#### TWINNING PROJECT FICHE

Further development of Competent Authorities' control systems to protect the human, animal and plant health

#### **1. Basic Information**

- 1.1 Publication reference notice: EuropeAid/ 137-823/IH/ACT/MK
- 1.2 Programme: Instrument for Pre-accession Assistance (IPA) National Programme for 2012 under the IPA Transition Assistance and Institution Building Component (TAIB)
- 1.3 Twinning Number: MK 12 IB AG 01
- 1.4 Title: Further development of Competent Authorities' control systems to protect the human, animal and plant health
- 1.5 Sector: Food safety, veterinary and phytosanitary policy. Twinning sector: Agriculture and Fisheries
- 1.5 Beneficiary country: The Beneficiary country<sup>1</sup>

#### 2. Objectives

#### **2.1 Overall Objective(s):**

The overall objective of the project is to further develop the systems in the country to protect the human, animal and plant health, to increase the competitiveness and sustainability of domestic products of animal and non-animal origin and to promote their placing on the market into EU and other international markets, as well.

#### 2.2 Project purpose:

The purpose of this project is to provide additional assistance to the Food and Veterinary Agency in order to complete and consolidate an EU-compliant food and feed safety and animal health control systems, allowing a stable-to-table coherent approach and also further strengthening of the capacity of Phytosanitary system.

# **2.3** Contribution to National Development Plan/Cooperation agreement/Association Agreement/Action Plan

The project will address the following Accession partnership priorities: Continuous alignment of legislation on veterinary and phytosanitary policy, focusing on framework

<sup>&</sup>lt;sup>1</sup> As per Financing Agreement concerning the National Programme Transition Assistance and Institution Building – TAIB 2012 from the Instrument for Pre-Accession Assistance under the Transition Assistance and Institution Building Component –entered into force on 2<sup>nd</sup> October 2013.

legislation compatible with the EU acquis; Further alignment of the animal disease and animal health control systems with EU legislative and institutional requirements and the contingency plans for notifiable diseases; Further development and upgrading the national authorities responsible for plant health and plant protection, including seed and propagation for proper implementation of legislation; Further alignment of the phytosanitary legislation with the acquis.

The project will contribute towards the implementation of the **Stabilisation and Association Agreement** Article 100 on gradual harmonisation of veterinary and phytosanitary legislation with Community standards.

The **Multi-annual Indicative Planning Document (MIPD) 2011-2013** in the description of the sector Agriculture and Rural Development stipulates that: "An important factor for the modernization of the agricultural sector is its gradual alignment to the EU acquis and the relevant standards in the food safety, veterinary and phyto-sanitary field". Furthermore, the overall sector objective for EU support over next three years is to contribute to the sustainable development of the agricultural sector as well as the implementation of EU standards and acquis concerning the common agricultural policy and related policy areas like food safety, veterinary and phyto-sanitary issues, including adapting to climate change.

**National Programme for Adoption of the Acquis (NPAA) revision 2015-2017** in Chapter 12 Food safety, Veterinary and Phytosanitary Policy, General principles, stated that further improvement in the FVA transparency in the area of sanitary and phytosanitary measures, establishing of operational and functional techniques to improve cooperation between relevant sectors is envisaged. Competent authorities will continuously transpose the new EU Acquis in the area of the veterinary policy, especially in the food and feed safety area and also in the area of Plant protection products, plant health, phytosanitary measures/ISPM standards.

Further strengthening of the administrative capacities of the FVA has been achieved with the IPA 2009 project (currently in the final stage of implementation) regarding the preparedness for accreditation of the inspection services of the FVA according ISO 17020. Also a support has been given in the following areas:

- The food and veterinary and phytosanitary administration with regard to organizational structure, management, coordination and staff capacity to be capable of executing food safety control and surveillance in line with EU standards;
- Some of the sector specific guidelines operating procedures and manuals have been prepared,
- The risk analysis system in line with EC regulation 178/2002,
- Methodology for data collection and evaluation of the data,
- Functional information modules compatible with the current IT system in the FVA with emphasis on human resources management and integrated administrative work, as well as and upgraded platforms for food control and consumer protection,
- Increased capacity for surveillance and monitoring of harmful organisms and plant protection products.

Under implementation is also the Twinning contract- *Institutional strengthening of the capacities of Competent Authorities for implementation of the acquis for food safety, veterinary and phytosanitary policy* (MK/10/IB/AG/01). With this project the following results will be realized:

- Monitoring/surveillance programmes regarding food safety and animal health developed based on previous sector analysis and effectively implemented;
- Strengthening of the capacities for control of animal diseases in the country;
- Introducing bio-security measures;
- Implementation of standards in primary production for food of animal origin;
- Strengthening of the phytosanitary border inspection control;
- Strengthening the capacities for plant health and control of plant protection products;
- Establishment of a Phytosanitary Information system.

#### Link with national/ sectoral investment plans

- National Food Safety Strategy 2013-2018;
- Monitoring Programme for Food Safety;
- Phytosanitary Monitoring Programme- Monitoring Programme for quality of plant protection products and residues from plant protection products in the primary agricultural products;
- Action Plan for Improvement of Quality of Raw Milk.

#### 3. Description

#### **3.1 Background and justification:**

#### Background

The authorities responsible for activities in the area of food and feed safety, veterinary and phytosanitary policy are the following:

- 1. Food and Veterinary Agency;
- 2. Phytosanitary Directorate;
- 3. Directorate for Seed and Seedling Material;
- 4. State Phytosanitary Laboratory;
- 5. State Agriculture Inspectorate.

**Food and Veterinary Agency** is the competent authority for coordination of activities in food safety area in the country and also responsible for communication with EU institutions for the subjects covered under Chapter 12, Food safety, Veterinary and Phytosanitary policy.

The Agency is competent for:

- performance of activities related to food and feed safety;
- organization and responsibility in performing the veterinary activity;

- implementation, control, supervision and monitoring of the veterinary activities related to animal health;
- protection and welfare of the animals in regard to their rearing, keeping, care and accommodation, farm movement, transport, slaughtering or killing, protection and welfare of the dogs and pets, ZOO animals and the animals which are used in experimental and other scientific purposes;
- performing activities related to by-products of animal origin;
- identification and registration of farmed and other animals;
- performance of the activities related to veterinary medicinal products;
- control of the quality of food with exception of the primary agricultural production.

Ministry of Agriculture, Forestry and Water Economy (MAFWE) is responsible for control of food safety in primary production of food of plant origin, plant health and implementation of measures for prevention and containment of harmful organisms, though the Phytosanitary Directorate and State Agriculture Inspectorate.

The Phytosanitary System includes:

- Phytosanitary Directorate (PD) National Plant Protection Organization (NPPO) that creates national policies and drafts legislation in the area of plant health, sustainable use of plant protection products, fertilizers, biostimulators and soil improvers;
- Directorate for Seed and Seedling Materials (DSSM) creates a national policy and preparation of legislation in the area of seed and seedling material, in particular marketing and quality of the seed and seedling material;
- State Agriculture Inspection (SAI) main tasks are inland and border phytosanitary controls on consignments for plant and plant products;
- State Phytosanitary Laboratory (SPL)- single laboratory which is involved in analysing samples taken in import and internal market checks and responsible for carrying out tests on plants, plant products, soil and pests; carrying out analyses on the risk of the spread of plant quarantine organisms.

