant health activity including:

- Phytosanitary control;
- Plant protection products control

The activity, structure and organization of work and staff of the NSPP are arranged in the structural regulations.

Since 1991, the NSPP has received Phare assistance on the above areas, in order to meet the requirements of the European Union in the plant health sector. When the Phare assistance started, the common efforts in the area of the phytosanitary control and biologic testing were orientated to the equipping of NSPP structures and laboratories on the territory of the country and to the personnel training on the harmonized legislation. Now, when the new equipment delivered under the former Phare projects is available and the personnel is trained, for NSPP appears the need to guarantee the quality of the control activities. The best way to do this is to work in accordance with the EN ISO Standards or GLP standards. This might not be an *acquis* requirement but will have definitely beneficial impacts.

Phytosanitary Control

In order to improve the phytosanitary control of plants and plant products and to guarantee quality of the performed analyses, checks and surveillances, it is necessary to strengthen laboratories and other units carrying out such controls, i.e.:

- the Central Laboratory for Plant Quarantine (CLPQ), the reference laboratory conducting the official determination of harmful organisms listed in the annexes of Directive 2000/29/EEC, have to be prepared for accreditation on EN ISO 17025;
- the Regional Laboratories which are involved in routine determination of harmful organisms also have to be prepared for accreditation on EN ISO 17025;
- the Regional Services which are responsible for the routine surveys of domestic production and the recognition of protected zones as per Directive 92/70/EEC have to be prepared for accreditation on EN ISO 9001:2000;
- the border inspection posts where introduction of risk pests from third countries may occur as per the requirements of Directive 98/22/EEC have to be prepared for accreditation on EN ISO 9001:2000;
- the NSPP HQ, as a body responsible for the performance of phytosanitary control and for the control over this activity, have to work (and what is very important to audit the RSPP and BIP activity) have to be prepared for accreditation on EN ISO 9001:2000.

Biological testing

The testing of plant protection products is carried out in order to evaluate their biological efficacy, but in accordance with Directive 91/414/EEC, the testing has to be carried out through both GEP and GLP (or EN ISO 17025). Since the Central laboratory for control of pesticides, nitrates, heavy metals and fertilizers (CLCPNHMF), which is the only laboratory responsible for pesticide residues analyzes, is accredited on EN ISO 17025, the biological testing of plant protection products carried out by the 13 RSPP have to be accomplished in accordance with GEP. As a result of Phare project BG9913-02, started GEP introduction within three of them: Vratza, Plovdiv and Pleven. A lot of procedures were prepared, but the quality managers need assistance in auditing, audit planning and closing the whole GEP cycle.

Sub-project 3

In the past Bulgaria had a rendering industry with more than 15 rendering plants. After privatisation of this sector in the 90s the number has until now been reduced to 5 plants in operation, 2 of them operating on a non-regular basis only. Bovine materials, including specified risk material and fallen stock, have always been rendered together with materials from other species. The main Community rules governing the disposal and processing of animal by-products (entire bodies or parts of animals or certain products of animal origin not intended for human consumption) are set out in Regulation (EC) No 1774/2002 which replaces the rules laid down in Directive 90/667/EC and the rules laid down in Directive 92/118/EEC with respect to animal by-products not intended for human consumption. Animal by-products are classified into three categories— Category 1, Category 2 and Category 3 and according to the Regulation there must be clear separation during collection, transport, storage and processing of the different categories of animal by-products.

With a view to complying with the requirements of Council Directive 90/667/EEC (transposed into Bulgarian legislation), the NVS requested the assistance of TAIEX Office for assessment and advice on the questions of:

- the number of rendering plants in the country needed to cope with collection and rendering harmless of high risk and specified risk material of animal origin

- the alternatives of (i) designing and constructing a new processing plant or (ii) developing a new separate facility within one of the currently existing operational rendering plants.

According to the recommendations of the final report of the mission a new processing plant for high-risk material (HRM) and specified risk material (SRM) shall be required to cover the western half of Bulgaria (ref. TAIEX /4507/ Rendering /Bulgaria/02-05.09.02).

A pre-feasibility study was implemented in 2003 without EC financial assistance. A full-fledged feasibility study is budgeted under Phare 2003. It will include environmental impact assessment, design, etc. Because of the time necessary to finalise this feasibility study, the activities have been budgeted under Years 2 and 3.

The processing plant will focus on Category 1 and 2 materials (which cover both HRM and SRM).). Nevertheless, because of the type of activity, of the regional needs, and of economic conditions, the processing plant will also process Category 3 material.

In the framework of the BSE crisis in Europe and in view of its future accession to EU, Bulgaria has taken the full commitment to establish a EU compliant rendering system of animal wastes.

After a careful analysis of the issues that need to be addressed in order to develop a processing plant for Bulgaria, it was decided to undertake the activity in three stages:

- 1. The pre-feasibility study stage, which identified the provisional capacity, volumes and defined the potential technical solutions that are to be confirmed by the next stage under Phare 2003. The pre-feasibility study was implemented under the Programme for Technical Co-operation between the Federal Republic of Germany and the Republic of Bulgaria. The project was completed December 2003.
- 2. The feasibility study phase comprising all preparatory studies (technical feasibility study, economic study, environmental assessment, technical design ready for tendering) under Phare 2003 funding.
- 3. Construction and supplies phases- under Phare 2005 and 2006 funding.

Sub-project 4

The Ministry disposes of a variety of laboratories in each of the many sectors of agricultural activity. These laboratories are numerous, and many have either been included in past Phare projects, or are included in the current fiche.

Laboratories are an important service provider, necessary for human and animal or vegetal health protection, trade, export-import approvals, control, etc. They perform therefore a major task that impacts on health and trade.

The important role of laboratories is matched by their cost. They request premises, trained staff, equipment, consumables, running costs, etc. Very often, laboratory equipment is composed of very expensive supplies.

Bulgaria is a country with a rich agricultural and technical experience. The Ministry of Agriculture disposes of a satisfactory network of laboratories, which was developed in the past. The new laboratory techniques nevertheless put this situation under question. Equipment is more performing, but also more expensive. As such, the needs related to the quantity of laboratories need to be reassessed in the light of their capacity, cost of equipment, cost of running and operations, and transport facilities.

In these circumstances, it is useful to check whether the current network can be streamlined, for instance by sharing laboratory facilities between the different sectors. For instance, milk testing are performed by the Veterinary Services, and will be performed by the National Dairy Board. Or DNA testing equipment (real time PCR) have been requested and will be developed for the seeds agency, the fish agency, and already exist in the agro-bio institute. Could the existing facilities perform services "horizontally", not only to their nominal service but also to other

services of the Ministry, to avoid duplicating capacity, mobilising resources in equipment that will not be used to a satisfactory level.

It is on the other hand difficult to combine laboratory activities that serve totally different purposes (quality management, health control, export or import licenses, etc.).

A project is proposed to look into the issue, and initiate a debate on whether it is feasible to steamline laboratory activities. In order to fulfil this, technical assistance will in particular look in the current laboratory services, their capacity, equipment, and functions. In doing so, special attention will be given to the way activities are planned, how the budget is calculated and implemented, and whether the equipment is used to it full capacity.

3.2. Sectoral rationale: NA

3.3. Results:

Sub-project1:

The precision and the efficiency in conducting of the variety testing trials and seed analyses by the Seed Testing Laboratories of the Agency will bring about the improvement of the scope of activities and reliability of results relating to listing of plant varieties in the National Variety List and in the EU Common Catalogues. That will speed up the entire variety testing and certification process which on its part will guarantee the quality of seed and propagating material produced in Bulgaria.

The results expected from the realisation of this project for strengthening of the Agency's activities are the following:

- Improved technical conditions and facilitites at the Agency's Regional Stations and Laboratories for conducting of more accurate variety testing and precise analyses for the certification of seed and propagating material;
- A more efficient functioning structure meeting the EU standards and requirements for variety testing and seed control activities;
- Recognized DUS tests conducted in the Bulgarian variety testing system by the EU countries and Bulgarian varieties listed in the European Common Catalogues;
- Improved administrative capacity of the Agency Variety Testing Directorate and Directorate for Field Inspection and Seed Control for variety testing and control on seed and propagating material
- Improved level of variety testing, seed control and certification process in compliance with the EU requirements (EC Directives, UPOV Rules, OECD schemes and ISTA Rules).

Sub-project 2:

Phytosanitary control

- Varna, Plovdiv and Haskovo RSPP had established Quality Assurance System and are ready for accreditation on EN ISO 9001:2000;
- NSPP HQ had established Quality Assurance System and organizes, audits and controls the RSPP phytosanitary activity in compliance with the relevant procedures;
- CLPQ and Varna, Plovdiv and Haskovo regional quarantine laboratories are ready for accreditation on EN ISO 17025:2000;

Biological testing

- Pleven, Plovdiv, Vratza, Burgas, Russe and St. Zagora RSPP are ready for accreditation on GEP;
- NSPP HQ audits and controls RSPP biologic testing activity according to GEP in compliance with the relevant procedures.

Sub-project 3

Year 2

- Operational processing plant for animal by-products not intended for human consumption meeting the EU requirements, with two separate lines one for Category 1 and one for Category 2 material;
- Equipment for **two separate lines** for processing Category 1 and Category 2 material delivered and installed;
- Trucks and transport containers delivered.

Year 3

- Operational processing plant for animal by-products not intended for human consumption meeting the EU requirements, with one separate line for Category 3 material;
- Equipment for **one separate line** for processing Category 3 material delivered and installed;
- An Intermediate plant (collection plant) for Category 1, Category 2 and Category 3 material constructed.
- Operational systems for wastewater treatment, air purification and heating;
- Trucks and transport containers delivered.

Sub-project 4

- Review of existing facilities (list of laboratories, staffing, equipment, functions, budget, capacity) existing
- Strategy proposed by project, including which laboratories and services could be merged and presenting the advantages and inconvenients
- 3.3. Activities:

Sub-project 1:

In view of the controlling functions, which are responsibility of the Agency, it is necessary to strengthen laboratories and facilities carrying out of such controls.

