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Project Fiche for Phare / Pre-accession instrument 2006

1. Basic Information

1.1 CRIS Number: 2006/018-343.03.04

- 1.2 Title: Improvement of the Plant Protection control system in Bulgaria and implementation of EU requirements related to phytosanitary control on quarantine organisms, biological testing, authorization and control on plant protection products
- 1.3 Sector: Agriculture1.4 Location: Bulgaria
- 1.5 Duration: one year (from November 2008 to November 2009)

2. Objectives

2.1 Overall Objective(s):

Strengthen the capacity of the National Service for Plant Protection under the Ministry of Agriculture and Forestry (MAF) to implement EU requirements related to control the quarantine organisms, to implement GEP based biological testing and authorization and control of the plant protection products, in order to limit the potential risk for human health, animal health, biodiversity conservation and environment for inappropriate usage of PPPs

2.2 Project purpose:

Strengthening of the administrative and technical capacity of NSPP for:

- 1. effective control on quarantine organisms in compliance with EU requirements
- 2. establishment of reliable Pest Risk Analyses for Quarantine Pests (PRAQP),
- 3. biological testing carried out in compliance with GEP standards
- 4. quality control on the application of the Plant Protection Products (PPPs)
- 2.3 Accession Partnership (AP) and NPAA priority (and implementing measures envisaged by the Action Plan for AP priorities related to strengthening administrative and judicial capacity)

Accession Partnership:

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

Complete alignment of veterinary and phytosanitary legislation in order to enforce internal market control systems and imports from third countries fully and effectively; continue to implement veterinary, phytosanitary and food safety legislation, including animal disease control measures.

According to the Regular Report of the EC for 2003 in Chapter 7, Agriculture, Overall assessment it is outlined that despite of further measures taken to enhance its capacity, the

National Service for Plant Protection still lacks sufficient equipment, adequate numbers of qualified staff and operational budget to adequately fulfil its tasks.

Effective implementation of Acquis communautaire related to the phytosanitary control in order to prevent introduction and spread of harmful organisms listed in the Annexes of Directive 2000/29/EC.

Improvement of the phytosanitary protection

Continuation of the alignment of the phytosanitary legislation with the acquis

Increasing efficacy of plant protection in terms of creating conditions for manufacturing and trading with plant protection products

Building up stations for biological testing of plant protection products and adoption of GEP standards

Building up relevant administrative capacity

Implementation of the EU *acquis* in terms of use of plant protection products and creation of a common market network for plant protection products

Placing on the market and use of efficient and safe plant protection products

Efficient implementation of the acquis with regard to the conduct of biological testing.

"The administrative capacity for enforcing the rules on the spot with particular reference to the plant passport system, registration and use of pesticides and monitoring of their residues, collection and processing of statistical data and the laboratory capacities, including quality control, still needs strengthening." (Regular Report of the EC on R Bulgaria 2004)

According to the recommendations of the Monitoring Report 2005 Bulgaria should further implement effective enforcement of the phytosanitary passport and control measures, related to quality control.

According to the Action Plan for 2006 NSPP will continue training of phytosanitary inspectors; the greater part of the latter ones are trained in the Central laboratory for plant quarantine.

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

The Strategy for the Development of the National Service for Plant Protection is attached in Annex 6

2.5 Cross Border Impact

Effective implementation of control measures according to all the transposed acquis communautaire will have essential impact on facilitation of the cross-border trade with plants and plant products.

Pest Risk Analysis (PRA) for Quarantine Pest is essential part of general strategy in Phytosanitary control of the country. Implementation of standardized of methods and procedures for PRA for Quarantine Pest is important for Bulgaria as a future border in 2007 and EC.

Border Inspection Posts for the control of imports from third countries will be operated on the future external border of EU in Bulgaria (this includes 12 long term BIPs)

3. Description

3.1 Background and justification:

This section is devided into purposes 1-4 as different control functions of NSPP need further strengthening for better implementation of all the transposed acquis communautaire

To purpose 1:

The urgent need of improvement of the quarantine containment measures at CLPQ was pointed out by the MS experts during the Twinning programme BG2001 IB AG 01TL: Final Report of Twinning programme BG2001 IB AG 01TL (24 November 2003 – 24 July 2004)

Owning and handling quarantine organisms is regulated as stated by EU directive 95/44/CE. It has to be now duly respected. CLPQ, like all other laboratory dealing with quarantine organisms, should have taken strong measures against non intentional release of those organisms from its facilities. It means that special care should apply on solid, liquid and gaseous waste.

At CLPQ the solid waste (culture media, contaminated single use tools...) seem to be disposed after appropriate autoclaving. This could be improved by the use of special containers allowing a decontamination by heat without direct contact with items to be processed.

For liquid wastes, i.e. fluids escaping through wash basins, wastes from soil cleaning, effluents from the glasshouse, no treatment is done. This is a very weak point which should find a solution without any delay.

Concerning gaseous wastes, i.e. contaminant transmitted by air draughts (fungal spores, insect or mite transmitted viruses, etc), no equipment has been delivered under Phare.

A clear evaluation of risks needs to be immediately initiated in order to ban experiments which represents too high risks while waiting for appropriate containment measures.

A point should be made on the brand new glasshouse, which is definitely not adapted to prevent contamination by liquid or gaseous wastes. Only experiments generating only solid wastes should be done there, and special attention should be taken about risks of escape through water drainage pipes.

Specific requirements for the containment of certain quarantine organisms are drawn in the relevant EU legislation, e.g. ANNEX VII of Council Directive 98/57/EC of 20 July 1998 on the control of *Ralstonia solanacearum* (Smith) Yabuuchi et al.

Additional requirements for retention and conservation of test samples are drawn in the relevant EU legislation, e.g. ANNEX III of Council Directive 98/57/EC and ANNEX II of Council Directive 93/85/EEC of 4 October 1993 on the control of potato ring rot.

Related to all the components of purpose 1 there were no supplies funded under Phare programmes so far.

To purpose 2:

As a future border of EU Republic of Bulgaria should established well structured and efficient control systems including laboratory and testing capacity and to enforce internal control schemes with respect to plant health. According to the Bulgarian Plant Protection

Law the National Service for Plant Protection (NSPP) is responsible to provide efficient phytosanitary control.

PRA as a process of evaluating biological or other scientific and economic evidence to determine whether a pest should be regulated and the strength of any phytosanitary measures to be taken against it. It consists of three stages: 1. Initiation the process for analyzing pest risks, 2. Assessing pest risk, and 3. Pest Risk management.

The Plant Protection Institute (PPI) as a part of NSPP is charged with initiation (partly) and assessing pests risk analysis for quarantine pest. The other department of NSPP included of the PRA is Central Laboratory for Plant Quarantine (CLPQ) where the other part of initiation and management of PRA will take part. Faster implementation of PRA QP is also connected with recognition of Bulgaria as protected zone (Directive 92/70/EEC), free of several quarantine pests (e.g. Pantoea stewartii, Ceratitis capitata, etc.).

Technical equipment of PPI is quite outdated and a renovation started at the time the Institute became a part of NSPP at the end of 2003. All activities connected with PRA for quarantine pests (e.g. diagnostics, species/race identifications, hosts plant range, vector hosts, and etc.) should be conduct in accordance of Good Laboratory Practices (GLP) standards. There are few Acquis requirements related to PRA, but the implementation of these analyses would have a definite impact on the control of the border and the territory of the country against spread of harmful organisms. The specialists of PPI have to obtain extra qualification on PRA procedures and GLP standards as well. Efficiency of PRA depends on development and applicability of database systems, constructed on detailed investigations and experiments. PPI undertakes development of database system for quarantine pests of Bulgaria.

At present the status quo of the database is as follows: Basic data on occurrence, distribution and spread of quarantine and economically important pets exist on paper and DOS files for 30 years in the PPI. The data is stored in the section "Prognosis" in PPI, it consists data on Economically Important Pests (EIP) including quarantine and regulated pests. The database should be transferred to electronic files and made accessible by PPI scientific researchers and all NSPP structures (HQ, Laboratories, RSPPs with BIPs) through a operational network.

Related to all the components of purpose 2 there were no supplies funded under Phare programmes so far

To purpose 3:

In order to authorize a plant protection product in Bulgaria, data should be available to demonstrate its efficacy against those pests for which an application for biological testing has been submitted to the NSPP. Data on its toxicology and ecotoxicology should also be available. Tests proving biological efficacy of a plant protection product are carried out at the stations for biological testing of the NSPP /respectively RSPP/. Council Directive 91/414/EEC provides that biological testing is carried out satisfying GEP standards introduced by Directive 93/71/EC.

Biological testing is conducted in Bulgaria at 13 stations for biological testing of the NSPP in collaboration with some of the leading plant protection institutes. It helps satisfy the agricultural, plant health and environmental (including climatic) conditions of the distinct areas of the country. All NSPP stations for biological testing should comply with same standards, those of GEP, to make sure that results issued following these procedures are compatible and comparable. It would make the products' quality evaluation more accurate during the authorization process. Data through biological testing are compiled

following a previously fixed routine and are issued as reports from single trials (from a station with regard to a plant protection product) and from trails as a series (from a group of stations with regard to a plant protection product). Those data help the applicant draw up a biological assessment dossier needed during authorization.

The state of play of introducing the Good Experimental Practice in the NSPP is as follows: Standard Operative Procedures (SOPs) are elaborated together with Instructions how to apply the Ordinance for Biological Testing of Plant Protection Products. The SOPs are elaborated and endorsed at central level and are further applied in the Biological Testing Stations (BTS) in the Regional Services. All BTSs apply one and same SOPs, but results of the 5 non-equiped are not yet comparable with the results of the rest as they are not provided with all the necessary equipment and they use old equipment that is out of date. All experts of the Regional Services, Responsible for Biological Testing are trained in one methods, and elaboration of a single Quality manual on GEP is part of the activities under Phare project BG 2004/016-711.03.02 "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".

Up to now there are 6 RSPPs that have been equipped under PHARE projects. The equipment was financed through Financing Memoranda 1998, 1999 and 2001.

A PHARE Project (BG0201.05) was settled to provide the remaining 7 RSPPs with equipment. It was adopted but wasn't contracted in the part related to biological testing equipment due to circumstances beyond the authority of the NSPP.

In 2005 the NSPP partially purchased equipment for 2 more stations for biological testing thus increasing the total number of stations equipped under GEP to 8.

In order to build up a complete and efficient network for biological testing of plant protection products under GEP standards in Bulgaria, 5 RSPPs must also be equipped under a PHARE Project. The network would allow complete and efficient biological testing of plant protection products with respect to the creation of database for efficacy and the definition of Good Agricultural Practices (regarding to pesticide residues) in accordance with Council Directive 91/414/EEC. Therefore NSPP should also be provided with agrometerological stations in order to build up the whole network of biological testing on the territory of the country. Therefore the NSPP would need the following equipment:

- Biological testing equipment for 5 RSPPs (RSPP Blagoevgrad, RSPP Vidin, RSPP Varna, RSPP Haskovo, and RSPP Dobrich). The premises for the rest of the Biological Testing Stations (BTS) in these Regional Services are ready and refurbished to accept the equipment.
- Agrometeorological stations for 11 points (RSPP Varna, RSPP Dobrich, RSPP Vidin, RSPP Vratsa, RSPP Ruse, RSPP Pleven, RSPP St. Zagora, RSPP Burgas, RSPP Haskovo, RSPP Blagoevgrad, and RSPP Kjustendil) to cover the whole range of areas where biological testing is carried out.

To purpose 4:

Achieving purpose 4 is intended to strengthen the effective control on the application and usage of plant protection products /PPPs/, with these means the whole cycle of control functions related to PPP will be closed. Purpose 4 concerns equipment of mobile stations for testing the technique for application of plant protection products.

Implementation of the EU acquis in the area of the application of PPP and to ensure the food safety - plants and products of plant origin from pesticide residues and improvement

of control on the technique for application of plant protection products. - Regulation 178/2004/EC, Regulation 852/2004/EC, Regulation 882/2004/EC and Directive 91/414/EEC

As a future external border of the EU, Republic of Bulgaria should establish well structured and efficient entire control system on its territory, related to the PPP application in order to ensure Plant health, Food safety, Human health, Animal health, biodiversity conservation and environment for undergrounded usage of PPP.

More attention should be paid to control the application of the PPP and to control the technique for PPP application.

The Bulgarian law designates the NPPS to the Ministry of Agriculture and Forestry as the official body responsible for the adoption and enforcement in Bulgaria of the EU plant health legislation and the implementation of EU Acquis. In connection with the future EU membership of Bulgaria in 2007 NPPS prepared draft amendments and supplements of the Plant Protection Law (PPL) fully transposing Directive 91/414 EEC, especially provisions of Article 3, Regulation 178/2004 and Regulation 852/2004 in order to protect the environment, human health and food safety from the harmful effect of the pesticides. The draft text has already received Parliament approval. By the amendments the NPPS introduces a system to control the application of plant protection products by accomplishing testing and control on the technique for application of PPP. As a followup activity of the PPL amendments, NPPS currently prepares draft Ordinance for control of the technique used for PPP application. According to the provisions of the Ordinance, every officially registered farmers is obliged to presented the technique used for PPP application to the NPPS authority every two years in order to be tested and if it is in good working order shall receive official authorization for usage. If non-authorized technique is used, the farmer shall be sanction.

At the moment, the control on the application of PPP carried by the NPPS is reduced to: Control on the market of PPP:

Control of the trade with PPP:

Monitoring of pesticides residues in plants and products of plant origin in the field;

Monitoring of chemical and biological contamination in plant raw materials and products of plant origin;

Monitoring of chemical and biological contamination in soil and in irrigating waters;

Documentation control of the "Field diary of application of PPP, and used fertilizers, soil improvements and biological active substances". This control is carrying out from the Regional Plant Protection Services (RPPS) inspectors.

Currently NPPS is not able to carry out control on the technique for application of the PPP because of lack of any equipment for testing. For that purpose, NPPS needs to be equipped urgently with mobile stations for carrying out tests on the technique for application of the plant protection products. These mobile stations shall test the technique for application of the plant protection products used by farmers on the entire territory of Bulgaria. NPPS envisages starting this control activity with at least seven mobile stations for technique control: six of them shall be used for equipping RPPS – Vratza, V.Turnovo, Dobrich, Blagoevgrad, Plovdiv, Bourgas, and one mobile station shall be situated in Sofia and shall be used as a referent station for testing the working order of the others. This referent station in Sofia should be testing the operation mode of the other six and their correspondence with EN: 13790 requirements. This European Quality standard is elaborated especially to "Agricultural machinery – sprayers – Inspection of sprayers in use" and it refers explicitly in its part 1 to field crop sprayers and in its part 2 to Airassisted sprayers for bush and tree crops. During recent years, several countries have

developed systems for inspection of field crop sprayers in use. Developments in this direction in Bulgaria will further be stimulated by public concern about risks and the aim of reducing the use of plant protection products (PPPs). There are 3 main arguments for the inspection carried by an official control body NSPP: test operator safety, less potential risk of environmental contamination by PPPs, good control of the pest with the minimum possible input of PPPs. The standard defines the requirements and test methods for sprayers in use in order to use PPPs in plant production in Europe safely. The major part of EU Member States, including the last accessed countries apply this standard.