On 16.02.2009 as a result of amendments of the Law on State Agriculture Inspectorate (Official Gazette no. 20/09) the Sector for phytosanitary inspection was separated from the Phytosanitary Directorate and became part of the State Agriculture Inspectorate.

#### Transposition of the EU Acquis

Transposition of the EU legislation into a national legislation is ongoing process in accordance with the transposition methodology applied for the legislation covered by Chapter 12, Food safety, veterinary and phytosanitary policy, which enables possibility for full transposition of the EU legislation into national one. Transposition of the national legislation with the EU legislation is carried out according to the time frame set up in the National Programme for the Approximation of the Acquis (NPAA) approved by the government.

All relevant primary legislation aligned with the corresponding EU legislation is in place.

The Law on food safety (OG No. 157/2010, 53/2011, 1/2012, 164/2013, 187/2013, 43/2014, 72/2015 and 129/2015) is a national food safety framework legislation and provides overall legal basis for food hygiene rules, specific rules for products of animal origin, control rules and specific rules for control of products of animal origin.

The Law on Veterinary Health (OG 113/2007, 24/2011, 136/2011, 123/2012, 123/2015 and 154/2015) is framework legislation in the field of veterinary policy. It ensures the organization of the veterinary service and animal health requirements in the internal movement, control measures of animal diseases.

# Other relevant adopted legislation as regards food safety and veterinary policy:

- Law on By-products of animal origin (Official Gazette No 113/2007, 144/2014 and 149/2015);
- Law on protection and welfare of animals (Official Gazette No 149/2014 and 149/2015 );
- Law on Animal Identification and Registration (Official Gazette No 95/12, 27/2014 and 149/2015);
- Law on veterinary medicinal product (Official Gazette No 42/2010, 136/11 and 149/2015);
- Law on feed safety (Official Gazette No 145/2010, 53/2011, 1/12, 33/2015 and 149/2015).

# **Reference list of relevant legislation in the field of phytosanitary policy:**

- Plant Health Law ("Official Journal 29/05, 81/08,20/09, 57/10, 17/11, 148/11, and 69/13);
- Law on products for plant protection (" Official Journal" No. 110/07, 20/09, 17/11, 53/11 and 69/13);
- Law on seeds and seedling material for agricultural plants ("Official Journal" 39/06, 89/08,171/10 and 53/11);
- Law on breeders rights (Official Journal No. 52/09).

As regards food safety and veterinary policy, a majority of secondary legislation is adopted. However, implementing legislation, supporting documents for inspection services such as guidelines, procedures for performance of a daily work of the official controls and check lists are still at early development phase. Adoption of such documentation is necessary for enforcement of the legislation at regional level in a uniform and transparent manner.

# **Justification**

The competent authorities in the country bear the responsibility for ensuring EU integrated food safety approach in aiming to assure implementation of adequate and effective control systems and compliance with EU standards in the food and feed safety, animal health, animal welfare, animal nutrition and plant health within the country and should take all measures that are necessary to guarantee a high level of protection of consumers' interests and fair practice in food trade.

To fulfil the requirements as provided by EU acquis in the field of food safety, veterinary and phytosanitary sectors, it is necessary to adopt/revise relevant control plans, monitoring programmes, elaborate reporting system assuring effective organization of official inspections.

As an obligation set by the Law on veterinary health and the responsibilities given by the membership in the World animal health Organization (OIE), the beneficiary country is obliged *to define animal health status* for animal diseases that currently are not monitored or surveyed by the competent authority. As a candidate country acquiring accession to EU, the beneficiary country should have favorable animal health status for the diseases declared as free in most of the territory of EU.

At the moment, due to lack of resources (insufficient staff, appropriate trainings) and financial constrains there *is no monitoring and surveillance of certain diseases* in the country and also a lack of epidemiological data.

Therefore, *obtaining training/ courses* to improve the collection of epidemiological data and increase the knowledge (facts, theoretical/practical) of diseases situation and diseases impact and spatial and temporal distribution of diseases for better implementation of monitoring and surveillance of diseases is essential.

At the moment there *is no data or inaccurate data related to the presence of vector born and parasitological diseases* in the country. In addition, at the moment there is no plan or programmes in place for monitoring of such diseases. For that reason a strategy and identification of priority vector born and parasitological diseases should be established.

Due to the fact that the responsibilities for safe food and feed production are shared between several stakeholders, as food and feed business operators, Food and Veterinary Agency and etc. (operators are responsible for compliance with legislative provisions, FVA is responsible for ensuring food and feed safety standards are respected by operators, etc.) there is a clear *need for further development of consistent*, complete approach to the established national control systems on food and feed safety and its *up-grade*, with emphasis on occurrence of *zoonosis and alimentary intoxications*. Such control system will improve the quality of controls and consequently raise food and feed safety standards. For that purpose there is a need of further development of operational criteria that should be meet by FVA and development of control guidelines, programmes and plans to promote coherent national strategies and identified risk based priorities and the most effective control procedures and indicators of performance. This will lead to protect human health from possible risks caused by food and feed.

Veterinary medicinal products are intended for treatment of animals and prevent diseases in animals, while avoiding damage to the human health and environment.

At the moment the status of awareness for marketing, distribution, pharmacovigilance and use of veterinary medicinal products is not satisfactory, especially the awareness and knowledge in *public health risk of antimicrobial resistance*.

Phytosanitary system includes protection of plants and plant products against harmful organisms with efficient and economically justifiable measures ensuring proper health, standard and competitive production and provides protection against any threats of plant

harmful organisms from the international trade of plants and plant products and seed and propagating material.

Phytosanitary Directorate, responsible for drafting of the phyosanitary policy and legislation, adopted a number of secondary legislation in the area of plant health and plant protection products. Moreover, International Standards for Phytosanitary Measures (ISPMs) within the International Plant Protection Convention are integrated in the national legislation that is guidelines to build up proper phytosanitary services and phytosanitary procedures.

In September 2014, the Minister of Agriculture, Forestry and Water Economy established a working group, chaired by the State Secretary, for realization and coordination of the reforms and activities in the phytosanitary system.

In 2014 the PD prepared the draft text of the National Phytosanitary Strategy for the period 2015-2020. The main objective of the Draft Strategy is to provide a national framework aiming to enhance and strengthen the ability of the country to fulfil international and EU and to create and to provide an appropriate protection against risks threatening plant life and health and to enhance national competitiveness on the regional, EU and global market. Technical assistance for finalization of the draft Strategy is provided within IPA-TAIB 2010 Twinning Project- *Institutional strengthening of Authorities for implementation of the EU acquis for food safety, veterinary and phytosanitary policy*.