In order to meet the EU standards and ensure minimum conditions for conducting variety testing (DUS and VCU) of vegetable and agricultural crops in conformity with EC Directives 2002/53/EC, 2002/55/EC, 2002/8/EC and Regulation 930/2000/EC the following equipment is needed to be supplied to the Agency's Variety Testing Stations:

- Supply of supplementary laboratory equipment for seed testing to Central Laboratory in Sofia
- Supply of basic machines and accessories for the Agency's regional Variety Testing Stations
- Supply of lab equipment for the needs of DUS Department at Central Office of the Agency

In addition, a twinning light project is foreseen to provide training as described below:

- Training in DUS testing procedures related to agricultural and vegetable crops in compliance with EC Legislative Acts: Regulation 930/2000/EC; Decision 90/639/EEC; Directive 72/168/EEC (on min. conditions for inspecting vegetable varieties); Directive 72/180/EEC (on min. conditions for examining agricultural varieties; Directive 2003/90/EC (amending Dir.72/168/EEC) and 2003/90/EC (amending Dir 72/180/EEC).
- Training in VCU testing procedures (value for cultivation and use)
- Training in Control on the production of "Standard Seed" category from vegetables which presently does not exist in Bulgaria EC Directive 2002/55;
- Training in Control on the production of "Commercial Seed "category EC Directives 66/401, 2002/57;
- Training in Control on the activities of authorized private physical persons, conducting field inspection and of juridical persons (laboratories) conducting seed testing by the official controlling institution (according to the provisions of LSPM) EC Directives: 66/401, 66/402, 2002/54, 2002/55, 2002/57. Experience in this field is missing;
- Control on small EC packings EC Directives 2002/54, 2002/55.

<u>Training of Bulgarian experts in the following topics:</u> Variety Testing:

- DUS testing of hybrid *maize* and *sunflower* varieties grouping of the varieties, setting of the trials, reading out of the results and processing of the data 10 experts;
- DUS testing of *beans* and *soyabean* varieties grouping of the varieties, setting of the trials and reading out of the results and processing of the data 12 experts;
- DUS testing of *tomato* and *pepper* varieties and hybrids grouping of the varieties, setting of the trials, reading out of the results and processing of the data 12 experts;
- DUS testing of *potato* varieties grouping of the varieties, setting of the trials, reading out of the results and processing of the data -7 experts;
- Training under a software programme DUST9 for processing of DUS data received from agricultural and vegetable plant species for proving of distinctness and homogeneity with the purpose of acceptance and listing of the plant varieties in the National Variety List -8 experts;
- Expertise procedure for the denominations of plant varieties 6 experts;
- Expertise procedure for the origin of plant varieties 8 experts.
- VCU testing procedure (value for cultivation and use) and recognition of plant varieties from the basic groups of crops: cereals and fodder crops, fibre and oil crops, technical, beet (sugar and fodder), vegetables and fruit plant species ; Acquaintance with:
 - Rules for the work of an Expertise Commission with the purpose of listing of plant varieties in List 'A' of the Official Variety List;
 - Criteria for evaluation of the plant varieties;
 - Methods for the complex evaluation.

Period: depending on the crops requiring observation:

April, - setting of the trials-spring crops;

July and August - observation of vegetation phases, and reading out of the results for some of the crops (wheat, barley, etc.);

- September-October reading out the results from winter crops (sunflower, maize)
- Software programme(s) for establishment of data base for VCU testing results
- Software programme(s) and their application for carrying out mathematical and statistical processing of the results from competitive variety trials for one year and multi-year period of testing.
- Methods applied in VCU variety testing, technical facilities used in conducting of trials, reading out of the results, and presentation of generalized results for consideration by Expert Commissions -Practical training.

• Methods for conducting Electrophoresis (EF) for control of varietal purity with wheat, barley and vegetable crops

Certification and Controls:

- Training of authorized private physical persons conducting field inspection and juridical persons (laboratories) conducting seed testing by the official controlling institution 10 experts;
- Training in control on the activities of authorized private physical persons conducting field inspection and juridical persons (laboratories) conducting seed testing by the official controlling institution 10 experts;
- Training in control on "Standard Seed" category with vegetables 20 experts;
- Training in control on "Commercial Seed" category 20 experts;
- Training in control on small EC packages 10 experts;
- Training in control on trade of not-finally certified seed between EU Member States and third countries-OECD members 6 experts.
- Training in control on certified and standard propagating material as well as on propagating material from farmers' lists 20 experts;
- Training in control on ornamental seed and propagating material 8 experts;

The strengthening of the professional capacity of the Agency's experts will assure conditions for unification of the variety testing methods with those of EU, improvement of the level of activities related to variety testing and control on seed and propagating material.

The efficient control on field inspection and seed testing conducted by private physical and juridical persons will bring about the improvement of the level of the certification and controls process, and the latter on its part will guarantee the quality and free movement of seed and propagating material produced in Bulgaria. Possibilities will be created for carrying out joint trials and exchange of information with related organizations from EU Member States.

Sub-project 2:

The activities related to technical assistance for the adoption of Quality Assurance System shall be divided in following two direction:

1) Phytosanitary control: Introduction of EN ISO 17025 and EN ISO 9001:2000 principles related to the phytosanitary control activities

Assistance for the introduction and establishment of Quality Assurance System by providing necessary documentation, guidelines, methodology and trainings related to the relevant ISO standards, as well as assistance in drawing up procedures and quality manuals, planning and demonstration of audit.

- Development of Quality Manuals, working procedures and control procedures, under the requirements of EN ISO 9001:2000, in order to guarantee the quality of Varna, Plovdiv and Haskovo RSPP activity, concerning the import, export, production of plants and plant products and territory survey;
- Development of working procedures and control procedures, under the requirements of EN ISO 9001:2000, in order to guarantee the quality of the activity of the BIP inspectors from the above three RSPP, concerning the import and export of plants and plant products (including taking and sending samples for laboratory analyses);
- Preparation for EN ISO 17025 accreditation of the laboratory activity of CLPQ and Varna, Plovdiv and Haskovo regional quarantine laboratories;
- Development of Quality Manual, methods and scheme, so that NSPP HQ could carry out internal audit and control on the implementation of the phytosanitary activity according to EN ISO 9001:2000.

2) **Biological testing**: Introduction of GEP principles related to biological testing as a part of plant protection products registration.

Assistance for the introduction and establishment of Quality Assurance System by providing necessary documentation, guidelines and trainings related to GEP standards as well as assistance in drawing up procedures and quality manuals, planning and demonstration of audit.

- Preparation for GEP accreditation of Pleven, Plovdiv, Vratza, Burgas, Russe and St. Zagora RSPP;
- Development of Quality Manual, methods and scheme, so that NSPP HQ could carry out internal audit and control on the implementation of the biologic testing activity according to GEP.

Sub-project 3

Year 2

- Construction of a processing plant for animal by-products not intended for human consumption meeting the EU requirements with **two separate lines (one for Category 1 and one for Category 2 material)**, each of them including
 - o reception area;
 - processing premises;
 - o storage area for finished products;
 - o dispatch area.
- Supply, installation and putting into operation of equipment for reception, processing and storage of Category 1 and Category 2 material;
- Supply of specialized transport vehicles and transport containers.

Year 3

- Construction of a processing plant for animal by-products not intended for human consumption meeting the EU requirements with one separate line for Category 3 material.
- Supply, installation and putting into operation of equipment for reception, processing and storage of Category 3 material;
- Construction of an intermediate plant (collection plant) for Category 1, Category 2 and Category 3 material.
- Supply and installation of cleaning and disinfection equipment for trucks, premises, equipment and containers;
- Supply, installation and putting into operation of equipment for waste water treatment, purification and heat generation for the whole plant;

Supply of specialized transport vehicles and transport containers.

Sub-project 4

- Review of the quantity of laboratories, equipment, organisation
- Analysis of quantity of tests actually made
- Analysis of responsibility of each laboratory
- Analysis of use of private laboratories to perform specific activities
- Review of budget calculation and approval system Estimation of percentage of use of the capacity Workshops on possible streamlining Legal review related to streamlining Drafting of legal documents for streamlining Budget, staff and equipment analysis
- Recommendations

3.4. Linked activities:

Sub-project 1:

Phare project **BG 9507-02-08 "Strengthening of the Chief Inspection for Field Inspection and Seed Control"** (Technical assistance and supply, implemented in 1997)

As a result of this project a small number of equipment was supplied to the previously existing Chief Inspection for Field Inspection and Seed Control (now a Directorate under the Agency). The equipment was distributed among the Laboratories of the Inspection (Central Seed Testing Station and Regional Labs) in order to strengthen their seed testing and seed control capability. Technical assistance was rendered in preparation of Seed Regulations.

Phare project **BG99/IB/AG01-B** "Improvement of Activities for Field Inspection and Seed Control" (Twinning project)

- Harmonization of 6 EEC Seed marketing Directives into Bulgarian legislation: 66/400/EEC (= 2002/54), 66/401, 66/402, 66/403 (=2002/56/EC), 69/208/EC (=2002/57/EC) and 70/458/EC (=2002/55), elaboration of Ordinances under the Law on Seed and Propagating Material (LSPM);
- Follow-up restructuring of the Directorate for Field Inspection and Seed Control;
- Improvement of the system for seed certification and seed control in compliance with the EU requirements, OECD Schemes and methods and the ISTA Rules;

Phare project BG9913-03/EQT - Supply of equipment

Equipment was supplied for several seed testing Laboratories of the Directorate for Field Inspection and Seed Control for improvement of their seed testing and certification capabilities. A software product was developed for data base management in the seed certification process.

Sub-project 2:

Completed projects:

- Project BG9507-02-03 "Technical assistance for NSPPQA"
- Project BG98/IB/AG-02 "Improvement of the phytosanitary control, the registration of plant protection products and the control of their residues and, setting up of a system for the control and certification of organic production"
- Project BG99-AG-01-A "Improvement of the phytosanitary control, the registration of plant protection products and the control of their residues and, setting up of a system for the control and certification of organic production"

Relevant output of the project was:

• Improvement of the biological testing of pesticides (training of technicians and laboratory specialists according to GEP) and strengthening of registration procedures.

Current projects:

• Project BG01-AG-01-A "Improving phytosanitary control & plant protection"

The project's outputs as envisaged:

- Improvement of the phytosanitary control of plants and plant products carried out by laboratories, regional services and BIPs;
- Improvement of the biological testing and registration of plant protection products;
- Improvement of the control of contaminants in plant products;

• Setting up of a system for audit on independent-bodies responsible for the organic farming control and certification

Project BG 0201-05 "Improvement of phytosanitary control, biological testing & registration of plant protection products"

Sub-project 3

- Phare Project BG 0201.06 TSE (Transmissible Spongiform Encephalopathies) control not started yet. The main expected result of the project is: "EU TSE control practice transposed in Bulgaria."
- Pre-feasibility study for the construction and equipment of a processing plant for animal by-products not intended for human consumption in Bulgaria to be implemented under the Programme for Technical Co-operation between the Federal Republic of Germany and the Republic of Bulgaria. The pre-feasibility study will identify provisional capacity, volumes and define potential technical solutions that will then be confirmed by the next stage under Phare 2003. The project is to be completed by the end of 2003.
- Feasibility Study for the construction and equipment of a processing plant for animal by-products not intended for human consumption in Bulgaria approved for financing under Phare National Programme 2003. The expected results of the Feasibility study are:
- Technical feasibility study for a new processing plant for animal by-products completed.
- Economic/financial study completed.
- Environmental impact assessment carried out;
- Tender documentation including working designs ready for WORKS tender;
- Tender documentation ready for SUPPLY tender, including detailed list and specification of the technical equipment required to satisfy the operation of the processing plant (in line with relevant EU norms);
- Overall strategy for animal waste management including organization structures prepared.
- The Feasibility Study is envisaged to start in May 2004.