Related to all the components of purpose 4 there were no supplies funded under Phare programmes so far

3.2 Sectoral rationale

Not applicable

3.3 Results

- 1a. The glasshouse at CLPQ is fully equipped and operates according to the quarantine containment requirements of Directive 97/46/EC.
- 1b. Liquid wastes from the laboratory and the glasshouse are disposed appropriately, according to the requirements of the relevant EU legislation (Commission Directive 97/46/EC, Council Directive 98/57/EC).
- 1c. Proper retention and conservation of test samples is carrying out
- 2a. NSPP performs Pest Risk Management according to ISPM
- 2b. PPI performs implementation of standardized methods and procedures of PRA of Quarantine Pests in Bulgaria according to standards ISPM No.11 (Rev.1) and Directive 94/3/EC.
- 2c. Laboratory block of diagnostics of PPI is fully equipped to provide PRA for Quarantine Pests
- 2d. Specialists involved in the PRA for Quarantine Pests are trained how to perform studies and analyses in order to meet the relevant requirements
- 2e.Bulgarian database system on quarantine pests established and operational.
- 2f. PPI specialists are trained to operate with the database system
- 3a. Five (5) RSPPs (RSPP Vidin, RSPP Varna, RSPP Haskovo, RSPP Dobrich, and RSPP Blagoevgrad) are equipped and carry out trials for biological testing of plant protection products in compliance with GEP standards. The Biological testing network is built up allowing to satisfy the agricultural, plant health and environmental (including climatic) conditions in Bulgaria referred to in Council Directive 91/414/EEC;
- 3b. Eleven Agrometeorological provide date on agroometeo condition s necessary for buiological testingstations are installed at 11 points (RSPP Varna, RSPP Dobrich, RSPP Vidin, RSPP Vratsa, RSPP Ruse, RSPP Pleven, RSPP St. Zagora, RSPP Burgas, RSPP Haskovo, RSPP Blagoevgrad, and RSPP Kjustendil) covering all areas where Biological testing is carried out.
- 3c. Experts are trained to operate the equipment.

- 4a. Six mobile stations on the territory of RSPP Vratza, V.Turnovo, Dobrich, Blagoevgrad, Plovdiv, Bourgas are fully equipped to carry out control over farmer technique in relation with the PPP application in the field;
- 4b. One referent station in Sofia is testing the operation mode of the other six and their correspondence with EN: 13790 requirements;
- 4c. NSPP experts and inspectors are trained and operate with the devices for testing the technique for application of Plant Protection Products

3.4 Activities (including Means)

3.4.1 Twinning light contract

- 2c. Training and study visits related to implementation of the Acquis related to PRA:
- 2d. Training and study visits of PPI specialists on PRAQP procedures and the new methods of pest diagnostics and identification
- 2e. Training and study visits for operation and maintainance of the database system on quarantine pests (distribution area, hosts range, etc)
- 2f. Training and study visits of PPI specialists in operation of the database system
- 3c. Training and study visits of experts to carry out biological testing in the 5 stations according to the principles of GEP.
- 4c. Training and study visits of NSPP experts and inspectors to operate with the devices for testing the technique for application of PPPs

3.4.2 Supply contract

- 1a. Supply of equipment for the glasshouse with HEPA filters and devices for negative pressure,
- 1b. Supply of waste water storage and treatment devices
- 1c. Supply of equipment for a refrigerated room for proper retention and conservation of test samples;
- 2a. Supply of equipment for laboratories of virology, bacteriology, mycology, nematology and entomology at PPI;
- 2b. Supply of equipment for laboratory of Molecular diagnostics at PPI;
- 3a. Supply of equipment for Biological Testing for 5 RSPPs; training of operators
- 3b. Supply of Agrometeorological stations for 11 points;
- 4a. Supply of mobile stations for control over farmer technique for six RSPP;
- 4b. Supply of equipment for 1 referent station in Sofia for testing the proper operation of the other six and their correspondence with EN: 13790 requirements;

3.5. Linked Activities:

3.5.1. Completed projects:

Project BG9507-02-03 "Technical assistance for NSPPQA"

The task of the project was to improve the phytosanitary control carried out by the CLPQ. The outputs of the project are as follows:

Needs assessment;

Preparation of lists specifying the necessary additional laboratory equipment

On-site laboratory training of specialists held by EU experts

Technical visit of Bulgarian specialists to laboratories in The Netherlands

Project BG98/IB/AG02 "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

The project's outputs were the following:

- Improvement of the phytosanitary control carried out at BIPs and the phytosanitary control at production considering the recommendations under project BG9103-06-06 and the findings of the EU experts under the twinning project.
- Strengthening of the Central and 4 Regional laboratories for Plant Quarantine.
- Strengthening of the laboratory for Control of Potatoes (Samokov).
- On-site training courses of specialists and held by EU experts.
- Technical visit of Bulgarian specialists to MC laboratories
- Improvement of the biological testing of pesticides and setting up of registration schemes.
- Improvement of the control of pesticide residues and strengthening of the Central Laboratory for the Control of Pesticides, Nitrates, Heavy Metals and Fertilizers (CLCPNHMF).
- Legislation approximation.
- Training and needs assessment.

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"

The project's outputs were the following:

- Improvement of administrative structures for the phytosanitary control of imported plants and plant products, domestic production and monitoring of the territory of the country.
- Improvement of the biological testing of pesticides (training of technicians and laboratory specialists according to GEP) and strengthening of registration procedures.
- Strengthening of 11 Regional laboratories for Plant Quarantine.
- Training of laboratory specialists and phytosanitary inspectors in the identification of harmful organisms defined in the annexes of Directive 2000/29/EC.

- Improvement of the control of pesticide residues and other contaminants in foodstuffs (training of laboratory specialists).
- Setting-up of a system for the control and certification of organic products.

Project BG9913.02.03

Construction of a greenhouse for indicator plants for the needs of CLPQ.

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

The project's outputs were the following:

- 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" - results:

Sub-project 1. Phytosanitary control

Department "Phytosanitary control" at the Central office is equipped with IT

CLPQ (and Samokov-branch) IT equipped

14 RSPP and the 13 units to them are equipped for territory survey and control at the place of production

12 long-term BIPs equipped with IT equipment

1 Regional Laboratory in Kjustendil is equipped for routine analyses in entomology, mycology and bacteriology

Sub-project 2. Registration of plant protection products

- 7 regional services (Vidin, Varna, V. Turnovo, Haskovo, Dobrich, Blagoevgrad and Sofia) are equipped to carry out trials in relation with the biological testing of plant protection products in compliance with GEP standards (a total of 13 units have to be equipped through Phare assistance in order to establish a testing network enabling to cover the main climatic and soil conditions in Bulgaria as provided by Directive 91/414/EEC);
- The above 7 regional services and PPP Department within NSPP HQ are equipped with IT equipment;
- 7 RSPP, where Biological testing is accomplishing (Vratsa, Ruse, Pleven, St. Zagora, Burgas, Haskovo, Blagoevgrad) are equipped with Agro meteorological stations.

Forthcoming projects:

BG2004/016-711.03.02: 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, 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, EN ISO 17020, GLP and GEP requirements in order to guarantee the quality of NSPP control activities.

3.6 Lessons learned:

To purpose 1:

As recognized by the French training experts in Phare project BG 0101.03, huge improvement had occurred at CLPQ since 1999. Facilities are now rather well structured and organised even if some weak points are still existing, major pieces of equipment are available and staff increased. Main technologies are already available (traditional techniques, serological techniques) and staff trained for, and some others could be ready easily (like molecular biology, equipment is available, only working rooms and appropriate reagents are not).

To purpose 2:

Previous Phare activity supported other departments and laboratories of NSPP (e.g. CLPQ, RLPQ and BIPs) connected in Pest Risk Analyses for Quarantine Pests. As far as PPI was included in the structure of NSPP at the end of 2003 and became responsible for PRA activities in 2004 it remains the only one part of NSPP with insufficiency of update technical equipment to implement PRA procedures and GLP standards. Extra training on some new techniques and procedures of PPI specialists included in PRA will be also essential. 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. As result extra qualification of personnel and renovation of equipment is provided to CLPQ and its regional units which ensure 1st (partly) and 3rd stage of PRA.

To purpose 3:

In order to authorize a plant protection product in Bulgaria, data should be available to demonstrate its efficacy against those pests for which an application for biological testing has been submitted to the NSPP. Data on its toxicology and ecotoxicology should also be available. Tests proving biological efficacy of a plant protection product are carried out at the stations for biological testing of the NSPP /respectively RSPP/. Council Directive 91/414/EEC provides that biological testing is carried out satisfying GEP standards introduced by Directive 93/71/EC.

To purpose 4:

The NSPP experience shows that currently provided activities related to control of PPP application (field diaries and monitorings) are not enough in order to guarantee the food safety, limitation of the potential risk for human and animal health, biodiversity conservation,

environment protection from under grounded usage of Plant Protection Products. The implementation of Directive 91/414 EU, Regulation 178/2004 EU, Regulation 852/2004 EU is not completed.

4. Institutional Framework

Beneficiary of the project is the National Service Plant Protection.

NSPP was established in 1992 and is a part of the Ministry of Agriculture and Forestry (MAF). According to the Plant Protection Law (adopted on 25/09/1997 and amended on 25/10/2001 and 5/3/2004), the NSPP is the central official body responsible for the enforcement of the provisions relating to phytosanitary control. NSPP comprises 2 technical departments covering the above-mentioned sector — Phytosanitary Control Department (PCD) and PPI. Their official duties are ensured by CLPQ, 13 RLPQ and BIPs (there will be 12 BIPs after the accession as part of PCD) and Quarantine Department of PPI.

PPI was established in 1935 as both operative and scientific institution, and becomes a part of National Service for Plant Protection in 2003. According to the Law of plant protection (adopted 10/10/1997, amended 5/3/2004) and organization regulations of NSPP (adopted 28/5/2004), the PPI is responsible for following activities:

Development of Pest Management systems for agricultural crops

Elaboration of biological methods of pest control;

Conduction of plant immunity investigations in order to raise the resistance of crops to agricultural pests

Conduction of bionomical investigations on pests in agroecosystems

Conduction of ecological, toxicological and hygienic investigation in plant protection and assessment of the risk of contamination in plant production, soils and water by pesticides and technogenic contaminators

Development and submitting to NSPP new methods of diagnostics and identification of plant pests (including quarantine pests) and potential bioagents

Investigation on pesticide resistance of pest population and development of methods to surmount unfavorable consequences

Elaboration and submission to NSPP of new techniques and methods of information supplement for prognosis and signalization

Development and submitting to NSPP refined methods for analysis of pesticide residues Introduction and Assessment of Pest Risk Analysis for regulated pests;

The Institute consists of Eight Departments: Plant Quarantine; Phytopathology and Plant Immunity; Virology; Entomology; Biological and Integrated Pest Control; Herbology; Prognosis, and Toxicology with related laboratories. PPI staff consists of 85 persons (including 43 researchers and 31 technicians).

In order to prevent invasion, introduction and dissemination of quarantine pests and to ensure control of plants and plant products is necessary to provide Pest Risk Analysis (PRA). PRA is an essential part of phytosanitary control and development plant protection strategy of the country. PPI will provide PRA for Quarantine Pests in the Stage 1 (together with Central Laboratory for Plant Quarantine) and Stage 2. The other important obligation of PPI connected with PRA is development of logical frame of applicable database system for quarantine pests for Bulgaria.

The National Service for Plant Protection /NSPP/ is the competent body which is authorized to deal with all issues in the field of plant protection in the Republic of Bulgaria. It is

appointed as an Executive body of the Ministry of Agriculture and Forestry /MAF/ in accordance with the Plant Protection Law.

The NSPP was established in 1992. It consists of:

- Headquarters;
- Plant Protection Institute Kostinbrod;
- Central Laboratory for Plant Quarantine /CLPQ/ Sofia;
- Central Laboratory for Chemical Testing and Control /CLCTC/ Sofia;
- 14 Regional Services for Plant Protection.

The NSPP is accredited to perform the following activities:

- phytosanitary control of plants, plant and other products, quarantine measures at import, export, production, preservation, trade and movement of plants, plant and other products;
- biological testing and authorization plant protection products;
- prognosis, signalization, diagnosis, control;
- control of production, packaging, sales, preservation and application of plant protection products, biological active substances, mineral and organic fertilizers;
- control of raw materials from plant origin, soils and irrigated waters for presence of deleterious chemical and biological substances;
- control of imported and exported plant protection products, mineral fertilizers and other organic and non-organic products, used in agriculture.

The Plant Protection Products (PPP) Department is responsible for biological testing for efficacy authorization of plant protection products. Efficacy evaluation of plant protection products is carried out through field trails performed in 13 stations for biological testing at RSPPs. 30 agents from PPP Department are responsible for biological testing and authorization of PPPs. 8 agents out of 30 are situated in the Head Office.

A Council for plant protection products /CPPP/ to the Minister of Agriculture and Forestry is established as a consultative unit on matters related to the plant protection products. Its members are determined by an ordinance of the Minister of Agriculture and Forestry. They are representatives of the Ministry of Agriculture and Forestry, The Ministry of Health and the Ministry of Environment and Waters. The CPPP sits several times a year. During its sessions results from toxicology and ecotoxicology evaluation are reported as well as PPPs approved to be tested for efficacy. Upon a proposal made of the CPPP the Minister of Agriculture and Forestry authorizes by an order the placing on the market and the use of plant protection products or makes a motivated refusal

Legislation in the field of plant protection products is fully aligned with the acquis. Council Directive 91/414/EEC, Council Directive 93/71/EC and Council Directive 97/117/EC are implemented by:

- Plant Protection Act;
- Ordinance on Plant Protection Products Authorization;
- Ordinance on Biological Testing for Efficacy and Residues of Plant Protection Products and Official Recognition of Individuals and Companies to Undertake This Task;
- Ordinance On The Conditions And The Order for Labelling of Plant Protection Products.

According to the Plant Protection Law (adopted on 25/09/1997) and amended on 25/10/2001 and 5/3/2004), the NPPS is a central official body responsible for the enforcement of the provisions relating to the technical control on the application of plant protection products and the technique for application of plant protection products. The "Operative Plant Protection" Department within the National Plant Protection Service ensures the protection on plants and products of plant origin in Republic of Bulgaria from economically important pests and environment from pesticides contamination:

- 1. To ensure the quality application of plant protection products.
- 2. To ensure the safety application of plant protection products by testing the technique for application of plant protection products.
- 3. Within NPPS HQ there are 9 experts working in the "Operative Plant Protection" Department
- 4. In the Plant Protection Institute there are 3 scientific researchers, 2 specialists from section "Prognosis".
- 5. 14 RPPS there are 85 inspectors.

Specialists from NPPS are responsible for doing the quality control of PPP. An assessment of PPP is made concerning the physical and chemical parameters, transportation, packing and products quality.

32 specialists accomplish the activity of evaluation, authorization and control. Ten of them are situated in HQ.

The legal basis in the field of plant protection products is harmonized in accordance with the requirements of Directive 91/414.