In the following period PD will introduce a pilot scheme of plant passport, as well as will develop the specification and modules for establishment of the Phytosanitary Information System. Technical assistance is provided within IPA-TAIB 2010 Twinning Project-*Institutional strengthening of Authorities for implementation of the EU acquis for food safety, veterinary and phytosanitary policy.* 

PD prepared the draft text for the Law on plant protection products. The Draft Law is harmonized with the new EU legislation regarding plant protection products, more Regulations 32009R1107, 32009R1185, 32005R0396 and Directives specifically 32009L0128 and 32009L0127. Due to the complexity in implementation of this draft Law, the Phytosanitary Directorate analyzed the practical implementation, fiscal implications and arrangements European institutional in the countries. Morover, in order to familiarize the stakeholders with the draft Law, public hearing was organized in the different regions in the country.

According to the conclusions of EC Progress Report 2014: "Preparations in the phytosanitary area are at an early stage"

The Twinning is planned to further strengthen the enforcement capacities of the competent authorities for food safety, veterinary and phytosanitary policy and implementation of the priority monitoring and surveillance programs.

The Twinning will ensure the implementation of the general principles of food and feed law, as described in the Regulation No. 178/2002/EC, particularly related to a high protection of human life and health and the protection of consumers' interests, also guarantee fair practices

in food and feed trade, taking account of the protection of animal health and welfare, and plant health.

The Twinning refers to Article 17, Paragraph 2: "Member States shall enforce food law, and monitor and verify that the relevant requirements of food law are fulfilled by food and feed business operators at all stages of production, processing and distribution. For that purpose, they shall maintain a system of official controls and other activities as appropriate to the circumstances, including public communication on food and feed safety and risk, food and feed safety surveillance and other monitoring activities covering all stages of production, processing and distribution."

This Twinning also referred to the Article 41 of Regulation (EC) No 882/2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules especially about "development of systems to record the performance and results of control actions", as a part of Multi-annual national control plans that each Member State shall prepare for effective implementation of Article 17(2) of Regulation (EC) No 178/2002.

In addition to the above mentioned framework EU legislation, the project will ensure activities that will improve the implementation of the EU legislation related to animal health, alimentary intoxications and other food safety issues, feed safety, risk from antimicrobial resistance, as well as phytosanitary issues.

In order to enforce the newly adopted legislation in the phytosanitary area in compliance with EU standards and best practices, it is necessary to continue with the strengthening and modernization of appropriate infrastructure facilities, both administrative and technical. This project should provide exceeding technical support aiming to overcome the existing weaknesses and critical points in terms of administrative and operative procedures in the phytosanitary sector.

The Twinning should help the beneficiaries in the processing and analysis of the official control findings and results obtained from national monitoring programmes.

# 3.2 Linked activities

The below listed projects are complementing, and not overlapping the activities programmed under this Twinning Fiche:<sup>2</sup>

Reference No: 03MAC01/03/002 Project title: Strengthening the Veterinary Services in the beneficiary country Source of funding: CARDS Duration: 2003-2004 Description: Transposition of EU veterinary Acquis, first version of Veterinary Health Law was drafted.

<sup>&</sup>lt;sup>2</sup> The reference numbers are listed as registered in the Central Donor Assistance Database available at <u>http://cdad.sep.gov.mk/EN/search.aspx</u>.

Reference No: 04MAC01/06/001 Project title: MAFWE Structural and Legal Reform Source of funding:CARDS Duration: 2005-2006 Description: Legal approximation and preparation of primary legislation in the fields of Animal Health, Veterinary Public Health, Animal Welfare and Veterinary Border Inspection.

Reference No: 02MAC01/07/001 Project title: National Integrated Phytosanitary System Source of funding:CARDS Duration: 2004-2006 Description:

The Project covered technical assistance in the three following areas:

- approximation of the National phytosanitary legislation with *acquis communitaire*,
- strengtening of the institutional capacities, and
- establishement of the National State Phytosanitary Laboratory.

This was a long term technical support provided under the EU programs. Prevously, some introductory trainings were provided under Phare Programmes.

Reference No: 06MAC01/08/103

Project title: Strengthening food safety and quality control

Source of funding: CARDS

Duration: May 2007-May 2008

Description: provide support to strengthen the institutions involved in food safety control, improvement of the official control of food products in the country's market. provide assistance on testing facilities, and propose improvement in techniques and equipment. Supply of some equipment for food inspectors.

Reference No: EuropeAid/128546/C/SER/MK

Project title: *Capacity building of the veterinary service for implementation of EU Acquis* Source of funding: EU (IPA-TAIB)

Duration: September 2010- September 2012

Description: Contribution to the protection of animal and human health and to increase the profitability, competitiveness and sustainability of the food sector by improving the food safety and quality standards.

Reference No: EuropeAid/132281/C/SER/MK

Project title: Capacity building of the competent authorities for food safety, veterinary and phytosanitary policy

Source of funding: EU (IPA-TAIB)

Duration: December 2013- December 2015(Ongoing)

Budget: 1.750.000 EUR

Description: The purpose of the contract is to improve the institutional framework for food safety in the country, by strengthening the existing system of competent bodies and institutions in order to ensure an integrated multidisciplinary approach, covering all food chain stages.

In particular, the contract will incorporate:

- Administrative and institutional strengthening of the Food and Veterinary Agency, Phytosanitary Directorate and State Phytosanitary Laboratory,

- Preparation and implementation of phytosanitary monitoring programmes,
- Preparation for accreditation of inspection services.

#### Reference No.: MK10/IB/AG/01

Project title: Institutional strengthening of the capacities of Competent Authority for implementation of the acquis for food safety, veterinary and phytosanitary policy Source of funding: EU (IPA-TAIB)

Duration: November 2014- November 2016 (Ongoing)

Budget: 1.348.000 EUR

Description: The purpose of the contract is to improve the capacity of the competent authorities for food safety, veterinary and phytosanitary policy for implementation of EU Acquis. The overall objective of the project is to obtain functional market economy and the capacity to cope with competitiveness in the EU market while maintaining the consumer protection and achieving high food safety standards.

In particular, the contract components are:

- Improvement of the administrative and operational capacity of the Food and Veterinary Agency to ensure efficient enforcement of legislation;
- Strengthening of the capacities for veterinary issues at the central level and inspection units and implementation of hygiene standards in primary production for food of animal origin;
- Further improvement of the Phytosanitary system in the country;
- Improvement of sustainable capacities: training and dissemination of information.

#### 3.3 Results:

The project shall provide advisory support to the authorities responsible for the food safety, veterinary and phytosanitary system to further strengthen their capacities for efficient functioning.

#### The mandatory results to be achieved are:

# **Component 1: Improved administrative and operational capacity of the Food and Veterinary Agency to ensure further development and efficient enforcement of national legislation**

This mandatory result shall be achieved through the achievement of the following intermediary results:

#### 1.1 EU compliant implementing legislation regarding veterinary policy developed

#### Measurable indicators:

- Analysis report on compliance of the veterinary policy with relevant EU legislation prepared;
- Developed proposal for Law on Animal Health;
- Developed proposal for Veterinary Health Law;
- Developed proposal on Strategy and action plan for implementation of animal welfare rules;

- Number of other primary and implementing legislation, as well as working documents (including procedures and corresponding technical documentation i.e. guidelines, checklists, reports, etc.) developed.
- 1.2 Improved capacity of the Food and Veterinary staff to implement EU legislation and operating procedures

# Measurable indicators:

- Number of FVA staff trained for proper implementation of EU policies and adopted EU legislation;
- Number of FVA staff trained for performing official controls;
- Number of official controls conducted based on the newly adopted implementing legislation and working documents.