4. 3.5. Lessons learned:

Sub-project 1:

At the end of the training process under Phare project BG/IB/AG-01-B it was established by the Agency's experts that no substantial differences exist between the Bulgarian and the European seed certification procedures. It was learned that only with the Post Control testing of seed there is a necessity of conducting the testing by setting standard plant varieties next to the tested ones.

The new up-date equipment supplied to the Labs under Phare project BG99-13-03 is a valuable acquisition, replacing the more obsolete one. It was established that the new apparatuses provide conditions for better preciseness in conducting of the seed testing in the Labs where delivered. The machines supplied are of a better capacity and offer wider possibilities for application.

At the end of the training process under BG99/IB/AG01-B it was established by the Agency's experts that no substantial differences exist between the Bulgarian and the European seed certification procedures. It was learned that only with the Post Control testing of seed there is a necessity of conducting the testing by setting standard plant varieties next to the tested ones.

The new up-date equipment supplied to the Labs under BG9913-03/EQT is a valuable acquisition, replacing the morally old one. It was established that the new apparatuses provide conditions for better preciseness in conducting of the seed testing in the Labs where delivered. The machines supplied are of a better capacity and offer wider possibilities for application.

Sub-project 2:

After the completion of previous Phare twinning and supply projects related to improvement of the control activities, NSPP HQ realized that it is very important to unify the activities at all levels and to improve their trace-ability in order to improve the whole system for plant protection.

Sub-project 3:

- According to the recommendations of the final report of the expert mission to Bulgaria (carried out from 02.09 05.09.2002) for assessment and advice on the rendering of animal waste a new processing plant for high and specified risk materials shall be required to cover the western half of Bulgaria. (Ref. TAIEX /4507/ Rendering / Bulgaria/02-05.09.02/).
- The construction of Border Veterinary Inspection Post Kapitan Andreevo under Phare Project BG9913-01-03 demonstrated the extreme complication that can be caused by land allocation. Excessive delays were caused by the land expropriation procedure. For this reason, the allocation of land for the new processing plant has been taken as a priority. A working group was set up already in 2002 to address the issue. The working group will propose land plots for the construction of the processing plant to the Consultant who will carry out the Pre-feasibility study. On the basis of the Consultant's recommendation the Bulgarian authorities will select the plot. The allocation procedure shall be completed prior to the start of the Feasibility study.
- The situation with the existing processing plants has demonstrated the importance of appropriate economic studies in order to identify the expected costs related to the running of the plant.

4. Institutional framework

Executive Agency for Variety Testing, Field Inspection and Seed Control (EAVTFISC) was established by Council of Minister's Decree No 203 dated 10.11.1999, published in State Gazette issue No.105/02.12.1999(vide). The Structure Rules of EAVTFISC were published in the State Gazette issue No.43/26.05.2000. The amended Structure Rules were adopted vide CM's Decree No.148/10.07.2003.

The Agency is subjected to the Minister of Agriculture and Forestry. The EAVTFI&SC is headquartered in Sofia and consists of 1 Directorate "Administrative & Financial Management" and 3 specialized Directorates and it has 24 Regional Stations in total including 3 Post Control Plots. The EAVTFI&SC is the official controlling body of MAF in the seed sector.

In the competence of the Agency is the registration of producers, processors and traders of seed and propagating material and field inspectors.

<u>Directorate for Variety Testing</u> (DVT) conducts the official state variety testing for DUS (distinctness, uniformity and stability) and VCU (value for cultivation and use), carries out post control for establishment of varietal purity and identity and participates in the procedure for provision of legal protection to the plant varieties (Plant Breeder's Rights) and publishes annually the National Variety List of R Bulgaria.

Directorate for Field Inspection and Seed Control (DFI&SC) covers in its functions:

Field inspection, the inspection of imported, exported and home traded seed, official seed sampling, the issuance of seed & propagation material certificates and approval of seed lots, control of the enforcement of the Seed Law.

<u>Directorate "Central Seed Testing Laboratory"</u> conducts the seed testing of all samples from seed lots entered for certification based on applications from seed producers and seed companies and issues the

respective Quality Certificates. The Laboratory is ISTA (International Seed Testing Association) accredited, and it is also authorized to issue International Orange Certificates for the movement of seed on the international market.

National Service for Plant Protection (NSPP) was established in 1992 and is part of the Ministry of Agriculture and Forestry (MAF).

According to the **Plant Protection Law** (adopted 25/09/1997 and amended 25/10/2001), the NSPP within the MAF is the central official body responsible for the enforcement of the provisions relating to:

- Phytosanitary control;
- Biological testing of plant protection products.

The NSPP comprises 2 technical departments covering the above-mentioned sectors. In order to ensure their official duties, these departments benefit from the assistance of the Central Laboratory for Plant Quarantine (CLPQ), 14 regional services (plus 13 other decentralized units) and 13 regional quarantine laboratories for routine analyzes, and BIPs. Since 1 October 2000, all higher educated employees of the NSPP have become State officials (civil servants).

More specifically, the tasks assigned by law to the NSPP in relation to the Acquis are as follows:

• Phytosanitary control

The NSPP is the official body responsible for the enforcement of EU directives relating to the phytosanitary, which were transposed and implemented in Bulgaria.

Essentially the phytosanitary control consists of preventing the introduction and/or spread of harmful organisms that could jeopardize the agricultural production in Bulgaria (and later in the EU).

In order to prevent the propagation of harmful organisms, the NSPP also ensures the control of plants and plant products at the place of production or circulating in Bulgaria as provided for in Directive 2000/29/EC and other directives relating to the recognition of protected zones and the control of certain harmful organisms.

Biological testing

In early 2001 following the revision of the Law on Plant Protection, the Ministry of Agriculture and Forestry becomes the central official body granting authorizations for the placing of plant protection products on the market.

In the process of authorization, the NSPP is responsible for performing official biological testing of plant protection products for the generation and evaluation of efficacy data.

The recipient of the sub-project 3 is the National Veterinary Service (NVS), which is the institution responsible for the overall implementation of the project. The NVS is a specialized executive body of the Ministry of Agriculture and Forestry, responsible for the organization, coordination, management and control of veterinary activities. The responsibility for control of processing plants for animal by-products lies with the Animal Health Directorate (see Annex 6 - Structure of the NVS).

According to Ordinance No. 29 (SG 75/2.08.2002) on the veterinary and sanitary requirements for the collection and disposal of animal waste, aligned with Council Directive 90/667/EEC, the NVS shall be responsible for the approval of processing plants for animal by-products and issuing of veterinary licenses for operation of such plants. The NVS constantly controls the compliance of the rendering plants with the requirements of the above Ordinance.

Pursuant to Order of the Minister of Agriculture and Forestry of 13.March.2001 an Inter-institutional Expert Committee was set up to deal with the problems of rendering in Bulgaria. The Committee consists of representatives of the following institutions: the Council of Ministers, Ministry of Agriculture and Forestry, National Veterinary Service, Ministry of Environment and Water, Ministry of Health, Ministry of Economy, Ministry of Finance and representatives of the industry.

3.5. DETAILED BUDGET

Meuro

		Phare supp	ort			
	Investment	Institution		National Co-		
Year 1/Phase 1	support	building	Total Phare	Financing	IFI	TOTAL
Sub-project 1 Contract						
1-supplies	140,250		140,250	46,750		187,000
Sub-project 2 Contract						
2-TA		600,000	600,000			600,000
Sub-project 1 - Contract						
3 twinning		249,990	249,990	*		249,990
Subproject 4						
Contract 4 - TA		583,000	583,000			583,000
Total year 1	140,250	1,432,990	1,573,240	46,750	0	1,619,990
	Investment	Institution		National Co-		
Year 2/Phase 2	support	building	Total Phare	Financing	IFI	TOTAL
Sub-project 1						
Contract 5-supplies	312,675		312,675	104,225		416,900
Sub-project 3						
Contract 6-works	2,576,250		2,576,250	858,750		3435000
Sub-project 3						
Contract 7-supplies	5,415,750		5,415,750	1,805,250		7221000
Sub-project 3						
Contract 8-supervision	120,000		120,000	40,000		160,000
Total year 2	8,424,675		8,424,675	2,808,225		11,232,900
	Investment	Institution		National Co-		
Year 3/Phase 3	support	building	Total Phare	Financing	IFI	TOTAL
Sub-project 3						
Contract 9-supplies	4,882,500		4,882,500	1,627,500		6510000
Sub-project 3						
Contract 10-works	1,601,250		1,601,250	533,750		2135000
Sub-project 3						
Contract 11-supervision	116,250		116,250	38,750		155,000
Total year 3	6,600,000		6,600,000	2,200,000		8,800,000
GRAND TOTAL	15,164,925	1,432,990	16,597,915	5,054,975	0	21,652,890

* Note: * National co-financing up to 10% of the TC budget will be provided by the National Fund Directorate, Ministry of Finance.

The Phare contribution for the equipment will be no more than 75% of its costs, 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 running costs and the maintenance of the equipment will be provided by the final beneficiaries.

6. IMPLEMENTATION ARRANGEMENTS

6.1. Implementing Agency:

The CFCU in the Ministry of Finance will be the Contracting Authority responsible for tendering, contracting, payments and financial reporting and will work in close co-operation with the beneficiary. The Secretary General of Ministry of Finance will act as PAO of the project. His contact details are:

Secretary General of Ministry of Finance and PAO Address: 102 Racovski Str. 1040 Sofia tell: 359 2 985 927 72 fax: 359 2 9985 927 73

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. His contact details are:

Head of Phare Department Ministry of Agriculture and Forestry Address: 55 Hristo Botev Blvd 1606 Sofia tel: 359 2 981 6163 fax: 359 2 981 75 42 e-mail: demina@phare-agr.orbitel.bg

6.2. Beneficiary

Executive Agency for Variety Testing, Field Inspection & Seed Control

Contact details:

Contact person: Executive Director of the EAVTFI&SC Address: 125, Tzarigradsko Shosse Blvd., Block 1, 1113 Sofia, Bulgaria Tel: +359 2 - 870 03 75, 870 34 93, 71 36 35 Fax: +359 2 - 870 65 17 E-mail: <u>iasa@spnet.net</u>

National Service for Plant Protection

Beneficiary contact point is: Head of Integration Policy Department within NSPP Address: 17 Hristo Botev Blvd 1606 Sofia tel: 359 2 952 37 36 fax: 359 2 953 33 60

e-mail: v.tsvetkova@infotel.bg

National Veterinary Service

Expert in "International Cooperation, European Integration and Staff Training" Directorate National Veterinary Service 15A Pencho Slaveikov Blvd 1606 Sofia Tel No: + 359 2 952 09 18 Fax No:+ 359 2 954 95 93 E-mail: Denitsa.Tsanova@nvms.government.bg

The Steering Committees, overseeing the project implementation and securing exchange of information between the major stakeholders, has representatives of the following institutions:

The Contracting Authority,

The EC Delegation, MAF - Phare department, The Beneficiary, The Contractor.