The National agro-environment program, corresponding with EC Regulation N 1257/99 is based on the principals of the sustainable agriculture, which implement the principles of the good plant protection practice, the quality management system in plant protection, in respect to protect the environment from pesticide contaminations. The principals of sustainable agriculture are rational and reasonable uses of the natural recourses corresponding with the good experimental practice. NSPP is carrying out the analysis and management of risk assessment on economically important pests and pesticides contamination.

5. Detailed Budget

	Phare/Pre- Accession Instrument support:	Co	Total Cost: MEUR		
€M		National Public Funds (*)	Other Sources (**)	Total Co- financing of Project	
Investment support jointly co funded					
Supply of equipment	1.419	0.473		0.473	1.892

Investment support –	1.419	0.473	0.473	1.892
sub-total				
% of total public	max 75 %	min 25 %		
funds				

Institution Building support			
Twinning light	0.200		0.200
IB support	0.200		0.200

Total project	1.619	0.473		2.092

(*) contributions form National, Regional, Local, Municipal authorities, FIs loans to public entities, funds from public enterprises

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

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

6. Implementation Arrangements

6.1. Implementing Agency

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

Contact details of PAO are:

State Treasurer of Ministry of Finance and PAO

Address: 102 Rakovski Str.

1040 Sofia

Tel.: (+ 359 2) 9859 24 90 E-mail: <u>g.beremska@minfin.bg</u>

6.2.Beneficiary

NSPP contact points are:

Name: PhD Peter Nikolov, Director General Address: National Service for Plant Protection

Bulgaria, 1040 Sofia, 17 Hristo Botev Blvd

Tel No: +359 2 9173 701 Fax No: +359 2 952 09 87

E-mail: gen direktor@nsrz-bg.com

Name: Roumiana Krusteva, Senior Expert, IPIC Dept

Address: National Service for Plant Protection

Bulgaria, 1040 Sofia, 17 Hristo Botev Blvd

Tel No: +359 2 91 73 725 Fax No: +359 2 91 73 725

E-mail: rk integration@nsrz-bg.com

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

- Contracting authority
- EC Delegation
- MAF PIU
- Beneficiary
- Contractor

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

Contact details of the PIU:

Head of Phare Implementation Department Ministry of Agriculture and Forestry

Address: # 55 Christo Botev Blvd.

Sofia

Tel: 359 2 981 61 63 Fax: 359 2 981 75 42

e-mail: demina@phare-agr.orbitel.bg

6.3. Twinning

Twinning light project is envisaged for strengthening of the administrative capacity of the NSPP and training the experts after receiving the equipment.

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

6.5. Contracts

1. TWcontract: 0.200 EUR

2. Supply Contract: 1.892 EUR

7. Implementation Schedule

7.1.Start of tendering/call for proposals

TWL contract: October 2007
 Supply Contract: April 2007

7.2. Start of project activity

TWL contract: January 2008
 Supply Contract: October 2007

7.3 Project completion

TWL contract: June 2008
 Supply Contract: January 2008

8. Equal Opportunity

Equal opportunities for work of women and men will be assured during the project implementation. Women's participation needs no measuring as the prevailing number of employees in public administration is constituted by female experts.

9. Environment

The equipment to be supplied is intended for use at CLPQ, PPI and RSPPs, where strictest respect of safety rules related to safety for humans and nature is applied. After usage and application of previously Phare funded projects no harmful effects on the environment were registered.

10. Rates of return

The investment has no direct economic rate of return. NSPP has no production, only control functions. One of the expected results from the equipment supplied is better operativity and quality of control related to quarantine laboratory analyses, pest risk analyses, biological testing and usage of plant protection products. For meeting the EC requirement related to biological testing NSPP has applied for funding of the relevant equipment and has not received all the items; in order to comply with these requirement after the accession it has purchased a part of the necessary equipment, but due to shortage of national budget funding will be in no position to supply all of it by the beginning of this project.

11. Investment criteria (applicable to all investments)

11.1. Catalytic effect

See last sentence of the previous point.

11.2. Co-financing

The national co-financing is 25% for the investment component of the project and 10% for the Twinning light component.

11.3. Additionality

NA

11.4. Project readiness and size

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

11.5. Sustainability

The NSPP has a similar structure to the ones existing in all the EU Member States. It will continue functioning as a state control body of MAF. NSPP will continue using the equipment supplied under the project for strengthening its control functions. Personnel trained in the project will be available after project completion and NSPP will ensure maintainance of the equipment with necessary consumables.

11.6. Compliance with state aids provisions

NA

12. Conditionality and sequencing

General:

Staff available Refurbishment of premises

Availability of consumables

Specific to purpose 1:

Facilities intended to contain the equipment to be refurbished prior to supply.

Availability of experts responsible for implementation of the project and conducting of analyses.

Assurance of committement of laboratory managers, responsible for project implementation

Assurance of project co-financing

Specific to purpose 2:

NSPP ensures that the recipient laboratories of PPI are the officially responsible bodies for conducting the PRA activities.

NSPP ensures that PPI is included in the flow-chart mechanism for conduction of PRA for Quarantine pests.

The laboratory block of PPI will be refurbished before receiving the equipment mentioned. Availability of experts responsible for implementation of the project and conducting of analyses.

Assurance of project co-financing.

Specific to purpose 3

Facilities intended to contain the equipment to be refurbished prior to supply.

Availability of experts responsible for implementation of the project and conducting of biological testing.

Assurance of project co-financing

Specific to purpose 4

Before receiving the equipment described in Annexes 4, the relevant RPPS will ensure appropriate terrain for the allocation of the mobile stations be ready to receive the equipment.

Availability of experts (additional laboratory staff and inspectors for some of the BIPs are needed).

ANNEXES TO PROJECT FICHE

- 1. Logframe in standard format (<u>compulsory</u>) for each project *see Annex 6 of this Guide for guidance* plus (optional) sector monitoring sheet for sector programmes
- 2. Detailed implementation chart (compulsory for year 1, optional for future years)
- 3. Contracting and disbursement schedule, by quarter, for full duration of project (including disbursement period) (compulsory for year 1)
- 4. List of necessary equipment (compulsory)
- 5. Reference list of relevant laws and regulations (compulsory)
- 6. Reference list of relevant strategic plans and studies (may include institution sector strategies, development plans, business development plans, etc) (compulsory)— see annex 6
- 7. List of abbreviations
- 8. NSPP Structure (organigrame)

Annex 1

Log frame 2006

Project Logframe Title: Improvement of the Plant Protection control system in quarantine organisms, biological testing, authorizatio	Project name and number Contracting period expires Nov 2008	End of execution of contracts period expires: Nov 2009 Phare								
	2									
Overall Objective	Objectively Verifiable Indicators	Sources of Verification								
Strengthen the capacity of the National Service for Plant Protection under the Ministry of Agriculture and Forestry (MAF) to implement EU requirements related to control the quarantine organisms, to implement GEP based biological testing and authorization and control of the plant protection products, in order to limit the potential risk for human health, animal health, biodiversity conservation and environment for inappropriate usage of PPP.	Strengthen the capacity of the National Service for Plant Protection under the Ministry of Agriculture and Forestry (MAF) to implement EU requirements related to control the quarantine organisms, to implement GEP based biological testing and authorization and control of the plant protection products, in order to limit the potential risk for human health, animal health, biodiversity conservation and environment for inappropriate Effective management [limitation and eradication] of the quarantine organisms, specified in Directive 2000/29/EC. Trials evidencing that the PPPs are tested according to GEP procedures. Only authorized PPP are placed on the market. On-site (field) checks of PPP application. Effective management [limitation and eradication] of the quarantine organisms, specified in Directive 2000/29/EC. Trials evidencing that the PPPs are tested according to GEP procedures. Only authorized PPP are placed on the market. On-site (field) checks of PPP application.									
Project Purpose	Objectively Verifiable Indicators	Sources of Verification		ptions						
Strengthening of the administrative and technical capacity of NSPP for:	1. 100% of laboratory checks of the liquid waste materials are negative for presence of quarantine organisms by November 2009.	NSPP)	Changes in EU phytosanitary s	_						
 effective control on quarantine organisms in compliance with EU requirements establishment of reliable Pest Risk Analyses for Quarantine Pests (PRAQP), 	2. Plant Protection Institute (PPI) performs 100% of its programme for PRAQPs by November 2009, as per the International standards for phytosanitary measures (ISPM No.1 International Standard for Phytosanitary	MEW authorities NSPP Annual Reports, DB system on QP at the PPI, specific pests reports with recommendations.								

biological testing carried out in compliance with GEP standards	Measures, Directive 94/3/EC; Directive 95/44/EC; Directive 2000/29/EC and GLP).	DG SANCO reports EU consultants	
• quality control on the application of the Plant Protection Products (PPP)	3. The integral network of 14 stations for biological testing (SBT) carries out trials in accordance with GEP requirements.	NSPP Annual Report and SBT's ARs	
	4. PPP equipment tests and referent tests carried out by NSPP' 6 mobile stations and one referent mobile station.	Log books, tests protocols, etc. at the Dep. Operative Plant Protection at NSPP	
Results	Objectively Verifiable Indicators	Sources of Verification	Assumptions
1a. The glasshouse at CLPQ is fully equipped and operates according to the quarantine containment requirements of Directive 97/46/EC. 1b. Liquid wastes from the laboratory and the glasshouse are disposed appropriately, according to the requirements of the relevant EU legislation (Commission Directive 97/46/EC, Council Directive 98/57/EC). 1c. Proper retention and conservation of test samples is carrying out	1. The CLPQ is strengthened and carry out precise sanitary control for all harmful organisms listed in EU quarantine lists; equipment is delivered by November 2009	Acceptance certificates MAF authorities (including	Equipment is delivered on schedule
 2a. NSPP performs Pest Risk Management according to ISPM 2b. PPI performs implementation of standardized methods and procedures of PRA of Quarantine Pests in Bulgaria according to standards ISPM No.11 (Rev.1) and Directive 94/3/EC. 2c. Laboratory block of diagnostics of PPI is fully equipped to provide PRA for Quarantine Pests 2d. Specialists involved in the PRA for Quarantine Pests are trained how to perform studies and analyses in order to meet the relevant requirements 2e. Bulgarian database system on quarantine pests established and operational. 2f. PPI specialists are trained to to operate with the database system 	2. PPI provides Pest Risk Analysis for the basic Quarantine Pests of Bulgaria provided in accordance with PRA standards ISPM No.11 (Rev.1) and Directive 94/3/EC; Directive 95/44/EC; Directive 2000/29/EC and GLP by November 2009.		

3a. Five (5) RSPPs (RSPP Vidin, RSPP Varna, RSPP Haskovo, RSPP Dobrich, and RSPP Blagoevgrad) are equipped and carry out trials for biological testing of plant protection products in compliance with GEP standards. The Biological testing network is built up allowing to satisfy the agricultural, plant health and environmental (including climatic) conditions in Bulgaria referred to in Council Directive 91/414/EEC; 3b. Eleven Agrometeorological provide date on agroometeo condition s necessary for buiological testingstations are installed at 11 points (RSPP Varna, RSPP Dobrich, RSPP Vidin, RSPP Vratsa, RSPP Ruse, RSPP Pleven, RSPP St. Zagora, RSPP Burgas, RSPP Haskovo, RSPP Blagoevgrad, and RSPP Kjustendil) covering all areas where Biological testing is carried out. 3c. Experts are trained to operate the equipment. 4a. Six mobile stations on the territory of RSPP – Vratza, V.Turnovo, Dobrich, Blagoevgrad, Plovdiv, Bourgas are fully equipped to carry out control over farmer technique in relation with the PPP application in the field; 4b. One referent station in Sofia is testing the operation mode of the other six and their correspondence with EN: 13790 requirements;	RSPP Dobrich, and RSPP Blagoevgrad) are equipped to carry out trials for biological testing of plant protection products in compliance with GEP standards by November 2009 11 Agrometeorological are delivered and installed by November 2009 Six mobile stations in RSPP – Vratza, V.Turnovo, Dobrich, Blagoevgrad, Plovdiv, Bourgas are equipped and control farmers' technique by November 2009 One referent station in Sofia is testing the good working order of the other six and their correspondence with EN: 13790 requirements by November 2009;		
4c. NSPP experts and inspectors are trained and operate with the devices for testing the technique for application of Plant Protection Products;			
Activities	Means	Sources of Verification	Assumptions
 1a. Supply of equipment for the glasshouse with HEPA filters and devices for negative pressure, 1b. Supply of waste water storage and treatment devices 1c. Supply of equipment for a refrigerated room for proper retention and conservation of test samples; 		NSPP project coordinator for supply contract Project co-ordinator from NSPP and team /project	Reliable needs assessment of equipment is performed
2a. Supply of equipment for laboratories of virology,		leader/MS experts for the twinning contract	

bacteriology, mycology, nematology and entomology at PPI; 2b. Supply of equipment for laboratory of Molecular diagnostics at PPI; 2c. Training on implementation of the <i>Acquis</i> related to PRA:		
2d. Training of PPI specialists on PRAQP procedures and the new methods of pest diagnostics and identification 2e. Development of the database system on quarantine pests (distribution area, hosts range, etc) 2f. Training of PPI specialists in operation of the database system		
3a. Supply of equipment for Biological Testing for 5 RSPPs; training of operators 3b. Supply of Agrometeorological stations for 11 points; 3c. Training of experts		
 4a. Supply of mobile stations for control over farmer technique for six RSPP; 4b. Supply of equipment for 1 referent station in Sofia for testing the proper operation of the other six and their correspondence with EN: 13790 requirements; 4c. Training of NSPP experts and inspectors to operate with the devices for testing the technique for application of PPP; 		
		Preconditions
		Staff is available
		Refurbishment of premises

ANNEX 2

Detailed implementation chart

		2007										2008											
Component/Date	Jan	Feb	Ma r	Apr	Ma y	Jun	Jul	Au g	Sep	Oct	Nov	Dec	Jan	Feb	Ma r	Apr	Ma y	Jun	Jul	Aug	Sep	Oct	Nov
Contract 1							P	P	P	T	T	T	C	I	I	I	I	I	I				
Contract 2	P	P	P	Т	T	T	T	T	T	C	Ι	I	I										

P – Preparation

C – Contracting

 \mathbf{T} – Tendering

I-Implementation

ANNEX 3

Contracting and disbursement schedule, by quarter, for full duration of project (including disbursement period) (compulsory for year 1)

Dates	Jan 2007	Apr 2007	July 2007	Oct 2007	Jan 2008	Apr 2008	Jul 2008	Oct 2008
Contracted 1					0.200	0.200	0.200	
Disbursed 1					0.160	0.160	0.200	
Contracted 2				1.892	1.892			
Disbursed 2				1.134	1.892			

ANNEX 4

LIST OF NECESARRY EQUIPMENT

	Item	Qty	Price/item/Euro	Price/total/Euro
To purpose 1				
1	HEPA filters and instalation for negative			350 000
	pressure			
2	Instalation for waste water storage and			150 000
	treatment			
3	Refrigerated room for proper retention and			50 000
	conservation of test samples			
4	Technical designing and construction			160 000
5	Foot or knee operated taps, appropriate bench			10 000
	tops			
SUB-TOTAL 1				720 000 EUR
To purpose 2				
1	Autoclave			7200
2	Ultracentrifuge			22500
3	Safety cabinet			14000
4	Serial thermostate			4000
5	Incubators			9750
6	Purifying water-system			6000
7	Ice generator			1000
8	Nematode cyst extractor			10 000
9	Balances			12 000
10	Stereomicroscopes			12 000
11	Sequenator			80 000