#### **Component 2: Strengthening the capacity of Food and Veterinary Agency for enforcing animal health control**

This mandatory result shall be achieved through the achievement of the following intermediary results:

2.1. Performed Animal Disease impact and improving of collection of Epidemiological data

#### Measurable indicators:

- Number of staff trained-specialized on epidemiological investigation;
- Number of monitoring and surveillance programmes developed/ revised and implemented, based on epidemiological and statistical analysis;
- Number of reports prepared based on the collected, processed and analyzed data from monitoring and surveillance programmes.
- 2.2. Improved control related to priority vector borne and parasitic diseases

#### Measurable indicators:

- Priority vector borne and parasitic diseases of national importance defined and cost benefit study for control of these diseases prepared;
- Develop proposal for Strategy and action plan for monitoring and surveillance for vector borne and parasitic diseases of national importance;
- Legislation (if identified as needed during the project), procedures and check list for uniform application of the established surveillance and monitoring system developed;
- Official veterinarians and other relevant staff trained to perform the surveillance and monitoring system developed.
- 2.3. Strengthening the capacities of the area of contingency planning

#### Measurable indicators:

- Developed Contingency plans and operational manuals for diseases subject to contingency planning that are not available in the FVA;
- Developed guidelines in case of natural disasters and radiation;

- Developed monitoring and surveillance programs for diseases subject to contingency planning;
- Official veterinarians acquainted and trained with implementation of measures in case of outbreak of a disease subject to contingency planning.

# **Component 3: Strengthening the capacity of veterinary public health area**

This mandatory result shall be achieved through the achievement of the following intermediary results:

3.1 Improvement of the system for feed safety and application of the principles of risk analysis for feed safety

# Measurable indicators:

- Prepared monitoring programme regarding feed safety and animal nutrition;
- Prepared National Control Plan for control of undesirable substances in feed;
- Improved implementation of Good Feeding Practices and Animal Nutrition;
- Food and Veterinary Agency staff trained for the application of feed safety risk analysis.

3.2 Improvement of the system for Veterinary medicinal products (VMP)

#### Measurable indicators:

- Developed programme for antimicrobial resistance;
- Developed national action plan against the rising threats from antimicrobial resistance;
- Introduced functional system/centre for adverse reaction;
- Developed manuals, operative documents which include improved Good Veterinary Practices regarding prescribing practices for VMP and respecting of dosages by the private veterinarians;
- Control system on overuse and misuse of antimicrobial medicines in the veterinary field is operational;
- Official system for monitoring of adverse reaction of veterinary medicinal products is established.
- 3.3 Development of system for management zoonosis and alimentary intoxications

# Measurable indicators:

- Established rapid alert system on occurrence of zoonosis and alimentary intoxications;
- Established system for monitoring of trends and sources of zoonosis and alimentary intoxications;
- Established measures to prevent zoonosis and alimentary intoxication occurrence.

# Component 4: Strengthening of the Phytosanitary system

This mandatory result shall be achieved through the achievement of the following intermediary results:

4.1 National legislation regarding plant health and plant protection products, seed and seedling material developed in compliance with the relevant EU legislation

#### Measurable indicators:

- Prepared assessment report based on reviewed phytosanitary legislation in force, gaps identified and relevant legislation and inspection control procedures adopted in line with the new Plant Health Regime and legislation for sustainable use of pesticides;
- Monitoring and inspection control, prevention, administrative control, urgency and other types of measures regularly and properly implemented.
- 4.2 Strengthening the capacities within the Phytosanitary System and further development of the Phytosanitary Information System

#### Measurable indicators:

- Trained administration, inspectors, and laboratory staff in identification and forecasting of harmful organisms that contributes to decreased number of positive findings regarding plant health;
- Trained administration, inspectors, and laboratory staff for proper implementation of the legislation related to sustainable use of pesticides;
- Trained administration, inspectors, and laboratory staff for proper implementation of the legislation related to seed and seedlings;
- Increased number of inland official controls achieving decreased number of disease notifications for harmful organisms;
- Developed, unified and operative Registers (Phytoregister, Register for producers, Processors, Traders of plant and plant products and other objects; Registers for importers, traders and distributors of plant protection products and fertilizers etc.);
- Improved information exchange and Coordination between the competent authorities in the Phytosanitary system and other institutions and stakeholders involved in the Phytosanitary System.
- 4.3 Further Development of the National Plant Passport System

#### Measurable indicators:

- Established and functional National Plant Passport System for all nurseries in the country, including forestry seedlings;
- Trained administration, inspectors and laboratory staff and other stakeholders capable to properly carry out tasks and duties regarding the National Plant Passport System.

#### **3.4 Activities:**

# The activities listed below represent the minimum activities to be implemented in the course of the Twinning project. Member State(s) may propose additional activities in line with the methodology elaborated in its proposal.

The Twinning project should not be a one-way technical assistance from a Member State to a Beneficiary Country. It must help to introduce and share EU wide best practices in connection with EU legislation and specific needs of the Beneficiary Country in the field of food, veterinary and phytosanitary policy.

The set of proposed activities will be further developed with the Twinning partner when drafting the Twinning work plan, keeping in mind that the final list of activities will be decided with the Twinning partner. The components are closely interlinked and need to be sequenced accordingly.

The Twinning assistance will be provided in the form of know-how transfer, and will be delivered through:

- <u>Advice and coaching sessions</u>: Coaching and advice activities will be the predominant type of activity. They will help for drafting of new legal acts and/or amendments to the existing national legislation (laws and implementing regulation, by-laws) on the basis of actual EU legislation in force and existing drafts of new legislation in the area of food, veterinary and phytosanitary policy, further development of procedures, implementing provisions and control mechanisms and strengthening of the administrative and operational capacities of the competent authorities for veterinary and phytosanitary policy.
- <u>Sharing of experience</u>: Sharing of experience is fundamental. Specific activities for it will be foreseen, but it will also be included in all coaching and training activities.
- <u>Tailor made training programme</u>: This project will include the development and implementation of a tailor-made training programme. The programme will take into account the lessons learnt from the previous trainings and will be based on a training needs assessment of the target group. The training programme will focus on all aspects of improving the capacities of the competent authorities in the areas outlined above. On-the-job training, where applicable will be carried out.
- <u>Seminars, workshops and conferences:</u> The training programme will involve the organisation of seminars, workshops, conferences etc.
- <u>Legal acts, Guidelines, Manuals, procedures and check-lists</u>: The Twinning partner should review and propose new legal acts, guidelines, checklists, reports, control plans, programmes and/or amendments to the existing national legislation which regulates the area of veterinary and phytosanitary policy in line with the Acquis and EU best practice. This task will be done in close cooperation and consultation with the Beneficiaries.
- <u>Development, enforcement and implementation</u>: The Twinning partner will propose and provide assistance and guidance in the strengthening the capacities of the central level and inspection units of the competent bodies for veterinary and phytosanitary policy in enforcement the legislation and implementation of monitoring and surveillance programmes through elaboration of various inspection procedures, monitoring procedures, methodology for data processing, analysis and risk assessment. The Twinning partner will

provide assistance and guidance in the process of designing and drafting of annual reports, Multiannual Control Plans, Monitoring and surveillance reports, and development of corrective measures, Guidelines for implementation of the new legislation and communication strategies for the competent authorities to undertake public awareness campaigns. The Twinning partner will assist in further development of internal audit system. This task will be done in close cooperation and consultation with the beneficiaries.