6.3. Twinning: N/A

6.4. Non-standard aspects:

Practical Guide to contract procedures financed from the General Budget of the European Communities in the context of external actions and Twinning Manual will be strictly followed, with the following exception: real time PCRs (contract 5) which is- to the best of our knowledge – not produced in an eligible country.

6.5. Contracts

Contract Cost
187,000
600,000
249,990
583,000
416,900
3,435,000
7,221,000
160,000
6,510,000
2,135,000

Contract 11 Supervision 155,000

7. IMPLEMENTATION SCHEDULE

Contract 1 - Supply of equipment	
Start of tendering	January 2005
Start of project activities	August 2005
Completion of project activities	October 2005
Contract 2 - Technical Assistance	
Start of tendering	January 2005
Start of project activities	October 2005
Completion of project activities	September 2006
Contract 3 – Twinning	
Start of tendering	July 2004
Start of project activities	January 2005
Completion of project activities	July 2005
Contract 4 - Technical Assistance	
Start of tendering	January 2005
Start of project activities	October 2005
Completion of project activities	September 2006

8. EQUAL OPPORTUNITY

Equal opportunity for employment of men and women will be guaranteed.

9. ENVIRONMENT

The construction of the rendering plant will require a full fledged environmental impact assessment that will be performed in the first phase, foreseen under Phare 2003 funding. The results of the EIA will serve for the implementation of Year 2 and Year 3 activities.

10. RATES OF RETURN

One of the expected results of the Feasibility Study for the construction and equipment of a processing plant for animal by-products not intended for human consumption in Bulgaria to be implemented under Phare programme 2003 is a cost / benefit analysis.

11. INVESTMENT CRITERIA

- 1.1 Catalytic effect: NA
- 1.2 Co-financing:

The national co-financing is 25% for the investment component of the project.

- 1.3 Additionality: NA
- 1.4 Project readiness and size:

The ToR and the technical specification will be ready by the date of the start of the tendering procedures.

1.5 Sustainability:

Investment is sustainable, as rendering system will be set up in full compliance with EU norms. The NVS envisages amending the law on veterinary activities by the end of 2003. The law will lay down rules for financing and sharing the costs of processing animal by-products (defining the share of rendering costs to be covered by the state budget, by the slaughterhouses and the animals' owners), monetary incentives to ensure the effective operation of all rendering activities, as well as sanctions for breaching these provisions.

- 1.6 Compliance with state aids provisions NA
- 1.7 Contribution to NDP and/or Structural Funds Development Plan/SPD NA

12. CONDITIONALITY AND SEQUENCING

In general, beneficiaries of supply contracts have to prepare business plans – according to a standard format that will be obtained from the Ministry – to demonstrate the impact of the equipment (running, maintenance and operations costs) on their yearly budget.

In particular, the Delegation will not give any prior approval to contracts or procedures if satisfactory conditions related to installation, use, maintenance and operations budgets are not met, meaning that M&O budgets, premises, installations (electricity, heating or air conditioning, etc) must be available or – for budgets – committed.

This includes the existence of the legal basis for the activities to be performed with the procured equipment: the beneficiary must be empowered with a public service activity that specifically requires the equipment procured. Should the legal basis be absent (either because there have been changes during the lead time to procurement removing this role, or because there have not been the introduction of the law) then no endorsement can be given for any contract.

In some cases, supplies have been included in past projects for the same beneficiaries. Should this equipment procured in the past not be used (e.g. still packed), or should past commitments taken by the local authorities related to past supplies or programmes not be fulfilled, the Delegation reserves itself the right not to endorse contracts listed in this fiche.

Full commitment and participation of the senior management of the beneficiary institutions in the implementation of the project.

- Before receiving the equipment, the laboratories will be refurbished, and fully ready for receiving the equipment (staffed, refurbished, etc).
- For the GLP/ISO accreditation support, the beneficiary must guarantee that they will have funds available to pay for the accreditation of the laboratories, and any subsequent costs;
- Responsible staff available during the whole implementation of the project;
- Appointed quality managers available;
- Appropriate equipment and consumables available.

For sub-project 3

The study "Pre-feasibility study for the construction and equipment of a processing plant for animal by-products not intended for human consumption in Bulgaria –implemented under the Programme for Technical Co-operation between the Federal Republic of Germany and the Republic of Bulgaria" is made available to the contractor implementing the Feasibility Study.

- The land plot for the processing plant is legally available prior to the commencement of the Feasibility Study.
- New Law on Veterinary Activity adopted by Parliament by the end of 2004.
- New Ordinance transposing Regulation (EC) No 1774/2002 adopted by MAF by May 2004.
- Feasibility Study for the construction and equipment of a processing plant for animal byproducts not intended for human consumption in Bulgaria successfully completed by June 2005.

ANNEXES TO PROJECT FICHE

- 1. Logical framework matrix in standard format
- 2. Detailed implementation chart
- 3. Contracting and disbursement schedule by quarter for full duration of programme (including disbursement period)
- 4. Reference to feasibility/pre-feasibility studies
- 5. List of relevant Laws and Regulations
- 6. Re List of equipment foreseen under Contract 1 required for the strengthening of the EAVTFI&SC activities
- 7. Supply of equipment for control of GMO with seeds

ANNEX 1: LOGFRAME MATRIX FOR SUB-PROJECTS 1	, 2 AND 3		Program name and	Date of drafting:		
Project Number			Contracting period expires: Nov 2006	Disbursement period expires: Nov 2007		
Project Title: Improving the internal market co and biological testing, and bringing the animal	ntrol via variety testing and seed control, imp waste processing system in Bulgaria in line wit	rovement of the phytosanitary control h the EU requirements	Total Budget Year1 1, 370 000 MEUR	Phare contribution: 1, 323 250 MEUR		
Overall Objective	Objectively Verifiable Indicators	Sources of Verification		•		
Strengthen the capacity of the Ministry of Agriculture and Forestry (MAF) and its services to undertake the priorities for EU alignment and implement the reforms identified in the current Accession Partnership and the National Program for the adoption of the Acquis (NPAA).	 Bulgaria joins the EU in 2007 The plant varieties in Bulgaria are tested and protected through issuing of certificates for Plant Breeders Rights (PBR) by 2007 	MAF authoritiesEU authorities				
Project Purpose	Objectively Verifiable Indicators	Sources of Verification	Assumptions	and Risks		
Internal market procedures related to variety testing, seed control, seed certification procedures, plant protection and processing of animal by-products not intended for human consumption are harmonised with EU practice	 Listing of Bulgarian plant varieties accepted in the National Catalogues of other countries and in the EU Common Catalogues by End of Project Home marketed seed and seed allowed in the international trade by EoP Free movement of quality seed and propagating material on the EU internal market Quality Assurance System developed in the field of Plant Protection by EoP EN ISO 9001:2000, EN ISO 17025 or GLP and GEP introduced in activities of National Service for Plant Protection (NSPP) 	 MAF authorities (including NSPP) EU authorities 	 uding NSPP) Support by State budget The trained NSPP personn positions Enough personnel availabl regional laboratories and or BIPs 			
Results	Objectively Verifiable Indicators	Sources of Verification	Assumptions	and Risks		
 Sub-project 1: Improved technical conditions and facilitites at the Regional Stations and Laboratories of the EAVTFISC for conducting of more accurate variety testing and precise analyses for the certification of seed and propagating material; Recognized DUS tests conducted in the Bulgarian varieties listed in the European Common Catalogues. See attached LFW details of Contract 3 Sub-project 2: Phytosanitary control Varna, Plovdiv and Haskovo RSPP have established Quality Assurance System and are ready for accreditation on EN ISO 9001:2000; NSPP HQ have established Quality Assurance System and organizes, audits and controls the RSPP phytosanitary activity in compliance with the relevant 	 EAVTFI&SC's staff facilitated in conducting the variety testing activities and seed analyses relating to the seed control and certification of seed and propagating material and registration of plant varieties, Equipment supplied to the Agency's Variety Testing Stations, DUS Department and Central Laboratory for various types of seed analyses and plant cultivation activities Varna, Plovdiv and Haskovo RSPP are ready for accreditation on EN ISO 9001:2000; NSPP HQ organizes, audits and controls the RSPP phytosanitary activity in compliance with the relevant procedures; 	 MAF authorities (including NSPP) EU authorities Consultant Body 	 Good level of cooperinstitutions (MAF, E exists. Full commitment of management body to project objectives. Changes in EU stand 	ration between involved AVTFISC, CFCU,etc) the EAVTFISC the achievement of the lards		

 procedures; CLPQ and Varna, Plovdiv and Haskovo regional quarantine laboratories are ready for accreditation on EN ISO 17025-2000. 	• CLPQ and Varna, Plovdiv and Haskovo regional quarantine laboratories are ready for accreditation on EN ISO 17025:2000;		
ISO 17025:2000; Biological testing	Biological testing		
Diological testing Distance Division Division and St	Diological testilig		
 Pleven, Plovdiv, vratza, Burgas, Russe and St. Zagora RSPP are ready for accreditation on GEP: 	 Preven, Provary, Vratza, Burgas, Russe and St. Zagora RSPP are ready for accreditation on GEP: 		
• NSPP HQ audits and controls RSPP biologic testing activity according to GEP in compliance with the relevant procedures.	 NSPP HQ audits and controls RSPP biologic testing activity according to GEP in compliance with the relevant procedures. 		
Sub-project 3			
 Operational processing plant for animal by-products not intended for human consumption meeting the EU requirements, with three separate lines -one for Category 1 and one for Category 2 material and an additional line for Category 3 material An Intermediate plant (collection plant) for Category 1, Category 2 and Category 3 material constructed. Operational systems for wastewater treatment, air purification and heating; Trucks and transport containers delivered. Sub-project 4 Review of existing facilities (list of laboratories, staffing, equipment, functions, head was a start of the st	 Facilities for processing animal by-products not intended for human consumption constructed by May 2007. Equipment for processing animal by-products not intended for human consumption delivered, installed and put into operation by May 2007 		
Strategy proposed by project including which			
laboratories and services could be merged and			
presenting the advantages and inconvenients			
Activities	Means	Sources of Verification	Assumptions and Risks
Sub-project 1- contract 1:			-
 Supply of supplementary laboratory equipment for seed testing to Central Laboratory of EAVTFISC in Sofia Supply of basic machines and accessories for the EAVTFISC's regional Variety Testing and Seed Control Stations 	• Supply contract	 Project manager / coordinator from NSPP Consultant Body 	 The requested budget is approved Project starts on time Time schedule of implementation is observed
• Supply of lab equipment for the needs of DUS Department at Central Office of the EAVTFISC			U U U U U U U U U U U U U U U U U U U
Sub-project 2 contract 2:			
Activities related to technical assistance for the adoption of Quality Assurance System:			
Phytosanitary control : Introduction of EN ISO 17025 and			