SUB-TOTAL 2				178 450 EUR
To purpose 3				
1	Portable pH Meter	5	500	2500
2	Top Pan Balance	5	2300	11500
3	Laminar flow hood for the confinement of fumes	5	12000	60000
	Anemometer	5	450	11250
	Thermohygrometer	5	350	1750
	Thermometers	10	250	2500
	Equipment for Chemical Spillages	5	275	1375
	Fire Extinguishers	5	300	1500
	Microscope	5	2600	13000
	Aluminium Case	5	650	3250
	Vapour Proof Boxes	5	600	3000
	Knapsack Plot Sprayer with a test bench	5	22000	110000
	Air Assisted Knapsack Sprayer	5	850	4250
	Lever Operated Knapsack Sprayer	5	250	1250
	Filling cabinet for long-term storage of records	15	300	4500
	Small Tractor	5	30000	150000
	Cultivator	6	4000	24000
	Plough	6	4000	24000
	Disc harrow	6	4000	24000
	Universal mechanical seeder	5	6000	30000
	Small plot harvester for accurate harvesting	1	115000	115000
SUB-TOTAL 3 To purpose 4				598 625 EUR
I o p p o so	Sprayertest 1000	7	24 000	168 000
	Combined Testbox ROT-650/60/40/10			
		6	7 500	45 000
	Combined Testbox ROT-650/60/40/10 with			

TOTAL				1.889.675 EUR
SUB_TOTAL 4	Single nozzle stand ED 20	7	24 000	168 000 392 600 EUR
	Hydraulic Hand Held Test Pump	1	600	600
	Checking facility for the horizontal distribution	1	3 000	3 000
	additional devices	1	8 000	8 000

ANNEX 5

Reference list of relevant laws and regulations with schedule of transposition or implementation

Act of the acquis (Regulation/Directive)	Title of national legal act (Law/Ordinance/other)	Date of (planned) adoption	Date of entry into force	Date of submission of TOC	Date of planned submission of TOC	Drafts before colegium	Drafts under approval at MAF	Drafts under preparation at NPPS/EAVTFI SC/NFB
Plant Health								
Directive 69/464/EEC on control of Potato Wart Disease	Ordinance Nr 20 for control of potato wart disease caused by Synchytrium endobioticum (Schilb.)	02 July 2001	02 July 2001	Oct 2005				

Act of the acquis	Title of national legal	Date of	Date of	Date of	Date of	Drafts	Drafts under	Drafts under
(Regulation/Directive)	act (Law/Ordinance/other)	(planned) adoption	entry into force	submission of TOC	planned submission of TOC	before colegium	approval at MAF	preparation at NPPS/EAVTFI SC/NFB
Directive 69/465/EEC	Ordinance Nr 39 for control	08 Nov 2001	08 Nov 2001	Oct 2005				
on control of Potato Cyst Eelworm	of potato cyst eelworms							
Directive 74/647/EEC	Ordinance Nr 38 for control	08 Nov 2001	08 Nov 2001	Oct 2005				
on control of carnation leaf-rollers	of carnation leaf-rollers							
Directive 93/85EC	Ordinance Nr 19 for control	02 July 2001	02 July 2001	Nov 2005				
on control of Potato Ring Rot	of potato ring rot caused by							
	Clavibacter michiganensis							
	(Smith) Davis et al. ssp.							
	sepedonicus (Spieckermann							
	et Kotthoff) Davis et al.							
Directive 98/57/EC	Ordinance Nr 11 for control	10 April	10 April	Dec 2005				
on the control of	of potato brown rot disease	2001	2001					
Ralstonia solanacearum	caused by Ralstonia							
(Smith) Yabuuchi et al.	solanacearum (Smith)							
	Yabuuchi et al.							
Directive 92/70/EEC	Ordinance Nr 1 for	28 March	28 June	Jan 2006				
laying down detailed rules for surve	phytosanitary control	2003	2003					
to be carried out for purposes of the								
recognition of protected zones								
in the Community								
Directive 93/51/EEC	Ordinance Nr 1 for	28 March	28 June	Jan 2006				
establishing rules for movements of	phytosanitary control	2003	2003					
certain plants, plant products or								
other objects through a protected								
zone, and for movements of such								
plants, plant products or other object								
originating in and moving								
within such a protected zone								

Act of the acquis (Regulation/Directive)	Title of national legal act (Law/Ordinance/other)	Date of (planned) adoption	Date of entry into force	Date of submission of TOC	Date of planned submission of TOC	Drafts before colegium	Drafts under approval at MAF	Drafts under preparation at NPPS/EAVTFI SC/NFB
Directive 92/90/EEC establishing obligations to which producers and importers of plants, plant products or other objects are subject and establishing details for their registration	Ordinance Nr 1 for phytosanitary control	28 March 2003	28 June 2003	Dec 2005				
Directive 93/50/EEC specifying certain plants not listed in Annex V, part A to Council Directive 77/93/EEC, the producers of which, or the warehouses, dispatching centres in the production zones of such plants shall be listed in an official register		28 March 2003	28 June 2003	Dec 2005				
Directive 92/105/EEC establishing a degree of standardization for plant passports to be used for the movement of certain plants, plant products or other objects within the Community and establishing the detailed procedures related to the issuing of plant passports and the conditions and detailed procedures for their replacement	Ordinance Nr 1 for phytosanitary control	28 March 2003	28 June 2003	Feb 2006				

Act of the acquis (Regulation/Directive)	Title of national legal act (Law/Ordinance/other)	Date of (planned) adoption	Date of entry into force	Date of submission of TOC	Date of planned submission of TOC	Drafts before colegium	Drafts under approval at MAF	Drafts under preparation at NPPS/EAVTFI SC/NFB
Directive 98/22/EC laying down the minimum condition for carrying out plant health checks in the Community, at inspection posts other than those at the place of destination, of plants, plant products or other objects coming from third countries		28 March 2003	28 June 2003	Feb 2006				
Directive 95/44/EC establishing the conditions under which certain harmful organisms, plants, plant products and other objects listed in Annexes I to V to Council Directive 77/93/EEC may be introduced into or moved within the Community or certain protected zones thereof, for trial or scientific purposes and for work on varietal selections	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	04 January 2002	Dec 2005				
Directive 2002/63/EC of 11 July 2002 establishing Community methods of sampling for the official control of pesticide residues in and on products of plant and animal origin and repealing Directive 79/700/EEC	Ordinance N 31 of the Ministry of Health	Dec 2003	Dec 2003	Sept 2005				
Directive 76/895/EEC relating to the fixing of maximum levels for pesticide residues in and on fruit and vegetables	Ordinance N 31 of the Ministry of Health	Dec 2003	Dec 2003	Sept 2005				

Act of the acquis (Regulation/Directive)	Title of national legal act (Law/Ordinance/other)	Date of (planned) adoption	Date of entry into force	Date of submission of TOC	Date of planned submission of TOC	Drafts before colegium	Drafts under approval at MAF	Drafts under preparation at NPPS/EAVTFI SC/NFB
Directive 86/362/EEC on the fixing of maximum levels fo pesticide residues in and on cereals		Dec 2003	Dec 2003	Sept 2005				
Directive 86/363/EEC on the fixing of maximum levels fo pesticide residues in and on foodstu of animal origin	Ordinance N 31 of the Ministry of Health	Dec 2003	Dec 2003	Sept 2005				
Directive 90/642/EEC on the fixing of maximum levels fo pesticide residues in and on certain products of plant origin, including fruit and vegetables		Dec 2003	Dec 2003	Sept 2005				
Directive 94/3/EC establishing a procedure for the notification of interception of a consignment or a harmful organism from third countries and presenting imminent phytosanitary danger			28 March 2003	09 March 2006				
Directive 69/466/EEC on control of San José Scale	Ordinance for control of San Jose Scale				30 April 2006	Draft is under preparation		
Directive 69/464/EEC on control of Potato Wart Disease	Ordinance Nr 20 for control of potato wart disease caused by Synchytrium endobioticum (Schilb.)		02 July 2001	Oct 2005				

Act of the acquis (Regulation/Directive)	Title of national legal act (Law/Ordinance/other)	Date of (planned) adoption	Date of entry into force	Date of submission of TOC	Date of planned submission of TOC	Drafts before colegium	Drafts under approval at MAF	Drafts under preparation at NPPS/EAVTFI SC/NFB
Directive 2000/29/EC on protective measures against the introduction into the Community of organisms harmful to plants or plant products and against their spread within the Community	Ordinance Nr 1 for phytosanitary control	28 March 2003	28 June 2003		20 April 2006			
Directive 2004/103/EC on identity and plant health checks plants, plant products or other object listed in Part B of Annex V to Council Directive 2000/29/EC, which may be carried out at a place other than the point of entry into the Community or at a place close by and specifying the conditions	Ordinance for phytosanitary checks on the imports from third countries of plants, plant products or other products that have been carried out through points different from the designated points of entry to the territory of the European Community.				30 April 2006			Yes
Directive 2004/105/EC determining the models of official phytosanitary certificates or phytosanitary certificates for re-export accompanying plants, plant products or other objects from third countries and listed in Council Directive 2000/29/EC	Ordinance determining the models of official phytosanitary certificates and phytosanitary certificates for re-export accompanying plants, plant products or other objects from third countries.				15 April 2006			Yes

Act of the acquis (Regulation/Directive)	Title of national legal act (Law/Ordinance/other)	Date of (planned) adoption	Date of entry into force	Date of submission of TOC	Date of planned submission of TOC	Drafts before colegium	Drafts under approval at MAF	Drafts under preparation at NPPS/EAVTFI SC/NFB
Directive 2001/32/EC recognising protected zones exposed to particular plant health risks in the Community	Ordinance for the protected zones in the Community, exposed to particular plant health risk.				30 April 2006			Yes
Directive 91/414/EEC concerning the placing of plant protection products on the market	Amending Act to the Plant Protection Act ¹		March 2006 /planned/ 1		20 April 2006			
	Ordinance On Plant Protection Products Authorization		October 1, 2002, effective from January 1, 2006		30 April 2006			Amending draft is under preparation
	Ordinance 37 On Biological Testing for Efficacy and Residues of Plant Protection Products and Official Recognition of Individuals and Companies to Undertake This Task		October 10, 2002		30 April 2006			Amending draft is under preparation
	Ordinance On The Conditions And The Order for Labelling of Plant Protection Products		January 1, 2004		30 April 2006			

¹ The Amending Act to the Plant Protection Act fully implements Council Directive 91/414/EEC and Commission Directive 79/117/EEC. It is already adopted by the Parliament and is foreseen to be promulgated in St.G. by the end of March 2006 and come into force on the day of its promulgation in the State Gazette.

Act of the acquis (Regulation/Directive)	Title of national legal act (Law/Ordinance/other)	Date of (planned) adoption	Date of entry into force	Date of submission of TOC	Date of planned submission of TOC	Drafts before colegium	Drafts under approval at MAF	Drafts under preparation at NPPS/EAVTFI SC/NFB
Directive 79/117/EEC prohibiting the placing on the market and use of plant protection products containing certain active substances			March 2006 /planned/		30 April 2006			

List of other relevant laws and regulations

GOOD LABORATORY PRACTICES (GLP) standards ISPM No.11 (Rev.1)

ISPM NO. 11 (2004) Pest Risk Analysis for Quarantine Pests Including Analysis of Environmental Risks and Living Modified Organisms

EPPO Standards – Guideline on Pest Risk Analysis for Quarantine Pests PM 5/1 (1)

EPPO Standards – Pest Risk Analysis PM 5/2 (1)

EPPO Standards – Pest Risk Analysis Assessment Scheme PM 5/3 (1)

PLANT PROTECTION ACT – Gazette State of Republic of Bulgaria, Issue 91/19.10.1999 Amended N 96/9.11.2001, amend. N 18/5.03.2004, amended N 26 SG, 28.03.06

STRUCTURAL REGULATIONS OF THE NATIONAL SERVICE FOR PLANT PROTECTION - State Gazette Issue 46/28.05.2004; Amended № 32/12.04.2005

ANNEX 6

STRATEGY

OF

THE NATIONAL SERVICE FOR PLANT PROTECTION DEVELOPMENT

FOR THE PERIOD 2004-2009

The Republic of Bulgaria has been a Member of the World Trade Organization /WTO/ since 1997, signed the International Plant Protection Convention in 1990 and has been Member of the European and Mediterranean Plant Protection Organization since 1959, and also of *Codex Alimentarius*.

The competent body in the field of plant protection in the Republic of Bulgaria is the National Service for Plant Protection /NSPP/, which is an executive body of the Ministry of Agriculture and Forestry /MAF/ under the Plant Protection Law.

As it appears now, the NSPP was established in 1992 and now consists of:

- Headquarters
- Plant Protection Institute the town of Kostinbrod
- Central Laboratory for Plant Quarantine /CLPQ/ Sofia
- Central Laboratory for Chemical Testing and Control /CLCTC/ formerly Central Laboratory for Control of Nitrates, Pesticides, Heavy Metals and Fertilizers /CLCNPHMF/ - Sofia
- 14 Regional Services for Plant Protection

The NSPP carries out the following main activities:

- organizes, leads and accomplishes phytosanitary control of plants, plant products and other objects, activity; leads quarantine measures at import, export, production, preservation, trade and movement of plants, plant products and other objects and issues relevant documents;
- organizes, leads and conducts biological testing, registers, authorizes or prohibits the using of plant protection products and fertilizers;
- organizes, leads and accomplishes prognosis, signalization, plant protection diagnosis, prepares recommendations and accomplishes technical control of crop protection;
- exercises control of production, packing, selling, preservation and plant protection products application, biological active substances, mineral and organic fertilizers;
- controls raw materials from plant origin, soils and irrigated waters for presence of deleterious chemical and biological substances;

 controls declared contents and fitness of imported and exported plant protection products, mineral fertilizers and other organic and non organic products, used in agriculture.

The Republic of Bulgaria main policy purpose is full membership in EU at 2007. One of the main priorities of MAF in accordance with the fulfillment of Government Program after concluding the negotiation under Chapter 7 "Agriculture" since 2004 is the implementation of engagements on phytosanitary issues.

The NSPP, being directly responsible for realizing of these engagements, carries out activities in the following directions:

PHYTOSANITARY CONTROL

PURPOSES

In the field of plant protection EU main priorities are measures against the implementation and pests spread on plants and plant products. In this relation the development and strengthening of phytosanitary control are required at least for the following reasons:

- 1. With the acceptance of the Republic of Bulgaria for EU full Member State some of our borders will become EU external border and Bulgarian phytosanitary inspectors should be a sure barrier for preventing the import of quarantine pests for all Member States.
- 2. The insurance of hopeful control of plants and plant protection production in the country and effective surveillances on agriculture and forest fields are a precondition for timely discovering and helps for limited pests spreading.
- 3. The lab expertise quality, rules and precise pests identification represent the base of effective phytosanitary control.