- <u>Study visits</u>: Study visits will be organised for the representatives from the Department for animal health and animal welfare and Department for veterinary public health from FVA and representatives from the institutions involved in the implementation of the Component 4 from this project, to a Member State for exchange of good practices and experience in connection with the implementation of veterinary and phytosanitary policies and programmes in line with the European *Acquis*. The comparative qualitative and economic advantage of a study visit, compared to the activity taking place in the Beneficiary Country, is crucial for its eligibility.
- <u>Assessment:</u> Every activity within the programme will be assessed though practical tools. The results will be compiled and presented to the Steering Committee, and integrated in the quarterly reports. When it is relevant and possible, the other activities of the twinning project will be evaluated in the most relevant way.

#### 3.5 Means/ Input from the MS Partner Administration:

The project will be implemented in the form of a Twinning contract between the Beneficiary country and an EU Member State. The implementation of the project requires one Project Leader (PL), responsible for the overall supervision and coordination of project activities, one Resident Twinning Adviser (RTA), responsible for management and implementation of project activities foreseen and Short-Term Experts. It is essential that the team has sufficiently broad expertise to cover all the areas included in the project description. The interested Member State institution shall include in its proposal the CVs of the designated PL and RTA. The details of implementation of the Twining project will be agreed upon/during the preparation of the work plan.

#### 3.5.1 Profile and tasks of the Project Leader

#### Member State Project Leader

The Project Leader from the Member State must be a high-ranking public officer or equivalent staff of a Member State administration engaged in issues of veterinary policy within the Ministry (or relevant institution) that covers the area of veterinary policy in animal health and veterinary public health area with relevant working experience of at least 3 years.

The MS Project Leader will continue to work at his/her Member State administration but will devote some of his/her time to conceive, supervise and co-ordinate the overall thrust of the Twinning project, and ensure the attainment of the projected outputs. The Project Leader is fully responsible for co-ordination of the work of the experts.

The MS Project Leader will manage the implementation of the project with the Project Leader from the Beneficiary Country and is expected to devote a minimum of 3 days per month to the project in his/her home administration with an on-site visit at least every 3 months. The Project Leader's seniority will ensure his/her ability to mobilise the necessary

staff in support of the efficient implementation of the project. In addition, he/she should coordinate, on the Member State side, the Project Steering Committee (PSC), which will meet in Skopje at least every three months.

He/she will be supported by his/her Member State administration for logistic, accounting and administrative affairs.

# Qualifications and skills

- At least a University degree3 preferably in Veterinary science or equivalent field;
- At least 3 years of relevant experience in the field of veterinary issues, in animal health and veterinary public health area;
- Fluent written and spoken English.

#### Tasks:

- Conceive, supervise and coordinate the overall preparation of the project;
- Coordinate and monitor the overall implementation of the project including coordination and direction of the MS TW partner;
- Co-ordinate MS experts' work and availability;
- Communicate with the beneficiary, CFCD and EUD;
- Ensure the backstopping functions and financial management;
- Guarantee the successful implementation of the Project's Work Plan;
- Co-chairing the regular Project Steering Committee meeting with the Beneficiary Country Project Leader;
- Preparation and drafting of operative side letter, interim, quarterly and final report.

#### **Project Leader Counterpart**

The Beneficiary Country Project Leader (BC PL)will act as the counterpart of the MS PL, and will ensure close cooperation in the overall steering, co-ordination and management of the project from the beneficiary side. He/she will support the Twinning project team in managerial, organizational and technical matters and will also coordinate the Project Steering Committee (PSC) on behalf of the BC. The role of the BC PL and the MS PL are complementary.

# 3.5.2 Profile and tasks of the Resident Twinning Advisor (RTA)

One (RTA) will be appointed, and he/she will be located in the premises of the Food and Veterinary Agency in the Beneficiary country.

The secondment of the Resident Twinning Adviser will last 18 months, during which he/she will be responsible for the direct implementation of the project under the overall supervision of the MS Project Leader.

<sup>&</sup>lt;sup>3</sup> For reference on equivalent qualification see: EPSO website-Annex 1 (<u>http://</u><u>http://europa.eu/epso/doc/diplomes-fortheweb\_en.pdf</u>)

He/she will come from an EU Member State to work on a full time and day-to-day basis with the beneficiary administration. The Resident Twinning Adviser will have a key role in the coordination of the inputs required for the successful implementation of the project activities. He/she shall be supported by a pool of Short-Term Experts.

# Qualifications and skills of the Resident Twinning Adviser

- be a national of a Member State of the European Union;
- be a civil servant or equivalent staff seconded to work within departments/units of the institution in charge of veterinary issues in a Member State;
- have at least a University degree<sup>4</sup> preferably in Veterinary science or equivalent filed;
- have at least 3 years of professional experience in the field of implementation of EU veterinary legislation;
- have experience in implementation of control systems, monitoring and surveillance programs in the area of veterinary issues;
- be fluent in written and spoken English.

# Tasks of the Resident Twinning Adviser

As to the general responsibility of the day-to-day implementation of the Twinning project in the Beneficiary Country, the Resident Twinning Adviser (RTA) tasks will include:

- Coordination of all project activities and experts' inputs in the country;
- Providing technical advice, support and assistance the Food and Veterinary Agency and other beneficiary institutions in the context of a predetermined work plan;
- To coordinate and organize training activities, guide the training delivery and related study visit(s)
- To provide advice and assistance in drafting legal, application acts, instructions, manuals etc. for implementation of the new legislation and supporting documents;
- Providing assistance and guidance to implement enhanced management and control system and procedures;
- Ensuring day-to-day implementation of the Twinning project in the BC;
- Ensuring smooth correlation between the activities, deadlines and the envisaged results in the Work Plan;
- Preparation of the materials and documentation for regular monitoring and reporting;
- Preparation of side letters;
- Taking corrective actions, if necessary, inside the terms of the signed contract.

# **3.5.3** Profile and tasks of the short-term experts

Other specialized staff will be made available by the Twinning Partner to support the implementation of activities. Specific and technical matters not directly covered by the Resident Twinning Adviser can be taken over by short-term experts within the limits of the

<sup>&</sup>lt;sup>4</sup> For reference on equivalent qualification see: EPSO website-Annex 1 (<u>http://europa.eu/epso/doc/diplomes-fortheweb\_en.pdf</u>)

budget. The detailed expert input shall be established when drawing up the twinning workplan.

Short-term experts will cover and provide specific and technical advises in plant health and plant protection products areas.