-			
EN	ISO 9001:2000 principles related to the phytosanitary	Providing necessary documentation, guidelines,	
cor	trol activities	methodology related to the relevant ISO standards;	
•	Development of Quality Manuals, working procedures	Trainings in Bulgarian and Member State facilities;	
	and control procedures, under the requirements of EN	-Assistance in drawing up procedures and quality manuals,	
	ISO 9001:2000, in order to guarantee the quality of	planning and demonstration of audit.	
	Varna, Plovdiv and Haskovo RSPP activity, concerning		
	the import, export, production of plants and plant		
	products and territory survey;		
•	Development of working procedures and control		
	procedures, under the requirements of EN ISO		
	9001:2000 to develop, in order to guarantee the quality		
	of the activity of the BIP inspectors from the above		
	three RSPP, concerning the import and export of plants		
	and plant products (including taking and sending		
	samples for laboratory analyses);		
•	Preparation for EN ISO 17025 accreditation of the		
	laboratory activity of CLPQ and Varna, Plovdiv and		
	Haskovo regional quarantine laboratories;		
•	Development of Quality Manual, methods and scheme,		
	so that NSPP HQ could carry out internal audit and		
	control on the implementation of the phytosanitary		
	activity according to EN ISO 9001:2000.		
Bio	logical testing: Introduction of GEP principles related to		
bio	logical testing as a part of plant protection products		
reg	istration		
•	Preparation for GEP accreditation of Pleven, Plovdiv,		
	Vratza, Burgas, Russe and St. Zagora RSPP;	• - Providing necessary documentation, guidelines,	
•	Development of Quality Manual, methods and scheme,	methodology related to the relevant ISO standards;	
	so that NSPP HQ could carry out internal audit and	Trainings in Bulgarian and Member State facilities;	
	control on the implementation of the biologic testing	Assistance in drawing up procedures and quality	
	activity according to GEP.	manuals, planning and demonstration of audit.	
Su	o-project 3		
Co	ntract 5 (and contract 7)		
•	Construction of a processing plant for animal by-		
	products not intended for human consumption meeting		
	the EU requirements with two separate lines (one for		
	Category 1 and one for Category 2 material), each of		
	them including		
	- reception area;		
	- processing premises;		
	- storage area for finished products;		
C-	- dispatch area.		
	ntract o Complex installation and matting into an and i		
•	Supply, installation and putting into operation of		
	equipment for reception, processing and storage of		
1	Category 1 and Category 2 material;		

Contract 8		
• Supply, installation and putting into operation of		
equipment for reception, processing and storage of		
Category 3 material;		
Supply and installation of cleaning and disinfection on		
equipment for trucks, premises, equipment and		
containers;		
Supply, installation and putting into operation of		
equipment for waste water treatment, purification and		
heat generation for the whole plant;		
• Supply of specialized transport vehicles and transport		
containers.		
Contract 9 (and contract 10)		
• Construction of a processing plant for animal by-		
products not intended for human consumption meeting		
the EU requirements with one separate line for Category		
3 material.		
• Construction of an intermediate plant (collection plant)		
for Category 1. Category 2 and Category 3 material.		
Supply of specialized transport vehicles and transport		
containers		
Sub-project 4		
Contract 4		
Review of the quantity of laboratories equipment		
organisation		
Analysis of quantity of tests actually made		
Analysis of quantity of tests actually indee		
Analysis of responsibility of cach laboratory		
Analysis of use of private laboratories to perform specific activities		
Particle activities		
• Review of budget calculation and approval system		
Estimation of percentage of use of the capacity		
workshops on possible streamlining Legal review		
related to streamlining Drafting of legal documents for		
streamlining Budget, staff and equipment analysis		
Recommendations		
		D IV
		Pre conditions:
		• Full involve
		 Responsible
		implementat

- Appointed quality managers available.
 Appropriate equipment and consumables

available.

- •
- Pre-feasibility study completed by 2003 Feasibility study successfully completed • •
- Documentation for ownership of the land available at MAF
- New Law on Veterinary Activity adopted by Parliament by the end of 2004. •
- New Ordinance transposing Regulation (EC) No 1774/2002 adopted by MAF by May • 2004

LOGFRAME PLANNING MATRIX TWINNING CONTRACT 3

Project Number Project Title: Improving the internal market	control via variety testing and seed cont	rol, improvement of the	Programme name: and number: Contracting period expires:	Unallocated IB envelope BG03 Disbursement period							
phytosanitary control and biological testing, a with the EU requirements	hytosanitary control and biological testing, and bringing the animal waste processing system in Bulgaria in line <i>i</i> th the EU requirements										
		-	Total Budget: EUR 249 990	Phare contribution: EUR 249 990							
Overall Objective Strengthen the capacity of the Ministry of Agriculture and Forestry (MAF) and its services to undertake the priorities for EU alignment and implement the reforms identified in the current Accession Partnership and the National Program for the adoption of the Acquis (NPAA).	 Objectively verifiable indicators The plant varieties in Bulgaria are tested and protected through issuing of certificates for Plant Breeders Rights (PBR); Bulgarian plant varieties listed in the National Catalogues of other countries and in the EU Common Catalogues; Free movement of quality seed and propagating material on the EU internal market. EU standards, methods and schemes practically applied in variety testing and seed analysis for certification and control of home marketed and seed moving in the international trade. 	Sources of Verification Accession Partnership Regular Report Structural Funds Strategy • MAF • EAVTFI&SC	Assumpti DUS tests implemented in UPOV) are accepted by E The variety certificating i without checks) Adequate human, technic recourses at EAVTFI&SC necessary tests according	ions n Bulgaria (as member of EU MS without checks; s accepted by EU MS al and financial C to implement the to the law.							
Project purpose Implementation of the EU Acquis on control, production and trade of seed and propagating material, DUS testing and listing of plant varieties in the Bulgarian National Variety List and in the EU Common Catalogues.	 Objectively verifiable indicators EAVTFI&SC's staff capable of performing the activities for testing and registration of plant varieties, certification and control on seed and propagating material in compliance with EC requirements. Improved level of variety testing and control on seed and propagating material based on implementation of the Acquis. by well-trained Agency's staff. 	Sources of Verification Monitoring reports MS Experts 'Reports MAF EAVTFI&SC CFCU, PIU, ECD 	 Assumpti The EAVTFI&SC staff tr retained by the Agency an necessary people. 	ions ained as trainers is ad trains further the							
Results	Objectively verifiable indicators	Sources of Verification	Assumpti	ions							

						_	
	 <u>Improved administrative capacity</u> of the Agency - Variety Testing Directorate and Directorate for Field Inspection and Seed Control for variety testing and control on seed and propagating material. <u>Improved level of variety testing, seed control and certification process</u> in compliance with the EU requirements (EC Directives, UPOV Rules, OECD schemes and ISTA Rules). 	1. 2.	The Agency's staff (63 experts from Variety Testing Directorate and 104 experts from Directorate for Field Inspection and Seed Control) trained as trainers. Protection of foreign plant varieties in Bulgaria (PBR) and acceptance and listing of Bulgarian plant varieties in the National Catalogues of other countries and in the EU Common Catalogues.	•	Reports of MS experts Certificates obtained by trained staff	•	Good level of cooperation between involved institutions (MAF, EAVTFISC, CFCU, Twinners) exists. Full commitment of the EAVTFISC management body to the achievement of the project objectives.
Î	Activities		Means		Sources of Verification		Assumptions
	 Training in DUS testing procedures related to agricultural and vegetable crops in compliance with EC Legislative Acts: Regulation 930/2000/EC; Decision 90/639/EEC; Directive 2003/90/EC and Directive 2003/91/EC Training in Control on the production of "Standard Seed" category from vegetables which presently does not exist in Bulgaria - EC Directive 2002/55; Training in Control on the production of "Commercial Seed" category – EC Directives 66/401, 2002/57; Training in Control on the activities of authorized private physical persons, conducting field inspection and of juridical persons (laboratories) conducting seed testing by the official controlling institution (according to the provisions of LSPM) – EC Directives: 66/401, 66/402, 2002/54, 2002/55, 2002/57 . Experience in this field is missing; Control on small EC packings – EC Directives 2002/54, 2002/55. 	1.	Human resources required: EU experts in training on variety testing procedures and control on seed and propagating material; Provision of training by trainers and study visits to Member States		EAVTFI&SC, CFCU	•	Availability of adequate Agency experts responsible for integration, variety testing, seed and propagating material control. Full commitment to the achievement of the project objectives.
	 <u>Variety Testing:</u> DUS testing of hybrid <i>maize</i> and <i>sunflower</i> varieties - grouping of the varieties, setting of the trials, reading out of the results and processing of the data; DUS testing of <i>beans</i> and <i>soybean</i> varieties - grouping of the varieties, setting of the trials and reading out of the results and processing of the data; DUS testing of <i>tomata</i> and <i>nenner</i> varieties and hybrids - 	a. b.	Study Visit to MS of 10 BG experts to be trained as trainers (7 days) Short–term mission of MS expert for training of 12 BG experts				
	 but in the varieties, setting of the trials, reading out of the results and processing of the data; DUS testing of <i>potato</i> varieties - grouping of the varieties, setting of the trials, reading out of the results and 	c.	Study Visit to MS of 12 BG experts to be trained as trainers (7 days)				

 processing of the data; Training under a software programme DUST9 for processing of DUS data received from agricultural and vegetable plant species for proving of distinctness and homogeneity with the purpose of acceptance and listing of the plant varieties in the National Variety List; Expertise procedure for the denominations of plant varieties; Expertise procedure for the origin of plant varieties. <u>Certification:</u> Training of <u>authorized private</u> physical persons conducting <u>field inspection</u> and juridical persons (laboratories) conducting seed testing by the official controlling institution; Training of Agency's experts to control the activities of <u>authorized private physical</u> persons conducting field inspection and juridical persons (laboratories) conducting seed testing; Training in control on <u>"Standard Seed"</u> category with vegetables; Training in control on <u>small EC packages;</u> Training in control on trade of <u>not-finally certified seed</u> between EU Member States and third countries-OECD 	 d. Short-term mission of MS expert for training of 7 BG experts e. Short-term mission of MS expert for training of 8 BG experts f. Short-term mission of MS expert for : training of 6 BG experts training of 8 BG experts For the <u>2 topics</u>: Short-term mission of MS expert for training as trainers of 10 BG experts Study visit to MS of 8 BG experts For the <u>4 topics</u> : g. Short-term mission of MS expert for: training of 20 BG experts (theoretical) training of 20 BG experts " training of 20 BG experts " training of 6 BG experts " 	
 Training in control on <u>certified and standard propagating</u> <u>material</u> as well as on propagating material from farmers' lists; Training in control on <u>ornamental</u> seed and <u>propagating</u> <u>material</u>; 	 trainers (7 days) r the <u>2 topics:</u> Short–term mission of MS expert for: training of 8 BG experts training of 6 BG experts Study Visit to MS of 7 BG experts to be trained as trainers (7 days) in the 2 topics 	
	<u></u>	 Preconditions The Steering Committeee shall guarantee that a clear timetable is defined and IB assistance is in place before the end of 2005 EAVTFISC guarantees the allocation of appropriate human resources. Full commitment of senior management (MAF)