The main EU recommendation in the 2002 Annual Regular Report is acceleration of the process for application of adopted Legislation which is executed, but for the purpose additional resources are needed. The priority measures which should be accepted concerning the implementation of this recommendation are related to:

- 1. strengthening some NSPP structures with additional personnel /laboratories and BIPs/
- 2. improving necessary equipment for application of harmonized legislation.
- 3. training personnel on application of harmonized legislation.

STATE OF PLAY

State of play of harmonized Legislation, in the area of Phytosanitary control:

- 1. Plant Protection Law, SG 91/10.October 1997, amends. SG 90/15. October 1999, amends. SG 96/9.november 2001 implements the main principles of Directive 2000/29/EEC requirements.
- 2. Ordinance **Ordinance No 1 for phytosanitary control** SG 82/17. July 1998, amends SG 91/19.October 1999, amends SG 8/22.January 2002, amends. SG 28/28. March 2003, are implemented the follow Directives:

- **Directive 2000/29/EC** of 8 May 2000 on protective measures against the introduction into the Community of harmful organisms to plants or plant products and against their spread within the Community;
- **Directive 92/70/EEC** of 30 July 1992 laying down detailed rules for surveys to be carried out for purposes of the recognition of protected zones in the Community;
- **Directive 93/50/EEC** of 24 June 1993 specifying certain plants not listed in Annex V, part A to Council Directive 77/93/EEC, the producers of which, or the warehouses, dispatching centres in the production zones of such plants, shall be listed in an official register;
- **Directive 92/105/EEC** for plant passport;
- **Directive 92/70/EEC** of 30 July 1992 laying down detailed rules for surveys to be carried out for purposes of the recognition of protected zones in the Community;
- **Directive 98/22/EC** of 15 April 1998 laying down the minimum conditions for carrying out plant health checks in the Community, at inspection posts other than those at the place of destination, of plants, plant products or other objects coming from third countries;
- **Directive 93/51/EEC** of 24 June 1993 establishing rules for movements of certain plants, plant products or other objects through a protected zone, and for movements of such plants, plant products or other objects originating in and moving within such a protected zone;
- **Directive 94/3/EEC** of 21 January 1994 establishing a procedure for the notification of interception of a consignment or a harmful organism from third countries and presenting an imminent phytosanitary danger.
- 3. With separated Ordinances are harmonized the follow Directives:
- Council Directive 69/464/EEC of 8 December 1969 on control of Potato Wart Disease implemented in Bulgarian Legislation with Ordinance No 20 against Potato Wart Disease caused by Synchytrium Endobioticum (Schilb.)SG.65 from 24 July 2001, amend. SG.8 from 22 January 2002
- Council Directive 69/465/EEC of 8 December 1969 on control of Potato Cyst Eelworm implemented in Bulgarian Legislation with Ordinance No 39 for control against Potato Cyst Eelworms SG 99 from 20 November 2001, amend. SG 8 from 22 January 2002.
- Council Directive 74/647/EEC of 9 December 1974 on control of carnation leaf-rollers implemented in Bulgarian Legislation with Ordinance No 38 for control against Carnation Leaf-Roller SG 98 from 16 November 2001, amend. SG 8 from 22 January 2002
- Council Directive 93/85/EEC of 4 October 1993 on the control of potato ring rot implemented in Bulgarian Legislation with Ordinance No 19 against potato ring rot caused by Clavibacter Michiganensis (Smith) Davis et al. ssp.Sepedonicus (Spieckermann et Kotthoff) Davis et al. SG 62 from 13 July 2001, amend. SG 8
- Commission Directive 95/44/EC fully implemented in Bulgarian Legislation with Ordinance No 1 for the conditions under which certain harmful organisms, plants, plant products and other objects may be introduced into or moved within the Community or certain protected zones thereof, for trial or scientific purposes and for work on varietal selections, SG 8/22.01.2002
- Council Directive 98/57/EC of 20 July 1998 on the control of Ralstonia solanacearum (Smith) Yabuuchi et al. implemented in Bulgarian Legislation with

Ordinance No 11 against Potato Brown Rot Disease caused by Ralstonia Solanacearum (Smith) Yabuuchi et al .SG 40 from 20 April 2001, amend. SG 8 from 22 January 2002.

ADMINISTRATIVE CAPACITY

STRUCTURES

Phytosanitary control in the Republic of Bulgaria is a part of the NSPP activity. In terms of organization the Phytosanitary control consists of:

- "Phytosanitary control" Department in NSPP Headquarters
- Central Laboratory for Plant Quarantine /CLPQ/ Sofia
- "Phytosanitary control" Departments in 14 Regional Services for Plant Protection that include phytosanitary border inspection posts.

"Phytosanitary control" Department in NSPP Headquarters, conducts national policy in this field; prepares and participates in the elaboration of normative acts and harmonization of the Legislation with EU one; organizes and controls the activities of phytosanitary structures in the country.

Central Laboratory for Plant Quarantine /CLPQ/ accomplishes phytosanitary lab expertise, diagnosis and pests identification; leads methodically and participates in Monitoring Programs of quarantine pests and analyzes the phytosanitary risk; informs and trains inspectors for diagnosis and pests identification.

"Phytosanitary control" Departments in the Regional Services for Plant Protection/RSPP/ carries out:

- phytosanitary inspection of plants and plant products at import;
- control of production of plants and plant products and other objects and conducting measures for limiting the spread of quarantine pests;
- surveillance and monitoring of agriculture and forest areas and plantations for quarantine pests;
- inspection of consignments intended for export and movement within the country;
- issuing phytosanitary certificates and plant passports.

Border import inspection are carried out at BIPs, as follows:

- 1. Port on the Black Sea Burgas, Varna /port and ferryboat/ and Balchic.
- 2. With the Republic of Turkey Malko Tarnovo /road/, Capitan Andreevo /road/ and Svilengrad /railway /.
- 3. With the Republic of Greece Novo selo /road and railway/ and Kulata /road and railway/.
- 4. With the Republic of Macedonia Zlatarevo, Logodaj and Gueshevo, all road.
- 5. With Serbia and Montenegro Kalotina, Vrushka chuka and Bregovo on road and Dragoman on railway.
- 6. With the Republic of Romania of and along the Danube the ports in Vidin, Lom, Oriahovo, Svishtov, Ruse and Silistra, and ferryboats Vidin, Oriahovo and Ruse, railway stations Ruse and Kardam, road Ruse, Silistra and Jovkovo.
- 7. Airport -Sofia.

EQUIPMENT

Under Phare projects, the Central Laboratory for Plant Quarantine has purchased modern equipment and a greenhouse is build for indicator plants. The labs in RSPP Burgas, Varna, V.

Tarnovo and Plovdiv also are equipped for routine analyses. Under the same Projects 10 long-term BIPs have been granted basic equipment. They will be external EU border in the future.

FORTHCOMING ACTIVITIES

PERMANENT TASKS

- 1. Providing sufficient personnel for the long-term BIPs and for the labs in the system.
- 2. Training Headquarters specialists, inspectors and lab specialists from RSPP and CLPQ personnel for application of adopted Legislation and strengthening the control of their direct responsibilities.
- 3. Involving more inspectors as National Reporters on certain questions.
- 4. Monitoring Programs for quarantine pests on potatoes, vines, fruits, strawberries, cotton, corn, and forest species and in greenhouses, so we can be recognized as protected zone in within the frames of the Community.
- 5. Involving interns and Bulgarian Association for Plant Protection in the Monitoring Program and surveillance for pests.
- 6. Analysis of phytosanitary risk and on this base reassessment of lists of pests under Annexes of the Ordinance No1 for phytosanitary control.
- 7. Improving RSPP's and inspectors' acquaintance concerning the requirements and conditions of import of plants and plant products in third countries.
- 8. Strengthening contacts and mutual co-operation with Stakeholders of producers and importers of plants and plant products, institutes and others.

ASSIGNMENTS BY YEARS

2004

- 1. Equipment of the Regional labs for routine analyses as follows: RSPP Blagoevgrad, Vidin, Vratza, Dobritch, Pleven, Ruse, Stara Zagora and Haskovo, financed under PHARE program.
- 2. Equipment of BIP Gueshevo and airport Sofia with optic and other appliances for border control financed under PHARE program.
- 3. Opening BIP Ilinden /Gotze Deltchev Drama/, built and equiped, under PHARE program.
- 4. Building the new premises at BIP Capitan Andreevo and Gueshevo.
- 5. Starting of the building procedures for BIP, RSPP and CLPQ aiming at preparing the implementation of Quality Assurance System on phytosanitary control.
- 6. Pilot tests in work conditions on the revised information system on Plant Quarantine, allowing all the points to use information in real time.
- 7. Providing the CLPQ and Regional labs with more personnel, which would comprise 19 agents in total.

FINANCING – 2004

MEASURES	PHARE/EUR	BUDGET/BGN
1. Building premises for phytosanitary control at	-	100 000
BIP – Gueshevo		
2. Equipment and further equipment of CLPQ,	800 000	400 000

RSPP and BIP, building of the BIP		
3.Training personnel	150 000	100 000
4. Providing consumables for work for the	-	130 000
RSPP, BIP and labs		
5. Providing the CLPQ and Regional labs with	-	340 000
more personnel		

2005

- 1. Amendments of Ordinance № 1 for phytosanitary control, aiming at preparing the implementation of the Directive 2002/89/EEC and the Decisions of the European Commission 96/301/EC in the Bulgarian legislation.
- 2. Transferring serial potatoes analyses in Potato Lab in Samokov /Unit of CLPQ/ for viral and bacteriological analyses 2003.
- 3. Equipment of the regional lab of RSPP Kustendil for routine analyzes, financed under PHARE program.
- 4. Building new premises at BIP Kalotina
- 5. Equipment of RSPP with stock for production control, making a trail and others.
- 6. Implementation of Quality Assurance System in 3-4 BIPs, 2-3 RSPPs and the CLPQ.
- 7. Introducing on phytosanitary control the updated information system on Plant Quarantine, allowing all the points to use information in real time.
- 8. Providing the regional labs with personnel which would comprise 10 agents in total.

FINANCING 2005

MEASURES	PHARE/EUR	BUDGET/BGN
1. Equipment of the RSPP and regional lab in	800 000	500 000
Kustendil		
2. Repairing structures and premises, vehicles,		200 000
buying equipment		
3. Building new premises at BIP Kalotina	-	150 000
4. Training personnel	•	200 000
5. Providing consumables for work of the RSPP,		150 000
BIP and labs		
6. Providing the regional labs with personnel	-	170 000
7. Maintaining and improving "Plant quarantine"	-	50 000
Information System		

2006

- 1. Revision of Annexes 1-5 of Ordinance №1 for phytosanitary control and their approximation with the relevant Annexes of Directive 2000/29/EEC.
- 2. Building a purifying system on water waste at CLPQ.
- 3. Implementation of Quality Assurance system in all long-term BIPs and 7-8 RSPPs.
- 4. Implementation on phytosanitary control of updated information system on Plant Quarantine, allowing all the points to use information in real time.
- 5. Providing long-term BIP external border on EU with personnel, which would comprise 8 agents in total.

FINANCING - 2006

MEASURES	PHARE/EUR	BUDGET/BGN
1.Building a purifying system on water waste at	-	200 000
CLPQ.		
2. Repairing structures and premises, vehicles,	-	300 000
maintaining installations.		

3.Training personnel	-	200 000
4.Providing consumables for work of the RSPP,	-	300 000
BIP and labs		
5. Providing long-term BIP – external border on	-	170 000
EU with personnel		
5. Maintaining and improving "Plant quarantine"	-	50 000
Informational System		

2007-2009

- 1. Participation of Bulgarian experts in the Committee on EU phytosanitary measures.
- 2. Acting BIPs for EU: Port on the Black Sea Burgas, Varna /port and ferryboat/; with the Republic of Turkey Malko Tarnovo /road/, Capitan Andreevo /road/ and Svilengrad /railway/; with the Republic of Macedonia Zlatarevo, Logodaj and Gueshevo, all road; with Serbia and Montenegro Kalotina, Vrushka chuka and Bregovo on road and Dragoman on railway; with the Republic of Romania of and along Danube ports and ferryboats in Vidin and Ruse; Airport Sofia.
- 3. Elaboration of motivated requests to European Commission for additional financing for control on quarantine pests and for work at BIPs in accordance with the rules of Directive 2000/29/EEC.
- 4. Re-structuring BIPs as EU border posts responsible for the import control for all Member States.
- 5. Providing RSPP and labs with personnel.
- 6. CLPQ Balkans centre for diagnosis and training.
- 7. Implementation of Quality Assurance System in all NSPP structures.
- 8. Incorporating in informational system for fast announcing of EU "EUROFIT"

FINANCING - 2007-2009

MEASURES	PHARE/EUR	BUDGET/BGN
1. Repairing structures and premises, vehicles,	-	500 000
maintaining installations, buying computers and		
installations		
2.Training personnel	-	150 000
3. Providing consumables for work of the RSPP,	-	300 000
BIP and labs		
4. Maintaining and improving "Plant quarantine"	-	50 000
Information System		

BIOLOGICAL TESTING, AUTHORIZATION AND CONTROL OF PLANT PROTECTION PRODUCTS

STATE OF PLAY

The National Service for Plant Protection manages the biological testing for efficacy and organizes the plant protection products authorization.

Efficacy assessment of each product is carried out through field trails conducted in 13 Regional Stations in the country. Three of them – Plovdiv, Vratza and Pleven, are equipped with the facilities needed to carry out trails with plant protection products in conformity with the requirements of Good Experimental Practice (GEP). In 2004 another three stations are being equipped – Burgas, Stara Zagora and Ruse and in 2005 the other seven stations will do so.

The entire evaluation /toxicology and efficacy/ is carried out by the NSPP and the NCHMEN /National Centre for Hygiene, Medical Ecology and Nutrition/. The proposal for plant protection product authorization is made by the Council for Plant Protection Products. The Council consists of representatives from different departments, scientific workers and specialists.

Specialists from NSPP and CLCPNHMF are responsible for the quality control of plant protection products. An assessment of plant protection products is made, concerning the physical and chemical parameters, transportation, packing and products quality.

32 specialists accomplish the activity of evaluation, authorization and control. Ten of them are situated in Headquarters.

The legal basis in the field of plant protection products is harmonized in accordance with the requirements of Directive 91/414; Directive 93/71 and Directive 97/117 through:

- Plant Protection Law.
- Ordinance No 32 of 9 July 2001 for control of plants and plant products, fertilizers and growing medium for testing, registration and plant protection products control.
- Ordinance No 37 of 26 September 2002 for biological testing for efficacy and pesticide residues of plant protection products and approving of physical and legal persons for its accomplishment.
- Ordinance for the conditions and order for plant protection products labeling.
- Ordinance for plant protection products authorization.

PURPOSES

Creating favorable institutional, normative and administrative media for the development of plant protection.

In the field of biological testing, authorization and plant protection products control, this purpose is accomplished through:

- Approximation of Bulgarian Legislation, which should be accomplished in a way to guarantee a softer economic and administrative adaptation to the EU criteria, to the Bulgarian and foreign plant protection products producers and farmers.
- ➤ Penetration of the private sector in the field of biological testing of plant protection products.
- ➤ "Biological testing, authorization and control of plant protection products" Department is to be a permanent source of knowledge and practical skills in the field of plant protection and plant protection products.
- > Soft implementation of EU principles, related to plant protection products authorization, which ensures the normal flux of plant protection products for use and trade.