# Qualifications and skills:

Short-Term Experts will:

- have at least a University-level degree<sup>5</sup>,
- be civil servants or equivalent staff seconded to work within departments/units related to feed safety/ veterinary policy or phytosanitary policy in a Member State;
- have at least 3 years experience in implementation of the EU acquis in some of the areas of expertise which STEs are expected to cover (list is included below);
- have knowledge in writing legal acts, application texts and other relevant documents for efficient implementation of EU legislation for the relevant activities will be considered as an asset;
- be fluent in English, both oral and written.

Prior experience in implementation of twinning projects in other new Member States will be considered as an advantage.

#### Tasks:

Short-Term Experts will:

- prepare and implement specific tasks based mainly on practical cases and experience in compliance with their mission description and in accordance with Project activities;
- provide practical expertise/advices/support to relevant staff for execution of different tasks related to the project;
- contribute to the project reporting, contribute to the draft notes and other documents and report on their missions;
- address cross-cutting issues.

Short-Term experts will cover the following areas of expertise (non exhaustive):

- implementation of legislation regarding veterinary policy;
- implementation of procedures which will strengthen the capacity of FVA in the area of animal health control (collection of epidemiological data, control of vector borne and parasitic diseases and contingency planning);
- implementation of procedures which will strengthen the capacity of veterinary public health area (improvement of the system and application of the principles of risk analysis for feed safety, improvement of the system for Veterinary medicinal products and develop of system for management zoonosis and alimentary intoxications);

<sup>&</sup>lt;sup>5</sup> For reference on equivalent qualification see: EPSO website-Annex 1 (<u>http://europa.eu/epso/doc/diplomes-fortheweb\_en.pdf</u>)

• Strengthening of the Phytosanitary system through implementation of EU legislation into National legislation regarding plant health and plant protection products, seed and seedling material, further development of the Phytosanitary Information System and further development of the National Plant Passport System.

# 3.5.4 Profile and tasks of the RTA assistants

# 3.5.4.1 RTA Assistant:

• The RTA will be provided with a full-time **RTA assistant** acting as an assistant for technical and organizational support. The assistant will be contracted according to Twinning rules and paid from the Twinning budget. The assistant will be selected through an open call. The role of RTA Assistant is to support the RTA in the project management. In addition, the assistant will be responsible for organisation of meetings, seminars etc. and their logistics and also take part in translation and interpretation if needed.

# 3.5.4.2 Full-time translator / interpreter:

• A full-time translator / interpreter will be selected through an open call. The full-time translator / interpreter will be involved in all necessary project activities (training sessions, translation of project documents/reports and materials, organizational activities, etc.). The role of the translator / interpreter will be to provide translation and editing as well as interpretation services to the Twinning project in general.

#### 4. Institutional Framework

#### 4.1 **Beneficiary Institution(s)**

The Contracting Authority for this Twinning project is the Central Financing and Contracting Department (CFCD) within the Ministry of Finance.

Competent Authorities responsible for enforcement and control of the food and feed safety system are:

- 1 Food and Veterinary Agency;
- 2 Phytosanitary Directorate;
- 3 Directorate for Seed and Seedling Material;
- 4 State Phytosanitary Laboratory;
- 5 State Agriculture Inspectorate.

#### Food and Veterinary Agency (FVA)

The Agency is competent for the policy making and enforcement of the activities in the field of veterinary policy, food and feed safety, including, animal by products, veterinary medicinal products and performs the activities under its competence in accordance with the national legislation, international agreements ratified by the beneficiary country, the International Standards of the World Animal Health Organization (OIE), Codex Alimentarius as well as with other acts and standards to which the beneficiary country is obliged to adhere to.

Food and Veterinary Agency is consisted of the following departments:

- Department for animal health and animal welfare;
- Department for veterinary public health;
- Department for food of non-animal origin;
- Department for border inspection;
- Department for EU and international cooperation;
- Department for legal and administrative matters;
- Department for professional support.

**Phytosanitary Directorate** within MAFWE is responsible for policy making in phytosanitary field and SAI, MAFWE, amongst the responsibilities for enforcement legislation related to agriculture, is responsible for control of the implementation of relevant legislation regarding primary production for food of non-animal origin, respectively, as well as implementation of phytosanitary legislation.

Phytosanitary Directorate is consisted of the following Departments:

1. Department for Plant Health, monitoring and determination of harmful organisms responsible for the Plant Health, measures and obligations in connection with presence of harmful organisms on plants, plant products and other objects, prevention from their introduction and spreading, eradication measures, biological measures for protection of plants, access and exchange of information and information system, expenses and compensations, entrusted authorities, authorized services, authorities and bodies in the area of the plant health and other questions from the field of the plant health.

2. Department for Agro chemistry responsible for drafting the policy and legislation, as well as authorization, placing on the market, use of the plant protection products and preparation of Monitoring programmes.

3. Department for international cooperation and phytosanitary legislation responsible for technical support of the two other Departments within the PD and for establishment of PIS.

On 16.02.2009 as a result of amendments of the Law on State Agriculture Inspectorate (Official Gazette no. 20/09) the Sector for phytosanitary inspection was separated from Phytosanitary Directorate and became part of State Agriculture inspectorate.

**Directorate for Seed and Seedling Materials** is national body within the authority of Ministry of Agriculture, Forestry and Water Economy established in the beginning of 2000 and reorganization conducted in 2005. As the control of seeds and planting material is an integral part of plant health system, with organizational setup as follows:

- Unit for recognition, approval and protection of varieties;
- Unit for control and post-control of crops and plantings;

• Unit for National Gen Bank.

<u>State Phytosanitary Laboratory (SPL)</u> under Ministry of Agriculture, Forestry and Water Economy is the single laboratory which is involved in analyzing samples taken during import and internal market checks. SPL is responsible for:

- carrying out tests on plants, plant products, soil and pests;
- carrying out analysis on the risk of the spread of plant quarantine organisms.

SPL is consisted of the following sectors:

- Administrative sector;
- Diagnostic sector;
- Seed testing sector;
- Chemical testing of active substances of PPP.

The SPL is a central laboratory for analysis in the area of plant health with a capacity to become a reference laboratory.

<u>State Agriculture Inspectorate (hereafter – SAI)</u> as body within the Ministry of Agriculture, Forestry and Water Economy (MAFWE) is responsible for control of food safety in primary production of food of plant origin, plant health and implementation of measures for prevention and containment of harmful organisms.

# 4.2 Co-ordination mechanisms between institutions

A project Steering Committee (SC) will be established at the beginning of the project comprising senior representatives of the Beneficiary Institutions, the Delegation of the European Union and the Central Financing and Contracting Department within the Ministry of Finance.

The SC will monitor, supervise and co-ordinate the overall progress and implementation of the project. The SC will provide guidance for the different components of the project, will define priorities, approve and monitor budgets and approve the results.

# 4.3 Reporting requirements as per Art 6.4 of the Twinning Manual

Reports will follow the templates of Annex C4 of the Common Twinning Manual. In addition to these formal reporting stages, the twinning partners are obliged to inform in writing the Contracting Authority (CFCD) of any critical aspects or conditions of project implementation, or any amendments/modifications necessary within the budget.