ANNEX 2: TIME SCHEDULE OF IMPLEMENTATION

Title: Improving the internal market control via variety testing and seed control, improvement of the phytosanitary control and biological testing, and bringing the animal waste processing system in Bulgaria in line with the EU requirements

Component	2004							2005									2006															
	Μ	J	J	A	S	0	N	D	J	F	Μ	A	M	J	J	Α	S	0	Ν	D	J	F	Μ	Α	Μ	J	J	Α	S	0	N	
Contract 1 Supply	Р	Р	Р	Р	Р	Р	Р	Р	Т	Т	Т	Т	Т	Т	Т	С	Ι	Ι														
Contract 2 TA	Р	Р	Р	Р	Р	Р	Р	Р	Т	Т	Т	Т	Т	Т	Т	Т	Т	С	Ι	Ι	Ι	Ι	Ι	Ι	Ι	Ι	Ι	Ι	Ι			
Contract3 Twinning	Р	Р	Т	Т	Т	Т	Т	Т	С	Ι	Ι	Ι	Ι	Ι	Ι																	
Contract 4 TA	Р	Р	Р	Р	Р	Р	Р	Р	Т	Т	Т	Т	Т	Т	Т	Т	Т	С	Ι	Ι	Ι	Ι	Ι	Ι	Ι	Ι	Ι	Ι	Ι			

P- Preparation

C - Contracting

T – Tendering

I – Implementation

ANNEX 3: CUMULATIVE CONTRACTING AND DISBURSEMENT SCHEDULE

Title: Improving the internal market control via variety testing and seed control, improvement of the phytosanitary control and biological testing, and bringing the animal waste processing system in Bulgaria in line with the EU requirements

Dates	I 2005	II 2005	III 2005	IV 2005	I 2006	II 2006	III 2006	IV 2006	I 2007	II 2007	III 2007	IV 2007
Contracted 1			0.187	0.187								
Disbursed 1			0.112	0.187								
Contracted 2				0.600	0.600	0.600	0.600					
Disbursed 2				0.480	0.480	0.480	0.480	0.600				
Contracted 3	0.250	0.250	0.250									
Disbursed 3	0.200	0.200	0.250									
Contracted 4				0.583	0.583	0.583	0.583					
Disbursed 4				0.466	0.466	0.466	0.466	0.583				

ANNEX 4 REFERENCE TO SECTORAL FEASIBILITY STUDIES OR PLANS

SUB-PROJECT 1

1. BG9507-02-08 MASTER PLAN FOR DEVELOPMENT OF SEED CONTROL

A Master Plan for readjusting the seed certification and quality control system ready for Bulgaria's accession to EU was prepared in autumn 1997 under Phare BG9507-02-08 by EU expert. The objectives of the STE mission were to review the structure, resources and operation of the then existing Chief Inspection for Field Inspection and Seed Control (CICSC) (which is now a Directorate under the Agency for Variety Testing, Field Inspection and Seed Control) and to prepare with participation of the Beneficiary a Master Plan for development of the institution.

The Master plan of the Agency covered the period 1998-2002. Its objective is the readjustment of the seed certification and quality control system in preparation for Bulgaria's integration into the internal market of the EU and of strengthening of institutional resources and capacity to carry out effective seed quality control in the market economy. The master plan contains six major components:

- finalization and introduction of the new Seed Law and the drafting and adoption of EU equivalent seed regulations and standards to accompany the seed law;
- rationalisation of Agency' regional structure with activities being primarily focused on 16 regional inspectorates;
- adoption of EU and OECD seed quality control systems and methods;
- equipment of Agency' seed laboratories and post control centres as well as an improvement in the inspectorate's transport arrangements;
- introduction of an appropriate data management system;
- Agency' staff training in the new systems and methods as well as the training of licensed seed laboratory analysts and field inspectors;
- establishment of a Seed Industry Liaison Committee and the implementation of activities to inform seed industry participants in the new laws, systems and procedures.

The Master plan was aiming to assist Bulgaria achieving compliance with the seed aspects of EU Norms on agriculture. It was expected to support continued restructuring of the seed industry and Bulgaria's regional integration in EU seed trade. The training and technical assistance elements were envisaged in order to expose Agency' staff to the administrative and technical practices in the EU and the transposition of legislative *Acquis communautaire* into national law. To implement the Master plan funds were required for equipment, overseas training, local training, technical assistance and software programming. The total cost of the Master plan was estimated by EU expert to 1,670,690 Euro. This includes 1,046,970 Euro for Phase 1 (1998-99) and 623,720 Euro for Phase 2 (2000-02). It was recommended that the Master plan implementation is assisted by Phare programme, justified on the grounds of direct relevance to the key investment and institution building priorities contained in Phare' policy guidelines of the Accession Partnership.

The TA was successfully provided in 2001-02 by a twinning under BG9913-03-01 (see point 3.2. above). The most urgent laboratory equipment and machinery were supplied as well. The total amount of the Phare assistance was 1.1 MEuro, including the co-financing.

2. **SEED LAW FROM 2003**

With the establishment of marketing principles in Bulgarian economy and in agriculture in particular and with the privatization of the seed industry the Bulgarian seed trade has become internationally oriented. The Government is committed to prepare Bulgaria for integration into the internal market of the EU.

As part of this commitment the Ministry of Agriculture and Forestry with the active participation of the experts from the Agency for Variety Testing, Field Inspection and Seed Control has elaborated a new

Law on Seed and Propagating Material (LSPM) adopted by XXXIX National Assembly on 18 February 2003 and published in State Gazette issue No.20/04 March 2003.

The new Seed Law is compatible with the EC Directives on the marketing of seed and the Common Catalogue of plant varieties and species. The provisions of the new LSPM cover the basic provisions of the EC marketing Directives transposed into the Bulgarian legislation. The unification of the current procedures for variety testing, seed certification and seed and propagating material control which differ from those required by the EC Directives that are inherent in the EU seed control system was scheduled to be achieved through harmonization of the remaining EC Directives in the "Seed and Propagation Material" sector. Elaboration of relevant Ordinances was envisaged to set these procedures and their practical implementation in compliance with the EU ones.

The secondary legislative Acts under the new LSPM related to the transposed 6 EC basic seed marketing Directives were approved and adopted by end 2003(published in SG). The remaining EC Directives covering the official variety list and the propagating material were elaborated into relevant Ordinances by the end of 2003/beginning of 2004 (published in SG). An Ordinance laying down the conditions for approval of producers and processors of seed and propagating material and registration of traders was also elaborated (see details in Annex 5). The relevant EU *acquis* in the seed sector was transposed into 12 Ordinances.

Pursuant to the new LSPM private field inspectors and private laboratories will be approved and authorized to carry out field inspection of seed and propagating material production plots, and lab analyses respectively. The Agency will have to organize the training and exercise the control on the activities conducted by the approved private field inspectors and laboratories. For the purpose the Agency's experts need to undergo a relevant training by MS experts.

3. RESTRUCTURING OF THE AGENCY - 2003

The restructuring of the Agency's Directorate for Field Inspection and Seed Control envisaged in the Master Plan is connected with the provisions of the new LSPM. With the establishment of private field inspectors and private laboratories part of the Agency's functions as an official controlling body will drop off and will be delegated to private field inspectors and private laboratories to carry out activities in field inspection and seed testing under its control. This will result in diminishing the number of the Agency's regional offices exercising the state control. Under a Phare supported project BG99/IB/AG-01-B (see point 3.2 above) a proposal was prepared by a STE from MS outlining the phases for restructuring of the Agency in the period July 2003-2005. The Action Plan for the Agency's restructuring which was subject to approval by the competent Bulgarian authorities (MAF) was implemented. As a result, the total number of regional was substantially reduced (from 35 to 26).

The establishment of private field inspectors and private laboratories requires their preliminary training in order to make them capable of conducting these activities in accordance with the EU practices. In that direction the Agency's experts need to get familiarized and trained in the EU procedures for organizing the training and exercising the control on the private field inspectors and private labs.

The variety testing procedures following the UPOV Rules and Technical Guidelines must be brought in conformity with EU requirements in relation to DUS testing (distinctness, uniformity and stability) and VCU testing (value for cultivation and use). The elaboration of technical and regulatory procedures requires training of the Agency's experts by well-practiced and experienced MS experts.

Under the above indicated Phare project equipment was supplied to the Agency's seed testing laboratories and post control stations which provided conditions for a better precision in conducting of the seed analyses and improved the facilities for carrying out the seed control activities. Besides, using funds from co-financing budget three vehicles were purchased for the needs of the Agency thus providing better transport facilities for the seed control activities.

3. MEMBERSHIP IN INTERNATIONAL ORGANIZATIONS

The Agency for Variety Testing, Field Inspection and Seed Control is an associated Member of OECD schemes for seed certification. Its Central Seed Testing Station is an ISTA accredited Member.

The Agency is a UPOV Member since 1998 with the ratification of the UPOV Convention of 1991.

SUB-PROJECT 3

- Pre-feasibility study for the construction and equipment of a processing plant for animal byproducts not intended for human consumption in Bulgaria – to be implemented under the Programme for Technical Co-operation between the Federal Republic of Germany and the Republic of Bulgaria. The project is to be completed by the end of 2003.
- Feasibility Study for the construction and equipment of a processing plant for animal byproducts not intended for human consumption in Bulgaria – proposed for financing under Phare National Programme 2003. Expected date of project completion – June 2005.