BIOLOGICAL TESTING OF PLANT PROTECTION PRODUCTS

PRIORITIES

- Updating the legal basis.
- ➤ Implementation of Good Experimental Practice (GEP) principles. The RSPP and the NSPP are official testing stations, which accomplish biological testing following the EU requirements.
- > Implementation of European requirements for testing plant protection products for efficacy in the NSPP system.
- ➤ Implementation of European requirements for testing of plant protection products for efficacy in the NSPP system through a definition of clear requirements that physical and legal persons who want to be approved to carry out biological testing, should fulfill.
- ➤ Implementation of Quality Assurance System in the field of biological testing of plant protection products within the NSPP and a definition of criteria for the approved physical and legal persons.

ACTIONS

2004

- > Participation in working groups for amendments of Plant Protection Law
- ➤ Updating Ordinance No 37 in order to harmonize the Normative acts for biological testing of plant protection products with the EU one so Bulgaria could comply adequately with the EU requirements in this field.
- ➤ Implementation of EU Methodological Guidances for biological testing for efficacy of plant protection products.
- > Updating and development of new Standard Operative Procedures (SOP).
- > Training on statistical data processing from trails for efficacy of plant protection products.
- > Training in France and Bulgaria under GEP.
- ➤ Participation in different seminars and trainings concerning biological testing of plant protection products in EU Member States in order to implement things learned from practice within the country.

FINANCING - 2004

MEASURES	PHARE/EUR	BUDGET/BGN
1. Equipment under PHARE projects	273 612	-
2.Training personnel	59 338	-
3. Translating European Methodological	-	50 000
Guidances and other documents		
4.Repairing structures and premises of	-	200 000
Biological Testing Stations		
5. Providing consumables for biological testing	-	81 000

of plant protection products		
6.Providing with additional personnel – 2	-	34 000
specialists (Kostinbrod, Ruse)		
	TOTAL	415 000

RESULTS:

- ➤ A project of updated Ordinance No 37 will be prepared at the end of 2004. This project will be presented to the Ministry Collegium for approval.
- ➤ A Plant Protection Bill to be elaborated in the part for biological testing of plant protection products.
- Experts to be trained on statistical data processing and to get acquainted with the basic principles related to its application.

2005

- Training on accomplishment of trails for phytotoxicity, crop safety, impact on adjacent and succeeding crops, resistance, impact on useful varieties and others.
- ➤ Building information network between NSPP and Biological Testing Stations in order to improve information exchange.
- ➤ Introducing and translation of Guidances for accomplishing field trails for pesticide residues.
- > Training on accomplishment of an inspection for bases approval for carrying out a biological testing of plant protection products in institutes and in the private sector and preparation of the necessary documentation.
- > Training of Quality experts in Bulgaria and in EU Member States for implementation of Quality Assurance System on biological testing of plant protection products.
- Implementation of statistical data processing of the results received from single trails for biological testing of plant protection products as a part of the preparing of a report from serial trails in confirmation of Biological Assessment Dossier.

FINANCING - 2005

MEASURES	PHARE/EUR	BUDGET/BGN
1.Technical assistance under PHARE projects	150 000	-
2. Repairing structures and premises of	-	100 000
Biological Testing Stations		
3. Providing consumables for biological testing of	-	70 000
plant protection products		
4. Constructing Informational net	-	150 000
5. Additional personnel	-	10 000
6.Constructing Program for statistical data	-	20 000
processing		
7. Translating documents	-	50 000
8. Training experts in Bulgaria and EU Member	-	100 000
States		
	TOTAL	500 000

RESULTS:

- ➤ Improving data information exchange between the different testing stations, between them and the NSPP Headquarters.
- ➤ The experts who will accomplish inspections to approve physical and legal persons will get acquainted with the criteria, ways and necessary documentation during inspection.
- > Trails accomplishment for phytotoxicity, crop safety, impact on adjacent and succeeding crops, resistance, impact on useful varieties and others in confirmation of biological dossier.

2006

- ➤ Elaborating a Quality Manual for Biological Testing under Good Experimental Practice (GEP).
- ➤ Entire implementation of GEP principles in official testing stations in Bulgaria RSPP of NSPP.
- > Training on accomplishment of field trails for pesticide residues from plant protection products and under Good Laboratory Practice (GLP).

FINANCING - 2006

MEASURES	PHARE/EUR	BUDGET/BGN
1.Maintaining structures and premises of	-	100 000
Biological Testing Stations		
2. Providing consumables for normal work of	-	80 000
Biological Testing Stations		
3. Training experts in Bulgaria and EU Member	-	20 000
States		
4.Providing additional equipment for carrying		200 000
out pesticide residue samples		
5. Elaborating a Quality Manual for Biological	-	200 000
Testing under Good Experimental Practice		
(GEP)		
	TOTAL	600 000

RESULTS:

- > The RSPPs attached to the NSPP, which are official testing stations for the country, would work in accordance with the GEP requirements.
- ➤ The Quality Assurance System would be implemented.

Acquaintance with the basic principles for accomplishment of field trails for pesticide residues under GLP.

2007

- > Preparation for accreditation of NSPP system under GEP.
- > Accomplishing trails for pesticide residues from plant protection products under GLP
- > Securing the transition from the National Legislation system of the EU one.

FINANCING - 2007

MEASURES	PHARE/EUR	BUDGET/BGN
1.Maintaining structures and premises of	-	150 000
Biological Testing Stations		
2. Providing consumables for normal work of	-	80 000
Biological Testing Stations		
3. Providing additional equipment for carrying	-	100 000
out pesticide residue samples		
4.Providing additional personnel for carrying out	-	70 000
pesticide residue samples		
5. Translating documents and training personnel	-	100 000
	TOTAL	500 000

RESULTS:

- ➤ The bases within the NSPP system would work in accordance with the GEP requirements and the results would be recognized by other Member States.
- Accomplishment of trails for pesticide residues under GLP.

2008

- ➤ Elaboration and implementation of registers of the biological tested products and products for biological testing declared in the NSPP and stations for biological testing.
- ➤ Participation of Bulgarian specialists in EU Committees and working groups.
- ➤ Permanent tracing of changes in EU Legislation and their implementation in Bulgarian legislation
- ➤ Accreditation of NSPP system under GEP principles

FINANCING - 2008

MEASURES	PHARE/EUR	BUDGET/BGN
1.Maintaining structures and premises of	-	100 000
Biological Testing Stations		
2.Providing consumables for normal work of	-	80 000
Biological Testing Stations		
3. Training experts in Bulgaria and EU	-	100 000
4. Providing resources for accreditation	-	100 000

5. Translating documents and training personnel	-	70 000
	TOTAL	450 000

RESULTS:

- Accomplishment of biological testing in accordance with GEP requirements
- Recognition of the results from biological testing by other EU Member States.
- Accomplishment of trails for pesticide residues.
- ➤ Participation in EU committees and information exchange with the other EU Member States.

2009

- ➤ Participation of Bulgarian experts in different EU committees.
- Acquaintance with the updated EU legal basis and its implementation in Bulgaria

FINANCING - 2009

MEASURES	PHARE/EUR	BUDGET/BGN
1.Maintaining structures and premises of	-	100 000
Biological Testing Stations		
2.Providing consumables for normal work of	-	80 000
Biological Testing Stations		
3. Training experts in Bulgaria and EU	-	100 000
4. Fies for participation in EU Commissions	-	100 000
5. Translating documents and training personnel	-	50 000
	TOTAL	420 000

RESULTS:

- Accomplishment of biological testing in accordance with GEP requirements
- Recognition of the results from biological testing by other EU Member States.
- > Accomplishment of trails for pesticide residues.
- ➤ Participation in EU committees and information exchange with the other EU Member States.

PLANT PROTECTION PRODUCTS (PPP) AUTHORIZATION

PRIORITIES

- > Drawing up a draft for modifications of Ordinance on PPP authorization that complies with the EU requirements and at the same time secures a softer transition from the national legislation to the European one
- Drawing up an activity regulation of PPP Council
- ▶ Updating the legal basis Plant Protection Law in the part for PPP authorization
- > Trainings on technical processing of documentation related to PPP authorization under EU requirements
- Documents preparation (applications, certificates, guidelines, etc.), related to PPP authorization process
- ➤ Biological assessment dossier trainings analysis of presented dossier and preparation of a report and an assessment summary
- Drawing up Quality Manual on PPP authorization
- **>** Beginning of PPP re-registration under EU requirements
- Developing and adopting a data exchange system between NSPP, EC and EU Member States
- Developing a software for authorized PPP
- Periodical tracing of new EU decisions and their reflection in the Bulgarian legislation
- > Implementation of authorization for PPP parallel import, PPP mutual recognition by MS in Bulgaria, an authorization extension under EU requirements

ACTIONS

2004

- Participation in working groups destined to draw up a new Plant Protection Law (PPL)
- Amendments of Ordinance on PPP authorization
- > Trainings on administrative processing of documentation, related to PPP authorization under EU requirements
- Fraining on biological evaluation of dossiers for efficacy, assessment of resistance risk, crops safety, impact on succeeding and adjacent crops, useful varieties etc.
- Documents preparation related to PPP authorization process
- > Trainings on PPP parallel import, PPP mutual recognition by MS in Bulgaria, an authorization extension under EU requirements
- Trainings of PPP companies on PPP dossiers preparation

FINANCING

MEASURES	PHARE/EUR	BUDGET/BGN
1. Funding for training in the field of plant protection products authorization	-	150 000
2.Translating documents, Directives, Guidances	-	100 000
	TOTAL	250 000

RESULTS:

Prawing up a new, updated PPL that complies with EU requirements

- > Drawing up an updated version of the Ordinance on PPP authorization reflecting more accurately the EU requirements
- Acquaintance with the administrative processing of information
- Acquaintance with the general view of Biological assessment dossier
- Documents preparation in respect with the Ordinance

2005

- > Drawing up an activity regulation of PPP Council
- Developing a register of authorized PPP
- > Trainings on administrative processing of documentation, related to PPP authorization under EU requirements
- Trainings on Biological assessment dossier assessment of risk for crops (succeeding and adjacent) and resistance

FINANCING

MEASURES	PHARE/EUR	BUDGET/BGN
1. Funding for training in the field of plant protection products authorization	-	100 000
2. Developing a register for plant protection products authorization	-	50 000
3. Translating documents, Directives, Guidances	-	50 000
	TOTAL	200 000

RESULTS:

- > Creation of a system for reception and administrative processing of the documentation on authorization
- Detailed acquaintance with the content of the Biological assessment dossier
- Use of authorized PPP software

2006

- Creation of archives and trainings on keeping the documentation
- Beginning of drawing up a Quality Manual on authorized PPP
- > Training on drawing up reports on assessment of old and new active substances to be included in Annex 1 of Council Directive 91/114/EC
- Training on drawing up a report and a summary of the Biological assessment dossier
- Beginning of the PPP re-registration process in conformity with the EU requirements
- Practice on Biological assessment dossier

FINANCING

MEASURES	PHARE/EUR	BUDGET/BGN
1. Funding for training in the field of plant protection products authorization	-	100 000
2. Providing with PPP authorization specialists – 3 agents		51 000
3. Funding for plant protection products reregistration process	-	200 000
4. Translating documents, Directives, Guidances	-	100 000
	TOTAL	451 000

RESULTS:

- > Creation of archives for incoming documentation
- ➤ Beginning of PPP re-registration process
- Biological assessment dossier

2007

- Beginning of the implementation of a Quality Manual on PPP authorization
- Training on drawing up reports on assessment of old and new active substances to be included in Annex 1 of Council Directive 91/114/EC
- Biological assessment dossier
- Continuing the PPP re-registration process in conformity with EU requirements
- Periodical approximation of the legislation with new EU requirements

FINANCING

MEASURES	PHARE/EUR	BUDGET/BGN
1. Funding for training in the field of plant protection products authorization	-	100 000
2. Funding for plant protection products reregistration process	-	200 000
3.Translating documents, Directives, Guidances	-	50 000
	TOTAL	350 000

RESULTS:

- Completed PPP re-registrations that contain active substances included in Annex 1
- > Installation of the system for reception and administrative processing of documentation
- **>** Keeping the documentation and maintaining the archives

2008

- Definitive implementation of a Quality Manual on PPP authorization in Bulgaria
- Continuing the PPP re-registration process in conformity with EU requirements
- ► Biological assessment dossier and trainings of experts
- Participation of NSPP experts in EU standing committees

FINANCING

MEASURES	PHARE/EUR	BUDGET/BGN
1. Funding for training in field of plant protection products authorization	-	100 000
2. Funding for plant protection products reregistration process	-	200 000
3. Fees for participation in EU committees		100 000
4. Translating documents, Directives, Guidances	-	50 000
	TOTAL	450 000

RESULTS:

- PPP re-registration when active substance included in Annex 1
- > Processing, assessment and keeping the documentation in conformity with EU requirements
- Delivery of certificates to authorized PPP

2009

- > Developing and adoption of a data exchange system between the NSPP, EU Member States and EC
- Participation of NSPP experts in EU standing committees
- > Trainings of experts

FINANCING

MEASURES	PHARE/EUR	BUDGET/BGN
1. Funding for developing a data exchange	-	500 000

system between the NSPP, EU Member States and EC		
2. Fees for participation in EU committees		100 000
3. Translating documents, Directives, Guidances	-	50 000
	TOTAL	650 000

RESULTS:

- ▶ PPP re-registration when active substance included in Annex 1
- > Processing, assessment and keeping the documentation in conformity with EU requirements
- Delivery of certificates to authorized PPP
- Data exchange between the NSPP, EU Member States and EC

PPP CONTROL

PRIORITIES

- Amendments of the legal basis
- Control at import and transport of PPP
- Control on warehousing, trade and use of PPP
- Control on packing PPP
- Control on labeling PPP

2004

- Participation in working groups for Amendments of Plant Protection Law
- Amendments of the Ordinance on the conditions and order of labeling PPP
- Periodical controls (planned and on signal) at the workshops that pack PPP
- Periodical controls (planned and on signal) at the warehouses and agricultural pharmacies to secure correct labeling, packing and content of PPP
- > Preparation for replacement of the license regime with a registration regime for trade with PPP
- Preparation for transition of the registration regime activity to BAPP

FINANCING

- resources needed to carry out controls
- resources needed 20 000 lv

RESULTS:

- Updated information on licensed companies within the country for trade with PPP
- Complete list of RSPP warehouses destined to keep PPP within the country
- Updated list of companies that pack PPP within the country
- > Updated list of physical persons licensed to carry out the fumigation within the country

> Complete data concerning the assortment of PPP offered at the network of shops within the country

2005

- ► Amendments of Ordinance № 32
- Replacement of the license regime with a registration regime for trade with PPP
- Transition of the registration regime activity to BAPP
- Periodical controls at the workshops that pack PPP
- Periodical controls at the warehouses and agricultural pharmacies to secure correct labeling, packing and content of PPP
- > Preparation to draw up a legal basis concerning the control of the transport of PPP jointly with the Ministry of Interior
- Maintaining contacts with other administrations and non-governmental organizations Economic police, Inspection for Hygiene and Epidemiology, Commission on Protection of Consumers' Rights, BAPP, Ministry of Environment and Water, National Customs Agency, etc.
- Creation of a register of companies that run a commercial activity with PPP

FINANCING

- resources needed to carry out controls
- resources needed 20 000 lv.