All reports must be produced in the English in electronic and hard copy. These reports shall be signed by both project leaders. Each report must be presented in electronic format one week prior to the Steering Committee meetings and in two hard copies to the following addresses:

Central Financing and Contracting Department

Ministry of Finance "Dame Gruev" 12, 1000 Skopje

The final versions should incorporate any comments and discussions during the Steering Committee meetings.

# 5. Budget

The project will be implemented through a Twinning Contract estimated at a maximum of EUR 751.473,00 (out of which 95% IPA funds and 5% National co-financing).

| Twinning | Total (EUR) | IPA Communi | ty contribution | National Public | c contribution |
|----------|-------------|-------------|-----------------|-----------------|----------------|
| Contract | 751.473,00  | EUR         | %               | EUR             | %              |
|          |             | 713.900,00  | 95              | 37.573,00       | 5              |

The co-financing requirement foreseen under IPA will be considered fulfilled according to the provision of the relevant Financing Agreement.

In addition to the IPA and National co-financing as part of the Twinning Contract amount, as a rule, all twinning contracts must provide additional co-financing on the side of the Beneficiary Institutions, for the purpose of covering costs not covered under the project budget as per Twinning manual, point 5.13, as follows:

- Direct and indirect cost of the Beneficiary administration, civil servants and national private experts working for the project;
- Travel by the beneficiary officials from their capitals to a MS or between MS;
- Organization of seminars/ workshops/ trainings (incl. hall rental, printing seminar materials and other logistical support);
- Facilities for the Member State experts: adequately equipped office space; telephone; email services; fax; photocopiers; computer; internet access; secretarial support; access to information.

For the needs of the project, a full time RTA Assistant and full time translator-interpreter will be appointed under the project budget. The following expenses are also to be covered with the project funds:

- · Visibility Cost;
- $\cdot$  Audit certificate cost.

The project will be located in the premises of the Food and Veterinary Agency. The Agency will ensure appropriate facilities and basic equipment for the work of the experts.

#### **6.** Implementation Arrangements

6.1 Implementing Agency responsible for tendering, contracting and accounting

The Central Financing and Contracting Department (CFCD) of the Ministry of Finance will be the Contracting Authority and will be responsible for all administrative and procedural aspects of the tendering process, contracting matters and financial management including payment of project activities. The Head of CFCD will act as the Programme Authorising Officer (PAO) of the project:

#### Contact person

Mrs. Radica Koceva (PAO) Head of Central Financing and Contracting Department Ministry of Finance "Dame Gruev" 12, 1000 Skopje

6.2 Main counterpart in the BC

Food and Veterinary Agency will be the leading beneficiary institution. Regarding the phytosanitary part, the beneficiary institutions are the Phytosanitary Directorate, Directorate for Seed and Seedling, State Agriculture Inspectorate and State Phytosanitary Laboratory within the Ministry of Agriculture, Forestry and Water Economy.

Head of Department for EU and international cooperation in FVA acts as a SPO.

**Senior Programme Officer:** 

Mrs. Svetlana Tomeska Mickova, Food and Veterinary Agency Head of Department for EU and international affairs Senior Programme Officer

#### **RTA counterpart:**

Mr. Abdulezel Dogani Food and Veterinary Agency Deputy Director

#### **Project Leader counterpart:**

Mr. Zoran Popovski Food and Veterinary Agency Director

#### BC phytosanitary contact person

Ms. Nadica Dzerkovska Ministry of Agriculture, Forestry and Water Economy Phytosanitary Directorate Head of Unit for Phytosanitary Legislation and International Cooperation

6.3 Contracts

The project shall be implemented through one Twinning contract.

#### 7. Implementation Schedule (indicative)

7.1 Launching of the call for proposals (Date)

The estimated date for the launching of the call for proposals is: January 2016

7.2 Start of project activities (Date)

The estimated date for start of project activities is: October 2016

7.3 Project completion (Date)

The project implementation period (duration of the work plan) is 18 months after the commencement date of the Project.

7.4 Duration of the execution period (number of months)

The overall execution period of the Twinning project is 21 months with an implementation period of 18 months. (The execution period of the contract shall enter into force upon the date of notification by the Contracting Authority of the contract signed by all parties, whereas it shall end 2 months after the implementation period of the Action).

#### 8. Sustainability

The main contribution of this project will be the strengthening of the administrative capacities of Competent Authorities for implementation of the acquis for veterinary and phytosanitary policy. The project will have impact on improving the systems (strategic planning documents, strategic management), skills, practices, mechanisms, rules, by- laws and strategies of the relevant institutions.

The Member State Twinning partners shall transfer their best practices and know-how necessary to achieve the mandatory results to the Beneficiary administration. Staff benefiting from trainings shall transfer knowledge through subsequent training to their colleagues. Moreover and at the end of the implementation period a lesson learnt seminar will be held to disseminate the results and the best practices acquired and to foresee future relevant activities.

#### 9. Crosscutting issues

The cross-cutting issues will be addressed throughout the project. Throughout the project cycle, state actors specifically addressing (one of) the cross cutting issues shall be consulted.

The mainstreaming of the cross cutting issues is regarded on two different levels: (a) Ensuring that the internal policies, structure or operating procedures of the beneficiary

agency will conform to and promote the relevant principles outlined per section below and (b) ensuring that the products, outputs produced by the beneficiaries (e.g. laws, regulations, policies, and strategies) will conform to and promote the relevant principles outlined per section below.

# 9.1 Civil Society development and dialogue

Where appropriate the project activities will endeavor to involve input or the distribution of information to civil society groups relevant and active in the sector.

# 9.2 Environmental considerations

Any ecological friendly initiative which can be taken will have to be implemented.

# 9.3 Equal Opportunity and non-discrimination

The activities will include a specific component to train beneficiary staff in the different aspects of mainstreaming gender in the programme. Specific attention will be paid to reach out to female farmers to ensure their inclusion.

# 9.4 Minority and vulnerable groups

Where the main reference is the Ohrid Framework Agreement, in an EU context, the training activities will include a specific component to train beneficiary staff in the different aspects of mainstreaming minority and vulnerable groups in programme and project development as well as monitoring and evaluation.

# 9.5 Good governance, with particular attention to fight against corruption

Where appropriate the project activities will endeavor to align activities to broader Good governance themes and best practices.

# 9.6 Communication and publicity

All requirements to ensure the visibility of EU financing will be fulfilled in accordance with Regulation (EC). N.  $718/2007^{6}$ .

# 10. Conditionality and sequencing

# **10.1 Conditionality**

The project includes the following conditionalities:

1. Timely allocation of working space and facilities by the beneficiary for technical assistance before the launch of the tender process;

See Article 62 and 63 of Regulation(EC) N. 718/2007

- 2. Appointing counterpart personnel by beneficiary prior to launch of the project fiche;
- 3. Appointing relevant staff by the beneficiaries to participate in training activities;
- 4. Organization, selection and appointment of members of working groups, steering and coordination committees, seminars by the beneficiary as per work plan of the project.

#### **10.2 Sequencing**

Key milestones will be:

- 1) Approval of the Twinning project fiche;
- 2) Circulation of the Twinning Project Fiche to Member State National Contact Points;
- 3) Completion of the selection of the twinning partner;
- 4) Signature of the Twinning contract, including the Twinning Work Plan;
- 5) Commencement of the implementation of the twinning (inter alia, the arrival in the country of the Resident Twinning Adviser);
- 6) End of the implementation period;
- 7) Submission of the final report.