<u>ANNEX 5</u> LIST OF RELEVANT LAWS AND REGULATIONS:

SUB-PROJECT 1

1. Law on Seed and Propagating Material: newly adopted, published in State Gazette No.20 dd 04/03/2003.

2. Law on Protection of New Plant Varieties and Animal Breeds, State Gazette No.84 dd 04/10/1996,

amended SG No.27/1998, No. 20/1999, No.81/1999 and No.86/20.10.2000.

3. Ordinance No.10 / 19.03.2001– on the Official Variety List of R Bulgaria, State Gazette No.30 / 28.03.2001

4. EC marketing Directives on Seed and Propagating Material:

- 66/400/EEC (=2002/54 consolid.)	- on <i>beet</i> seed, inclusive small EC packages;
- 66/401/EEC	- on <i>fodder</i> seed;
- 66/402/EEC	- on <i>cereals</i> seed;
- 66/403/EEC (=2002/56 consolid.)	- on <i>potato</i> seed;
- 69/208/EC (=2002/57 consolid.)	- on <i>oil and fibre</i> seed;
- 70/458/EC (=2002/55 consolid.) small EC packages;	- on vegetable seed, inclusive 'Standard seed" and
- 93/48/EC, 92/34, 93/64,	
98/56, 93/49, 91/682, 93/61,	
92/33, 68/193/EC	- on propagating material.

4. EC legislative Acts on variety testing and Variety List:

- Directive 70/457/EEC (=2002/53/EC) on the Common European Catalogue of agricultural crops
- Regulation 930/2000/EC on denominations of varieties of agricultural plant species and vegetable species;
- Decision 90/639/EEC of 12 Nov.1990 on determining the names to be borne by the vegetable varieties;
- Directive **2003/91/EC** determining characteristics and minimum conditions for inspecting *vegetable* varieties;
- Directive.**2003/90/EC** determining characteristics and minimum conditions for examining *agricultural* varieties;
- Directive 2002/8 /EC of 6 Feb.2002 amending Dir.72/168/EEC and 72/180/EEC concerning characteristics and minimum conditions for examining vegetable and agricultural varieties respectively repealed

SUB-PROJECT 2

EU Act	Transposing national act(s)	Date of adoption (possibly expected date)
Harmful organisms		
Council Directive 69/464/EEC	Ordinance Nr 20 for control of potato wart disease caused by Synchytrium endobioticum (Schilb.)	02. July 2001
Council Directive 69/465/EEC	Ordinance Nr 39 for control of potato cyst eelworms	08. November 2001
Council Directive 69/466/EEC		
Council Directive 74/647/EEC	Ordinance Nr 38 for control of carnation leaf-rollers	08. November 2001
Commission Directive 92/70/EEC	Ordinance Nr 1 for phytosanitary control	28. March 2003
Commission Directive 92/90/EEC	Ordinance Nr 1 for phytosanitary control	28. March 2003
Commission Directive 92/105/EEC	Ordinance Nr 1 for phytosanitary control	28. March 2003
Commission Directive 93/50/EEC	Ordinance Nr 1 for phytosanitary control	28. March 2003
Commission Directive 93/51/EEC	Ordinance Nr 1 for phytosanitary control	28. March 2003
Council Directive 93/85EC	Ordinance Nr 19 for control of potato ring rot caused by Clavibacter michiganensis (Smith) Davis et al. ssp. sepedonicus (Spieckermann et Kotthoff) Davis et al.	02. July 2001
Commission Directive 94/3/EC	Ordinance Nr 1 for phytosanitary control	28. March 2003
Commission Directive 95/44/EC	Ordinance Nr 1 for the conditions, under which certain harmful organisms, plants, plant products and other objects may be used for scientific purposes and selections	04. January 2002
Commission Directive 98/22/EC	Ordinance Nr 1 for phytosanitary control	28. March 2003
Council Directive 98/57/EC	Ordinance Nr 11 for control of potato brown rot disease caused by Ralstonia solanacearum (Smith) Yabuuchi et al.	10. April 2001
Council Directive 2000/29/EC	Ordinance Nr 1 for phytosanitary control	28. March 2003
Plant protection products		
Council Directive 91/414/EEC	Ordinance on plant protection products	16. September 2002
Council Directive 99/45/EEC	authorization	26. September 2002
	Ordinance Nr 37 on biological testing for efficacy and residues of plant protection products and official recognition of natural and juridical persons to undertake this task	13. June 2003
	Ordinance on the conditions and the order for labelling of plant protection products	

SUB-PROJECT 3

- Commission Regulation 2001R1248EC L173/12 27/06/2001
- Commission Regulation (EC) No 1248/2001 of 22 June 2001 amending Annexes III, X and XI to Regulation (EC) No 999/2001 of the European Parliament and of the Council as regards epidemiosurveillance and testing of transmissible spongiform encephalopathies.
- 2001R1326EC L177/60 30/06/2001 Commission Regulation (EC) No 326/2001 of 29 June 2001 laying down transitional measures to permit the changeover to the Regulation of the European Parliament and of the Council (EC) No 999/2001 laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies, and amending Annexes VII and XI to that Regulation.
- 2002R270EC L45/4 15/02/2002 Commission Regulation (EC) No 270/2002 of 14 February 2002 amending Regulation (EC) No 999/2001 of the European Parliament and of the Council as regards specified risk material and epidemio-surveillance for transmissible spongiform encephalopathies and amending Regulation (EC) No 1326/2001 as regards animal feeding and the placing on the market of ovine and caprine animals and products thereof.
- 2002R1494EC 5/3 22/08/2002 Commission Regulation (EC) No 1494/2002 of 21 August 2002 amending Annexes III, VII and XI to Regulation (EC) No 99/2001 of the European Parliament and the Council as regards monitoring of bovine spongiform encephalopathy, eradication of transmissible spongiform encephalopathy, removal of specified risk materials and rules for importation of live animals and products of animal.
- 2003R260EC L37/7- 13/02/2003 Commission Regulation (EC) No 260/2003 of 12 February 2003 amending Regulation (EC) No 999/2001 of the European Parliament and of the Council as regards the eradication of transmissible spongiform encephalopathies in ovine and caprine animals and rules for the trade in live ovine and caprine animals and bovine embryos.
- 2003R650EC L95/15 11/04/2003 Commission Regulation (EC) No 650/2003 of 10 April 2003 amending Regulation (EC) No 999/2001 of the European Parliament and of the Council as regards the import of live ovine and caprine.
- 2003R1053EC L152/8 20/06/2003 Commission Regulation (EC) No 053/2003 of 19 June 2003 amending Regulation (EC) No 999/2001 of the European Parliament and of the Council as regards rapid test.
- 2003R1128EC L160/1 28/06/2003 Regulation (EC) No 1128/2003 of the European Parliament and of the Council of 16 June 2003 amending Regulation (EC) No 999/2001 as regards the extension of the period for transitional.
- 2003R1139EC L160/22 28/06/2003 Commission Regulation (EC) No 139/2003 of 27 June 2003

amending Regulation (EC) No 999/2001 of the European Parliament and of the Council as regards monitoring programmes and specified risk material.

- 2003R1234EC L173/6 11/07/2003 Commission Regulation (EC) No 234/2003 of 10 July 2003 amending Annexes I, IV and XI to Regulation (EC) No 999/2001 of the European Parliament and of the Council and Regulation (EC) No 1326/2001 as regards transmissible spongiform encephalopathies and animal feeding.
- Commission Decision 98/12/EC L004/63 8/01/1998 COMMISSION DECISION of 15 December 1997 amending for the fourth time Council Directive 82/894/EEC on the notification of animal diseases within the Community and temporarily amending the frequency of notification for bovine spongiform encephalopathy.
- European Parliament and Council Regulation 2001R999EC L147/1 31/05/2001 Regulation (EC) No 999/2001 of the European Parliament and of the Council of 22 May 2001 laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies.
- Directive of the EP and the Council 2001D10EC L147/41 31/05/2001 Directive 2001/10/EC of the European Parliament and of the Council of 22 May 2001 amending Council Directive 91/68/EEC as regards scrapie.
- Commission Regulation (EC) No 1774/2002 of the European Parliament and of the Council laying down health rules concerning animal by-products not intended for human consumption, as amended.
- Commission Regulation (EC) No 808/2003 of 12 May 2003 amending Regulation (EC) No 1774/2002 of the European Parliament and of the Council laying down health rules concerning animal by-products not intended for human consumption (*Official Journal L117, 13/05/2003, p. 1-9*).

Application texts

- Council Decision 98/256/EC L113/32 15/04/1998 COUNCIL DECISION of 16 March 1998 concerning emergency measures to protect against bovine spongiform encephalopathy, amending Decision 94/474/EC and repealing Decision 96/239/EC.
- Commission Decision 97/735/EC L294/7 28/10/1997 Commission Decision of 21 October 1997 concerning certain protection measures with regard to trade in certain types of mammalian animal waste.
- 98/351/EC L157/110 30/05/1998 Commission Decision of 29 May 1998 setting the date on which dispatch from Northern Ireland of bovine products under the Export Certified Herds Scheme may commence by virtue of Article 6(5) of Council Decision 98/256/EC
- 98/564/EC L273/37 9/10/1998 COMMISSION DECISION of 7 October 1998 amending Council Decision 98/256/EC as regards certain emergency measures to protect against bovine spongiform encephalopathy.
- 98/692/EC L328/28 4/12/1998 COMMISSION DECISION of 25 November 1998 amending

Decision 98/256/EC as regards certain emergency measures to protect against bovine spongiform encephalopathy.

- 2000/345/EC L121/9 23/05/2000 COMMISSION DECISION of 22 May 2000 setting the date on which dispatch from Portugal to Germany of certain products for the purpose of incineration may commence by virtue of Article 3(6) of Decision 98/653/EC.
- 2000/371/EC L134/34 7/06/2000 COMMISSION DECISION of 6 June 2000 setting the date on which dispatch of fighting bulls from Portugal to France may commence by virtue of Article 3(7) of Decision 98/653/EC.
- 2000/372/EC L134/35 7/06/2000 COMMISSION DECISION of 6 June 2000 setting the date on which dispatch of fighting bulls from Portugal to Spain may commence by virtue of Article 3(7) of Decision 98/653/EC.
- 2001/165/EC L58/43 28/02/2001 Commission Decision of 27 February 2001 amending as regards hydrolysed proteins Decision 2001/9/EC concerning control measures required for the implementation of Council Decision 2000/766/EC concerning certain protection measures with regard to transmissible spongiform encephalopathies and the feeding of animal protein.
- 2001/376/EC L132/17 15/05/2001 Commission Decision of 18 April 2001 concerning measures made necessary by the occurrence of bovine spongiform encephalopathy in Portugal and implementing a date-based export scheme.
- 2002/670/EC L228/22 24/08/2002 Commission Decision of 20 August 2002 amending Council Decision 98/256/EC concerning emergency measures to protect against bovine spongiform encephalopathy.
- 2002/1003/EC L349/105 24/12/2002 Commission Decision of 18 December 2002 laying down minimum requirements for a survey of prion protein genotypes of sheep breeds.
- 2003/100/EC L41/41 14/02/2003 Commission Decision of 13 February 2003 laying down minimum requirements for the establishment of breeding programmes for resistance to transmissible spongiform encephalopathies in sheep.
- Commission Recommendation 98/477/EC L212/58 30/07/199 COMMISSION RECOMMENDATION of 22 July 1998 concerning information necessary to support applications for the evaluation of the epidemiological status of countries with respect to transmissible spongiform encephalopathies.