RESULTS:

- Updated information on licensed companies within the country for trade with PPP
- Complete list of RSPP warehouses destined to keep PPP within the country
- Updated list of companies that pack PPP within the country
- Updated lis t of physical persons licensed to carry out the fumigation within the country
- ➤ Complete data concerning the assortment of PPP offered at the network of shops within the country
- > Updated list of authorized PPP within the country in conformity with the EU requirements

2006

- Periodical controls at the workshops that pack PPP
- Periodical controls at the warehouses and agricultural pharmacies to secure correct labeling, packing and content of PPP
- Maintaining contacts with other administrations and non-governmental organizations Economic police, Inspection for Hygiene and Epidemiology, Commission on Protection of Consumers' Rights, BAPP, Ministry of Environment and Water, National Customs Agency, etc.
- Controlling PPP advertising

FINANCING

- resources needed to carry out controls

- resources needed - 20 000 lv.

RESULTS:

- Updated register of companies that run a commercial activity with PPP
- > Updated list of authorized PPP within the country in conformity with the EU requirements

2007-2009

- Periodical controls at the workshops that pack PPP
- Periodical controls at the warehouses and agricultural pharmacies to secure correct labeling, packing and content of PPP
- Maintaining contacts with other administrations and non-governmental organizations Economic police, Inspection for Hygiene and Epidemiology, Commission on Protection of Consumers' Rights, BAPP, Ministry of Environment and Water, National Customs Agency, etc.
- Controlling PPP advertising
- Updating legal documentation in the field of control in conformity with EU requirements

FINANCING

- resources needed to carry out controls
- resources needed 20 000 lv.

RESULTS:

- Quality PPP offered at the commercial network
- > Full data on keeping, packing and offering PPP
- Register of authorized PPP offered within the country

CONTROL OF PESTICIDES, NITRATES, HEAVY METALS AND FERTILIZERS

The Central Laboratory for Chemical Testing and Control /CLCTC/ - formerly Central Laboratory for Control of Pesticides, Nitrates, Heavy Metals and Fertilizers has complex characteristics and it is the only lab in the MAF system that controls both products intended for agriculture - pesticides and fertilizers, and raw materials and foodstuff from plant origin.

Main activities:

- Residues analysis of contaminators in plant production, soil and irrigation waters
- Testing of PPP conformity
- Testing conformity of minerals, organic fertilizers and soil ameliorators
- Agrochemical analyses of soils, plants and irrigation waters, and fertilizing recommendations

In the frames of several Phare projects in 1999 – 2004 the Lab was equipped with most up-to-date analytical facilities and it does not succumb to leading European laboratories in terms of instrumental provision.

CLCTC /formerly CLCPNHMF/ disposes of highly qualified staff, trained in the frames of several Phare projects. Trainings were conducted in our country and in leading EU labs, mainly in the field of specific instrumental technics and analyses, as well as in the field of quality assurance in testing laboratories.

The Laboratory disposes of Quality Assurance System that is set up and functioning For all conducted activities CLCTC /formerly CLCPNHMF/ is accredited by EA "BAS" according to the Bulgarian State Standard EN ISO /IEC 17025 with Certificates No 17 LI (17) and No 18 LI (18) valid till 28.02.2007

Forthcoming activities in relation with the future EU accession of Bulgaria:

- 1. International accreditation of CLCTC /formerly CLCPNHMF/ for residues analysis of pesticides in and on products of plant origin.
- 1.1. Preparing CLCTC /formerly CLCPNHMF/ for application of an accreditation by European accreditation body for residues analysis of pesticides in and on products of plant origin.
 - Term: 2005 2006
 - Needed funds: 20 000 BGN
- 1.2. Obtaining accreditation by European accreditation body
 - Term: 2007
 - Needed funds: 30 000 BGN
 - Expected results: increased confidence in lab performance by the EU member states
- 2. Participation in national and internal organization programmes for monitoring of foodstuff of plant origin for pesticides residues and mycotoxins substance.
 - Term: 2004 2009
 - Needed funds: 80 000 BGN annually
 - Expected results:
 - to make assessment of levels of pesticide residues in plant production and relatively their conformity with the maximum safe norms according to Ordinance No 31;
 - to make risk assessment for Bulgarian consumer if pesticides residues in foodstuff of plant origin included in their menu;
 - to ensure correct applying of authorized PPP (doses for application, quarantine terms, their use for objectives that are authorized);
 - MAF, respectively NPPS to achieve experience and readiness for participation in the coordinated monitoring program of the European Community after 2007, provided we will appreciate it.
- 3. Participation in field trials for pesticides residues at biological testing of PPP
 - Term: 2007 –2009
 - Funds needed: in function of tested PPP
 - Expected results: ensuring of data necessary for compiling PPP dossiers in accordance with the requirements of Directive 91/414/EEC

- 4. Participation in the work of the PPP Council in the part of pesticides residues
 - Term: 2005 2009
 - Funds needed: no separate budget is necessary
 - Expected results: assisting the work of the PPP Council at reviewing and evaluation of PPP dossiers
- 5. Testing objects related to biological agriculture soils, organic fertilizers and soil ameliorators, authorized for use natural PPP, plant stuff produced from organic farming
 - Term: 2004 –2009
 - Funds needed: no separate budget is necessary
 - Expected results: promoting development of organic farming in Bulgaria.

Forthcoming activities in relation with the internal organization control and its efficiency

- 1. Improving coordination between the Headquarterss of NPPS and the RPPS
 - Term: 2004 2009
 - Expected results: raising effectiveness of control related to PPP, fertilizers and plant production
- 2. Raising opportunities for analysis of various contaminators in plant products
 - Term: 2004 2009
 - Funds needed: for raising experts' qualification in the frames of budget, assigned to CLCTC /formerly CLCPNHMF/.
 - Expected results: promoting export of plant products

Forthcoming activities related to improving quality of work in CLCTC /formerly CLCPNHMF/

- 1. Implementing new analyses methods for plant products, soils, waters, fertilizers and PPP
 - Term: 2004 –2009
 - Funds needed: in the frames of the budget assigned to CLCTC /formerly CLCPNHMF/
 - Expected results: possibly best satisfying of customers
- 2. Participation in cycle testing of suitability in the country and abroad
 - Term: 2004 2009
 - Funds needed: fees for participation in testing
 - Expected results: objective quality assessment of the activities performed in CLCTC /formerly CLCPNHMF/
- 3. Improving the quality assurance system of CLCTC /formerly CLCPNHMF/
 - Term: 2004 2009
 - Funds needed: in the frames of the budget assigned to CLCPNHMF
 - Expected results: permanent confidence raising in the laboratory performance

System of monitoring, diagnostics, prognostics and signalization

As a candidate for EU country the republic of Bulgaria should meet a number of criteria related to applying PPP and safety of produced foods and raw materials of agricultural origin. In the state of market economy, agricultural production sets new requirements to the state control bodies in plant protection.

Though it has multifunctional significance for agricultural crops protection, the main point of the system is to prognosticate pests emerge. In plant protection that means to foresee emerge of diseases and plant pests, regions and areas of their spread and extent of infection in order to predict expected harm. A conclusion of any prognostics in plant protection is signalization, i.e. determination and announcing of optimal terms at implementing plant protection measures in the region to the agricultural producers.

In modern plant protection the principles of Good Plant Protection Practice and Integrated Pest Management are laid; and also considering the negative effects of chemical methods, the system achieves further significance. To determine and recommend to agricultural producers pesticides applying in reasonable terms, having respect of a number of requirements (economic, environmental, ecological, sanitary-hygiene) has a priority importance.

In modern circumstances this is the only independent governmental structure, highly competent in issues of agricultural crops protection from pests of economic importance in our country.

New criteria and requirements of rapidity, promptness and quality of work are set ahead of the system of monitoring, diagnostics, prognostics and signalization in order to meet the new requirements and needs of producers.

OBJECTIVE

Protection of agricultural crops and plant production in Republic of Bulgaria from pests of economic importance and environment protection from pesticide pollution.

In response of these issues experts of the system organize and perform following activities:

Monitoring

Experts of the system perform regular monitoring of over 125 pests, 61 diseases and 46 weeds, listed in the list of agricultural crops pests of economic importance. They use over 100 methods and methodical guidance for monitoring and investigation of emerge, development and spread of "permanent objects of monitoring". They also use a great number of technical and other auxiliary means.

Diagnostics

In NPPS structure an orderly, level-based system is built up for diagnostics of diseases, pests and weeds that have been established in monitored regions. A system of laboratories on regional and national level that meets contemporary requirements is set up. Diagnostics conducted includes species, stage and phase identification of pests through visual and lab expertise.

Territory survey

Through investigation experts register crops phenophase, variety, localization, area size, pest stage or phase, extent of infestation and type of disease, weeds phenophase. Pest spread on the territory of the country and health condition of agricultural crops is defined. Density and infestation extent are tracked. In national scale the country is separated to 95 agroecological regions.

Emerge of pests throughout different years is not equal in time in space. This dynamics imposes tracing of pests population density and reporting of infested by disease and pests areas with density under and over thresholds levels of economic importance seasonly, tracing of conditions to create and pass over critical periods for their development.

Prognostics

Experts of the NPPS compose short-term, medium-term, seasonal and yearly prognostics of the development and spread of agricultural crops pests, this is distributed according to regions and for the country, and it is based on data on pest population status and spread as well as on multilateral analyses of biotic, abiotic and anthropogenous factors impact.

Based on the fore-mentioned:

Signalization

By signalization time of pests emerged, harmful stage/phase of their development, crucial phenophase of crops development are defined. Depending on infestation density and extent that have been established at region investigation, and the analysis and prognostics of pest development that have been performed, agricultural producers are signaled of hazards and optimal term of implementing plant protection measures is defined.

Experts of each RPPS periodically draft and send to agricultural producers "Bulletin of emerge, spread, density, development, infestation extent, terms, means and ways of pest control"; it is up to date for a certain period of time, usually via annual subscription.

At mass spread, crucial status, calamity and epiphitoty agricultural producers, NPPS and public are informed by a bulletin, communications to municipalities, local and national mass media.

Means and ways of control

In the "Bulletin" issued by RPPS agrotechnical and preventive measures of pest control are stated; use of biological pest control (preserving of agrocenosis parasites and predators) is substantiated; key attention is paid to reasonable use of chemical method of control.

Only authorized, in doses allowed for use, PPP against identified pests for relevant crops are recommended.

Comprehension absence of the place and role of the monitoring, diagnostics and signalization system, and misunderstood attitude towards it by former NPPS management caused the inadequate state of the system at present.

PRESENT SITUATION

Allocation of experts in prognostics and signalization in NPPS:

- NPPS Headquarters 47 numbers (in this number "Prognostics, biological and integrated pest management and fertilizers" Department 6 numbers)
- Plant Protection Institute 80 numbers (in this number "Prognostics" Section 5 numbers)
- RPPS 348 numbers (in this number experts in prognostics and signalization 85 numbers)

Number of available experts in prognostics and signalization at RPPS and experts per arable land in thousand dekars (0,1 ha) and necessary number of experts in prognostics and signalization.

RSPP	Available specialist	Cultivated lend on 1	Optimum area for	Needed specialists
Departments		specialist	maintenance from 1	-
		/thousand dka/	specialist	
			/ thousand dka /	
1. Blagoevgrad	4	120	100	1
2. Burgas	4	789	400	3
3. Varna	9,5	421	300	4
4. V. Tarnovo	4	763	300	2
5. Vidin	3	584	350	1
6. Vratza	6	792	350	2
7. Dobritch	5,5	940	400	3
8. Kiustendil	1,5	92	60	1
9. Pleven	5	881	400	6
10. Plovdiv	11	387	250	5
11. Ruse	7	488	350	3
12. St. Zagora	11	538	350	4
13. Sofia	7	329	250	1
14. Haskovo	5	399	250	2
Total	83,5		300	38

Analysis of correlation between number of experts in plant protection and area serviced according to Regions indicates that per one expert there are 940 000 to 329 000 dka with an optimal average norm of 300 000 dka per one emplyee. These data indicate insufficiency of system's administrative potential. As human factor is one of major importance in plant protection it is necessary to implement the program "Personal providing of NPPS" in order to respond to the tasks to be solved by the system.

PERMANENT TASKS FOR THE 2004 – 2009 PERIOD

To improve quality of prognostics and signalization NPPS will implement measures to extend contacts with agricultural producers; programs for experts training in major pests identification and safe and reasonable use of PPP will be drafted.

Measures will be implemented to improve collaboration with the Bulgarian Plant Protection Association, branch unions, agricultural companies, cooperations, farmers. Particular consideration will be given to recruit and train part-time collaborators to work in prognostics and signalization.

To achieve targets set in the strategy for development of monitoring, diagnostics, prognostics and signalization system NPPS will elaborate and apply into practice a number of **programs for**:

Building and equipment of the prognostics and signalization points.

Technical and informational (software and hardware) servicing of the system.

Representative charting of weeds of major agricultural crops.

Development, implementation and applying of integrated plant protection systems.

Development and maintenance of geographical information system (GIS) for pests.

Another element of major importance is personnel training in prognosis and signalization through:

- Qualification courses
- Practical training
- Laboratory work /exercise/
- Workshops
- Seminars

Material and technical provision of the system is defined by the system built of prognostics and signalization points (PSP) on the territory of different Regions. In recent years this PSP network was significantly reduced and in some regions only one – a regional point is maintained. This situation will change by restoration of former PSP and building new PSP in the agroecological areas under Regions.

One of main preconditions for composing of rapid, accurate and prompt prognosis and signalization is the availability of necessary meteorological and agrometeorological information. To this end equipping of a major part of PSP in the country with Automatic Meteorological Stations is foreseen. Using such information will allow implementation of mathematical models for prognosing pest development in particular microarea. Thus work quality and rapidity in terms of prognostics and signalization will improve considerably.

FUNDS FOR FINANCING THE SYSTEM FOR PROGNOSIS AND SIGNALIZATION FOR THE 2004 – 2009 PERIOD.

Year	Building new Prognosi	Maintenance and equi	Informational technolog	Total by years (tho
	signaling posts (the	(thousand leva)		leva)
	leva)			
2004	650	300	50	1 000
2005	700	250	50	1 000
2006	600	300	100	1 000
2007	700	250	50	1 000
2008	700	200	100	1 000
2009	-	200	100	300
Общо	3 300	1 500	450	5 300

Available and necessaries prognosis and signaling posts for building by years

RSPP/Department	Available prognosis	Needs for prognosis and signalization posts	
	and signaling posts	for building - by years	
1. Blagoevgrad	Blagoevgrad, Petrich, G.		
	Delchev, Razlog		
2. Burgas	Burgas, Karnobat	Sredetz	2005 г.
		Pomorie	2006 г.
		Aitos	2007 г.
3.Varna	Varna	Suvorovo	2005 г.

		D. Chiflic	2007 г.
Shumen	Shumen, Novi Pazar	Kaulinovo	2007 г.
Targovishte	Targovishte Popovo		2008 г
4. Vidin	Vidin	Novo selo	2008 г.
5. Vratza	Vratza	Oriaxovo	2005 г.
Montana	Montana, Lom		
6. Veliko Tarnovo	V. Tarnovo Pavlikeni Svishtov		2006 г. 2008 г.
Gabrovo	Gabrovo, Sevlievo		
7. Kustendil	Kustendil, Dupnitza	Kustendil	2005 г.
8. Dobritch	Dobritch	Kavarna	2005 г.
Silistra	Silistra, Tutrakan	Tutrakan	2007 г.
9. Pleven	Pleven, Guliantzi Belene		2008 г. 2006 г.
Lovetch	Lovetch, Troian Kneja Lukovit		2000 г.
10. Plovdiv	Ploviv, Sadovo, Hisar	Bresnik	2005 г.
Pazardjik	Pazardjik	Paragiurishte Septemvri	
Smolian	Smolian	Zlatogard	2007 г. 2009 г.
11. Ruse	Ruse, Dve mogily, Biala	Viatovo Slivo pole	2005 г. 2006 г.
Razgrad	Razgrad, Kardam	Razgrad Isperih	2006 г. 2007 г.
12. Sofia	Sofia, Samokov, Botevgrad	Kostinbrod	2007 г.
Pernik	Pernik	Radomir	2008 г.
13. Stara Zagora	Stara Zagora	Kazanluk Radnevo	2007 г. 2008 г.
Sliven	Sliven, Nova Zagora	Sliven	2008 г.
Yambol	Yambol	Elhovo	2005 г.
14. Haskovo	Haskovo	Harmanli	2006 г.
Kurdjali	Kurdjali		

Available and needed prognosis and signaling posts for equipment with automatic

meteorological stations by years

RSPP/Department	Available prognosis	Necessaries prognosis and signaling posts		
	and signaling posts	for building Automatic meteorological statio - by years		
1. Blagoevgrad	Blagoevgrad, Petrich, G. Delchev, Razlog	Blagoevgrad 2005 г. Petrich 2007 г.		
2. Burgas	Burgas, Karnobat	Burgas 2005 Γ. Karnobat 2007 Γ. Sredetz 2006 Γ.		
3.Varna	Varna	Varna 2007 Γ. Suvorovo 2008 Γ.		
Shumen	Shumen, Novi Pazar	Novi Pazar 2006 г.		

4. Vidin 5. Vratza Vratza Montana Montana, L 6. Veliko Tarnovo V. Tarnovo Gabrovo, Sc 7. Kustendil Kustendil, I 8. Dobritch Dobritch Silistra Silistra, Tut 9. Pleven	om	Popovo Vidin Vratza Oriahovo Montana Lom Veliko Tarnovo Pavlikeni Sevlievo Kustendil Dobritch Kavarna Silistra	2008 г. 2005 г. 2005 г. 2009 г. 2007 г. 2008 г. 2009 г 2007 г. 2008 г. 2008 г. 2008 г. 2008 г. 2008 г. 2008 г.
5. Vratza Vratza Montana Montana, L 6. Veliko Tarnovo V. Tarnovo Gabrovo Gabrovo, S. 7. Kustendil Kustendil, I 8. Dobritch Dobritch Silistra Silistra, Tut	om] evlievo S Dupnitza] rakan S iantzi]	Vratza Oriahovo Montana Lom Veliko Tarnovo Pavlikeni Sevlievo Kustendil Dobritch Kavarna Silistra	2005 г. 2009 г. 2007 г. 2008 г. 2005 г. 2009 г 2007 г. 2008 г. 2008 г. 2008 г. 2008 г.
Montana Montana, L 6. Veliko Tarnovo V. Tarnovo Gabrovo Gabrovo, S. 7. Kustendil Kustendil, I 8. Dobritch Dobritch Silistra Silistra, Tut	om	Oriahovo Montana Lom Veliko Tarnovo Pavlikeni Sevlievo Kustendil Dobritch Kavarna Silistra	2009 Γ. 2007 Γ. 2008 Γ. 2005 Γ. 2009 Γ 2007 Γ. 2008 Γ. 2008 Γ. 2007 Γ.
6. Veliko Tarnovo Gabrovo Gabrovo, S. 7. Kustendil 8. Dobritch Dobritch Silistra Silistra, Tut	om Jevlievo Sevlievo Sevli	Montana Lom Veliko Tarnovo Pavlikeni Sevlievo Kustendil Dobritch Kavarna Silistra Pleven	2007 г. 2008 г. 2005 г. 2009 г 2007 г. 2008 г. 2008 г. 2007 г. 2008 г.
6. Veliko Tarnovo Gabrovo Gabrovo, S. 7. Kustendil 8. Dobritch Dobritch Silistra Silistra, Tut	Pevlievo Supritza Sup	Lom Veliko Tarnovo Pavlikeni Sevlievo Kustendil Dobritch Kavarna Silistra Pleven	2008 Γ. 2005 Γ. 2009 Γ 2007 Γ. 2008 Γ. 2008 Γ. 2007 Γ. 2008 Γ.
Gabrovo Gabrovo, S. 7. Kustendil Kustendil, I 8. Dobritch Dobritch Silistra Silistra, Tut	Pevlievo Supritza Sup	Veliko Tarnovo Pavlikeni Sevlievo Kustendil Dobritch Kavarna Silistra Pleven	2005 г. 2009 г 2007 г. 2008 г. 2008 г. 2007 г. 2008 г.
Gabrovo Gabrovo, S. 7. Kustendil Kustendil, I 8. Dobritch Dobritch Silistra Silistra, Tut	Pevlievo Supritza Sup	Pavlikeni Sevlievo Kustendil Dobritch Kavarna Silistra Pleven	2009 г 2007 г. 2008 г. 2008 г. 2007 г. 2008 г.
7. Kustendil Kustendil, I 8. Dobritch Dobritch Silistra Silistra, Tut	Pevlievo Supritza Sup	Sevlievo Kustendil Dobritch Kavarna Silistra Pleven	2007 г. 2008 г. 2008 г. 2007 г. 2008 г.
7. Kustendil Kustendil, I 8. Dobritch Dobritch Silistra Silistra, Tut	Dupnitza 1 rakan 5 iantzi 1	Kustendil Dobritch Kavarna Silistra Pleven	2008 Γ. 2008 Γ. 2007 Γ. 2008 Γ.
8. Dobritch Dobritch Silistra Silistra, Tut	rakan Siantzi	Dobritch Kavarna Silistra	2008 Γ. 2007 Γ. 2008 Γ.
Silistra Silistra, Tut	rakan :	Kavarna Silistra Pleven	2007 Γ. 2008 Γ.
	rakan Siantzi	Silistra Pleven	2008 г.
	iantzi I	Pleven	
9. Pleven, Gul			2005 E
, in the second of the second			4003 T.
	1	Gulianzi	2005 г.
	1 4	Belene	2009 г.
Lovetch, Tr	oian	Lovetch	2008 г.
10. Plovdiv Ploviv, Sad	ovo, Hisar		
Pazardjik Pazardjik]	Pazardjik	2006 г.
]	Panagiurishte	2009 г.
Smolian Smolian	:	Smolian	2009 г.
11. Ruse Ruse, Dve i	nogily, Biala	Dve mogili	2005 г.
		Slivo pole	2006 г.
Razgrad		•	2005 г.
Razgrad, K	ardam	Razgrad	
12. Sofia	1	Kostinbrod	2005 г.
Sofia, Samo	Non Rotangrad	Samokov	2008 г.
Pernik Pernik		Pernik	2008 г.
13. Stara Zagora Stara Zagor	a	Stara Zagora	2005 г.
2000		Kazanluk	2008 г.
Sliven, Nov		Sliven	2006 г.
Yambol Yambol	,	Yambol	2006 г.
14. Haskovo Haskovo	1	Haskovo	2005 г.
114011010		Harmanli	2008 г.
Kurdjali Kurdjali		Kurdjali	2007 г.

RESULTS

- 1. Plant protection in the country at a European level.
- 2. Border points of Republic of Bulgaria a secure barrier to prevent import of quarantine pests in the Community.
- 3. Reliable control on production of plants and plant products in the country, ensuring untroubled export.

- 4. PPP testing and authorizing in accordance with European standards.
- 5. Authorizing, promoting and applying in pest control PPP with high degree of safety to people, animals and environment.
- 6. Effective and quality prognosis to ensure competitiveness at international markets and plant production safe to consumers.
- 7. Up-to-date laboratory and diagnostic network.

NECESSARY ADDITIONAL FUNDS IN BGN YEARLY:

YEAR	PHYTOSANITARY CONTROL	PROGNOSIS	BIOLOGICAL TESTING	TOTAL
2004	2 970 000	1 000 000	785 000	4 755 000
2005	3 020 000	1 000 000	820 000	4 840 000
2006	1 220 000	1 000 000	1 145 000	3 365 000
2007	1 000 000	1 000 000	950 000	2 950 000
2008	1 000 000	1 000 000	1 000 000	3 000 000
2009	1 000 000	300 000	1 170 000	2 470 000
TOTAL	10 210 000	5 300 000	5 870 000	21 380 000

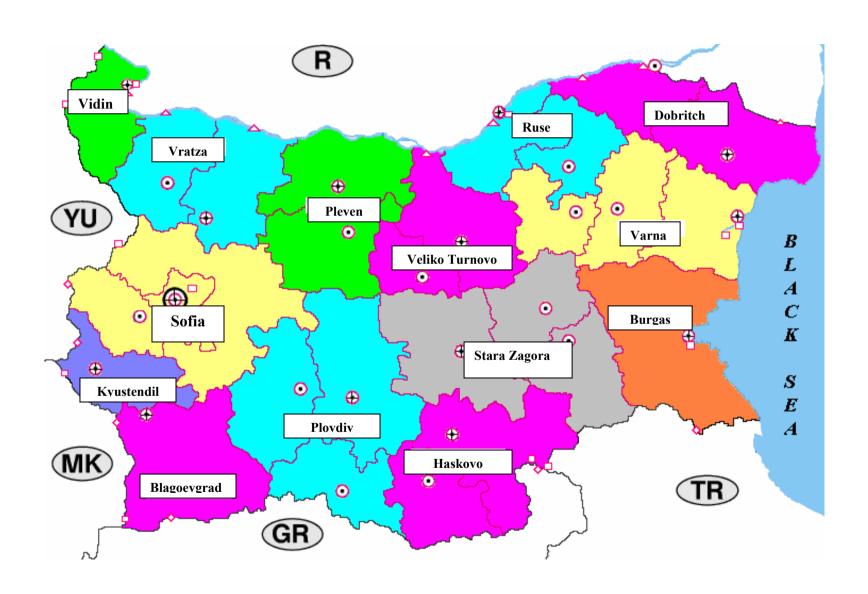
Sources of additional financing:

- Increase of proper incomes from penal decrees, consultant activities and other services
- European Commission
- State grants
- Bilateral cooperation with EU member states.

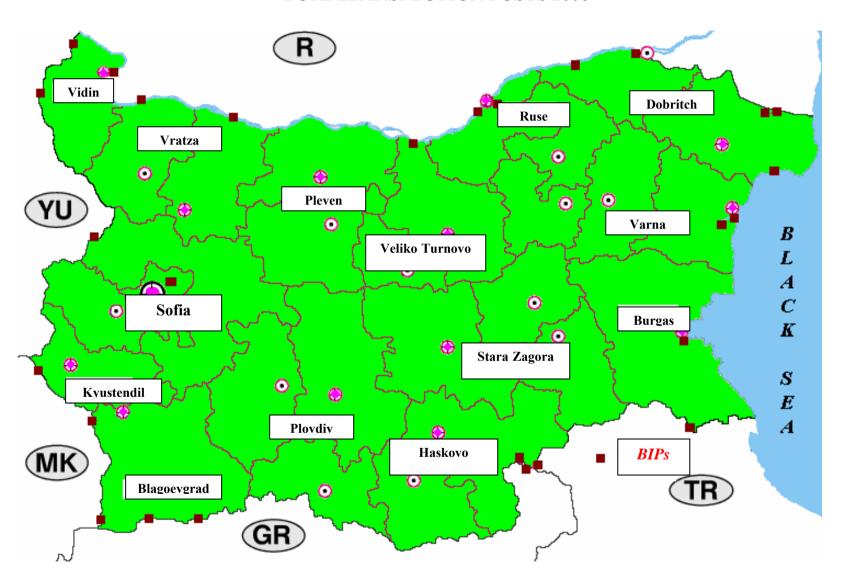
These funds are basic, provisional and preliminary; they do not include funs for wages, office materials electricity and heating energy, fuels, travel expenses and others – the average plan cost of a person in 2004 is $16\,000$ BGN.

In 2004 and 2005 funds there are 3 400 000 included as well: financing under Phare projects

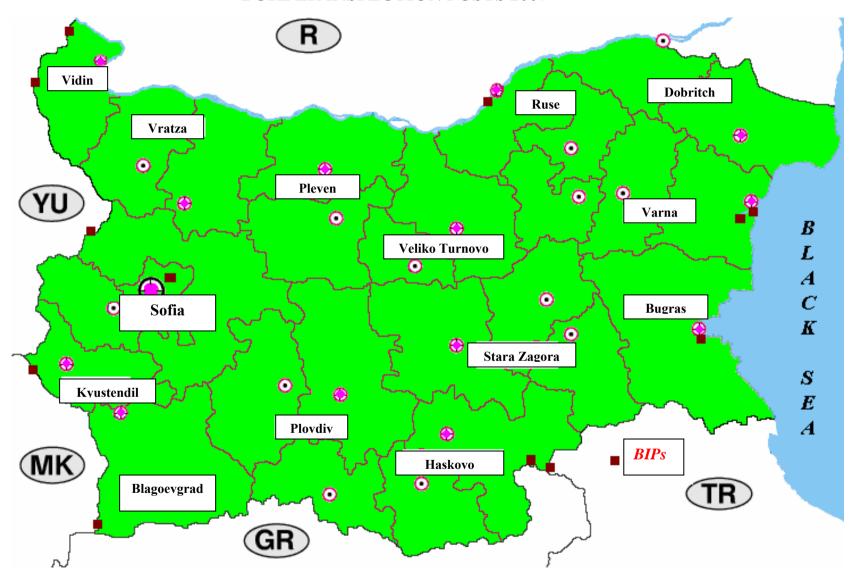
REGIONAL SERVICES



BORDER INSPECTION POSTS 2006



BORDER INSPECTION POSTS 2007



ANNEX 7

LIST OF ABBREVIATIONS

BIPs Border Inspection Posts

CLPQ Central Laboratory for Plant Quarantine

GEP Good Experimental Practice

GLP Good Laboratory Practice

MAF Ministry of Agriculture and Forests

NPAA National Programme for the Adoption of the Acquis

NSPP National Service for Plant Protection

PPI Plant Protection Institute

PRA Pest Risk Analysis

PRAQP Pest Risk Analysis for Quarantine Pests

RSPPs Regional Services for Plant Protection

HQ Headquarters

PPL Plant Protection Law

PPA Plant Protection Act /same as previous/

PPP Plant Protection Products