ANNEX 6

Sub-project 1

List of equipment foreseen under Contract 1 required for the strengthening of the EAVTFI&SC activities

Laboratory equipment

Contract 1

Digital image processing for Electrophoresis (Central Laboratory)	1
Mill for seed of high oil content (Central Lab-Chemical analysis unit)	1
Mortar-Grinder for samples of high moisture content (Central Lab-	1
Chemical analysis unit)	
Lab Mixer for universal use (Central Lab-Chemical analysis unit)	1
Automatic seed counter	3
Central Laboratory	1
VTS Brashlen	1
VTS Radnevo	1
Automatic seed counter and packer (DUS Department – CO)	1
Digital camera (DUS Department – CO)	1
Moisture meter for grain	7
VTS Bourgas	1
VTS Gorski Izvor	1
VTS Pordim	1
VTS Radnevo	1
VTS Selanovtzi	1
VTS Chepintzi	1
VTS Brashlen	1
Electronic balance	12
VTS Brashlen	1
VTS Burgas	1
VTS Gorski Izvor	1
VTS Dobrich	1
VTS Pavlikenni	1
VTS Pleven	1
VTS Pordim	1
VTS Yambol	1
VTS Radnevo	1
VTS Razgrad	1
VTS Selanovci	1
RS Dobrich	1
Test Weight measuring device (Libra)	9
VTS Brashlen	1
VTS Burgas	1
VTS Gorski Izvor	1
VTS Ognjanovo	1
VTS Pavlikeni	1
VTS Radnevo	1
VTS Razlog	1
VTS Selanovtzi	1
VTS Yambol	1
Thermostat	6
RS Burgas	1

RS Dobrich	1
RS Pleven	1
RS Razgrad	1
RS Shumen	1
RS Jambol	1
Laboratory seed-cleaning machine	2
VTS Bourgas	1
VTS Radnevo	1
Motor cultivator unit	3
VTS Novo Selo	1
VTS Plovdiv	1
VTS Parvomaytzi	1
Cars	6
Central Laboratory	1
VTS Plovdiv	1
VTS Varna	1
VTS Vratza	1
VTS Razgrad	1
VTS Stara Zagora	1

Contract 5

Agriculture machir	ies
Tractor 80-100 H.P	
	VTS Bourgas
Tractor for fruit trees	S
	VTS Novo Selo
Combine for seed pl	ots - cereals & row-crops
	VTS Brashlen
	VTS Radnevo
	VTS Pordim
	VTS Selanovtzy
Accessories - moun	ted
Sowing machine for	cereals seed 1.5 m
	VTS Bourgas
	VTS Gorsky Izvor
	VTS Pordim
	VTS Radnevo
Spraying machine w	rith rods
	VTS Gorsky Izvor
	VTS Radnevo

	Cultivator for cereals	
		VTS Brashlen
	Cultivator for earthed crops	
		VTS Brashlen
		VTS Bourgas
		VTS Gorsky Izvor
		VTS Radnevo
	Disc harrow	
		VTS Bourgas
	Plough- mounted	
		VTS Bourgas
		VTS Gorsky Izvor
	Seed-cleaning machine	
		VTS Brashlen
		VTS Pordim
		VTS Radnevo
		VTS Kubratovo
	Sowing machine for earthed crops	
		VTS Brashlen
		VTS Dobrich
		VTS Pordim
		VTS Radnevo
Transportable	climatic stations	
		VTS Bourgas
		VTS Brashlen
		VTS Radnevo
		VTS Novo Selo
		VTS Pordim
		VTS Dobrich
Digital Photo]	Equipment	
	Digital camera	
	-	Central Office
	Digital photo camera	
		VTS Bourgas
		VTS Brashlen
		VTS Radnevo
		VTS Novo Selo
		VTS Pordim
		VTS Dobrich

PC set + Lazer jet printer (colour) VTS Bourgas VTS Brashlen VTS Radnevo VTS Novo Selo VTS Pordim
VTS Bourgas VTS Brashlen VTS Radnevo VTS Novo Selo VTS Pordim
VTS Brashlen VTS Radnevo VTS Novo Selo VTS Pordim
VTS Radnevo VTS Novo Selo VTS Pordim
VTS Novo Selo VTS Pordim
VTS Pordim
, is fordim
VTS Dobrich
DUS Dept-(CO)-Kubratov
(for reference collection)
Software data base programme for reading out DUS results
DUS Dept- Central Office
PCR equipment for GMO control on DNA level
PCR equipment (quality and quantity control)
Centrofuge for DNA extractions
Greenhouse installation for vegetables -DUS testing
VTS Samovodene
Refrigeration chamber
Central Laboratory (CO)
Abreviations CL-Central Laboratory
CO-Central Office

ANNEX 7

SUPPLY OF EQUIPMENT FOR CONTROL OF GMO'S WITH SEEDS

BACKGROUND AND JUSTIFICATION

The control on GMO's (seeds, fodders and foods) is in the competence of 3 Ministries: Ministry of Environment & Waters, Public Health Ministry and Ministry of Agriculture. In respect to the control of GMO's with seed - it is entirely the responsibility of the Agency for Variety Testing, Field Inspection & Seed Control.

The relevant EC legislation in this field has been transposed in the new draft Law on GMO's which has already been accepted at first hearing by the National Assembly of R Bulgaria. It is expected to be adopted by Bulgarian Parliament by the middle of 2004. The Law is in full compliance with the following EU *acquis:*

- Directive **90/219/EEC** on GMO's contained use system;
- Directive **2001/18/EC** on deliberate emission of GMO's in the environment, amending Council Directive 90/220/EEC;
- Council Regulation 1946/2003/EC on transboundary movement of GMO's; and
- Regulation **1830/2003/EC** on detection and labeling of GMO's and tracing of foods and fodder produced from GMO, amending Dir. 2001/18/EC.

Pursuant to the new Law 2 Ordinances are due to be elaborated wherein the specific technical requirements and provisions will be laid down.

In order to acquire a capacity for control of GMO's with seeds the Agency needs to be equipped with adequate PCR equipment (polymerase chain reaction) which is a facility for detecting the presence of GMO's on DNA level and with a possibility for labeling of the controlled seed lots intended for home and international marketing in accordance with the EU requirements.

Activities:

- Supply of PCR equipment for detecting and labeling of GMO's (approx.. 60000 Euro)
- Subsequent training of Agency's staff to operate with the supplied specific equipment is a strong necessity.

Results:

Implementation of EU Legislative Acts on GMO's and full control and traceability of the genetically modified organisms in the seed sector.

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According to the Law on Seed and Propagating Material (LSPM) the control on imported and exported seed is delegated to EAVTFI&SC.

Presently the import of seed is effected only on the basis of a declaration on the part of the importer that the seed is GMO free (no presence of GMO). The Ministry of Agriculture and Forestry of R Bulgaria has already completed the harmonization of the Bulgarian legislation with EU legislation in the seed sector and from this point of view postponing of the start of the project for equipping of a GMO Laboratory for 2007 would mean that the Agency will not be capable of carrying out effective control and the latter will remain to be only a declared one, which would lead to lack of compliance with the commitments undertaken.

On the other hand, a GMO Laboratory stationed at EAVTFISC will have substantial functions in the variety testing procedure. Presently In the world and European practices the PCR equipment is used for determination of the homogeneity (uniformity) of the lines which are the parental components (male and female lines) in the hybrid seed production. With the re-orientation of the seed production from open pollinated varieties to hybrid ones the need of such type of equipment will be growing.

In view of the fact that the Electrophoretic method and the molecular tests conducted by using a PCR equipment are directly linked and are supplementary to each other we would propose training under the project of three (3) experts from the Agency's Electrophoresis Unit and one expert from DUS (distinctness, uniformity and stability) Department.

At present EAVTFISC carries out seed testing with the purpose of certification and admission to the domestic market and analyses totally around 15000 seed samples annually from imports and local production. For realization of an efficient control on the production and trade of seed and propagating material it is necessary to check the seed for presence of GMO in view of the circumstance that they might be mechanically contaminated with genetically modified ones.

Presently the trade of GMO's on the territory of Bulgaria and in EU is not permitted.

The requested equipment represents Real Time PCR. This equipment has a capacity to determine whether the seed samples analysed are genetically modified and if so it indicates the percentage of the quantitative modifications observed. The equipment has a capacity of carrying out quantitative measurements which is closely linked to the threshold adopted in the EU for the admissible genetic modifications, obtained as a result of purely mechanical contamination. As per preliminary data the value of a PCR equipment inclusive the respective software and hardware to it amounts to about EUR 70 000.

According to our own information in Bulgaria there is available equipment of such parameters at the National Center for Contagious and Parasitic Diseases.

EAVTFISC has available premises necessary for instalment and normal functioning of a PCR equipment.

Deriving from the average time needed for analysis of one seed sample – around 90 min. and with an average number of working days in a year– 265 days and average time loading of the equipment of around 6 hours, it will be possible to conduct analysis of around <u>1000 samples</u> per year which represents about 7% of the total number of samples analysed. These analyses are sufficient for carrying out of an efficient control on the genetically modified seeds.

For management of the equipment, preparation and conducting of the analyses are needed 3 persons, and the Agency can ensure their availability within the framework of the staff permitted.

The average value of the consumables per one analysis is around 50 Eur. The assets needed annually for provision of consumables are estimated to around 50 000 Eur. The Agency will collect respective fees for the analyses conducted from the importers of seed and seed producers in the country. The size of the fees will be calculated basing on the value of the necessary consumables, the expenditures for salaries and social insurance, additional expenditures involved by economic elements (water, electric .power, stationary materials, mail services, etc.) which will cover the necessary running costs of the equipment and will provide funds for its maintenance and ware and tare.

Under the above made economic calculations EAVTFISC will have the possibility to ensure the normal operation of the equipment and carrying out of the necessary analyses within the framework of its own income funds and budget support established.