#### **ANNEXES TO PROJECT FICHE**

1. Logical framework matrix in standard format (compulsory)

ANNEX I - Log frame in standard format

| LOGFRAME PLANNING MATRIX FOR Twinning Project Fiche: Further         | Programme name  | e and number: I  | National Programme  |
|--|---|--|---|
| development of Competent Authorities' control systems to protect the | under the IPA Transition Assistance and Institutio                                  |  |   |
| human, animal and plant health                                       | Building Component for 2012   |  |   |
|  | Contracting<br>period expires<br>two years from<br>the date of the<br>conclusion of | Execution<br>period<br>expires two<br>years from<br>the final date | Disbursement<br>period expires<br>one year from the<br>final date for<br>execution of |
|  | the Financing<br>Agreement  | for contracting  | contracts.  |
|  |   |  |   |
|  | Total budget :  |  | IPA budget:   |
|  | 751 473   |  | 713 900   |
|  |   |  |   |
|  |   |  |   |
|  |   |  |   |
|  |   |  |   |

| Overall objective  | Objectively verifiable<br>indicators   | Sources of Verification   |  |
|--|--|---|--|
| The overall objective of the project is to<br>further develop the systems in the<br>country to protect the human, animal and<br>plant health, to increase the<br>competitiveness and sustainability of<br>domestic products of animal and non-<br>animal origin and to promote their<br>placing on the market into EU and other<br>international markets, as well. | Comprehensive advancement<br>towards fulfilling EU<br>requirements regarding food<br>safety, veterinary and<br>phytosanitary policy (Chapter 12) | <ul> <li>EC regular report;</li> <li>Annual report of the Steering<br/>Committee;</li> <li>Project reports (quarterly,<br/>annual);</li> <li>European Commission<br/>annual reports.</li> </ul> |  |

| Project purpose   | Objectively verifiable<br>indicators  | Sources of Verification   | Assumptions   |
|---|---|---|---|
| The purpose of this project is to provide<br>additional assistance to the Food and<br>Veterinary Agency in order to complete<br>and consolidate an EU-compliant food<br>and feed safety and animal health control<br>systems, allowing a stable-to-table<br>coherent approach and also further<br>strengthening of the capacity of<br>Phytosanitary system. | Institutional development and<br>increased capacity over ability to<br>assume EU <i>Acquis</i> and<br>substantiate EU priorities<br>addressed in EP.              | <ul> <li>Documentation:         <ul> <li>Government progress<br/>reports;</li> <li>EU assessment and progress<br/>reports.</li> </ul> </li> </ul> | <ul> <li>Government<br/>maintains<br/>consistent<br/>policy and<br/>commitment to<br/>the EU<br/>accession;</li> <li>Follow up on<br/>EU priorities.</li> </ul> |
| Results   | Objectively verifiable<br>indicators  | Sources of Verification   | Assumptions   |
| Component1:Improvedadministrativeandoperationalcapacity of the Food andVeterinaryAgencytoensureenforcement of legislation   |   |   |   |
| 1.1. EU compliant implementing<br>legislation regarding veterinary<br>policy developed  | <ul> <li>Analysis report on compliance<br/>of the veterinary policy with<br/>relevant EU legislation<br/>prepared;</li> <li>Developed proposal for Law</li> </ul> | Reports on the realization of the<br>Action plans produced and<br>drafted.<br>Adopted manuals, guidelines,  | Full commitment of the parties  |

| 1.2 Improved capacity of the Food<br>and Veterinary staff to implement<br>EU legislation and operating<br>procedures | <ul> <li>on Animal Health;</li> <li>Developed proposal for<br/>amended Veterinary Health<br/>Law;</li> <li>Developed proposal on Strategy<br/>and action plan for<br/>implementation of animal<br/>welfare rules;</li> <li>Number of other primary and<br/>implementing legislation, as<br/>well as working documents<br/>(including procedures and<br/>corresponding technical<br/>documentation i.e. guidelines,<br/>checklists, reports, etc.)<br/>developed.</li> <li>Number of FVA staff trained for<br/>proper implementation of EU<br/>policies and adopted EU<br/>legislation;</li> <li>Number of FVA staff trained<br/>for performing official controls.</li> <li>Number of official controls.</li> <li>Number of official controls<br/>conducted based on the newly<br/>adopted implementing<br/>legislation and working<br/>documents;</li> </ul> | instructions and manuals.<br>New procedures introduced. | involved.<br>Continuing<br>adherence to<br>agreed policy<br>objectives.<br>Good and<br>continuous<br>interaction<br>between the<br>stakeholders. |
|--|--|---|--|
|  | adopted implementing<br>legislation and working  |   |  |

| Component 2: Strengthening the<br>capacity of Food and Veterinary<br>Agency for enforcing animal health<br>control   |   |  |
|--|---|--|
| <ul> <li>2.1. Performed Animal Disease impact<br/>and improving of collection of<br/>Epidemiological data</li> <li>2.2 Improved control related to priority</li> </ul> | <ul> <li>Number of staff trained-specialized on epidemiological investigation;</li> <li>Number of monitoring and surveillance programmes developed/ revised and implemented, based on epidemiological and statistical analysis;</li> <li>Number of reports prepared based on the collected, processed and analyzed data from monitoring and surveillance programmes.</li> </ul> |  |
| vector borne and parasitic diseases  | -Priority vector borne and<br>parasitic diseases of national<br>importance defined and cost<br>benefit study for control of these<br>diseases prepared;   |  |

|   | -Developed proposal for Strategy   |  |
|---|------------------------------------|--|
|   | and action plan for monitoring     |  |
|   | and surveillance for vector borne  |  |
|   | and parasitic diseases of national |  |
|   | importance;                        |  |
|   | -Legislation (if is identified as  |  |
|   | needed during the project),        |  |
|   | procedures and check list for      |  |
|   | uniform application of the         |  |
|   | established surveillance and       |  |
|   | monitoring system developed;       |  |
|   | - Official veterinarians and other |  |
|   | relevant staff trained to perform  |  |
|   | the surveillance and monitoring    |  |
|   | system developed.                  |  |
|   | system de versped.                 |  |
| 2.3 Strengthening the capacities of the |                                    |  |
| area of contingency planning            |                                    |  |
| area of contingency planning            |                                    |  |
|   | -Developed Contingency plans       |  |
|   | and operational manuals for        |  |
|   | diseases subject to contingency    |  |
|   |                                    |  |
|   | planning that are not available    |  |
|   | in the FVA;                        |  |
|   | -Developed guidelines in case of   |  |
|   | natural disasters and radiation;   |  |
|   | -Developed monitoring and          |  |
|   | surveillance programs for          |  |
|   | diseases subject to contingency    |  |
|   |                                    |  |

| Component 3: Strengthening the<br>capacity of veterinary public health<br>area  | <ul> <li>planning;</li> <li>Official veterinarians acquainted<br/>and trained with implementation<br/>of measures in case of outbreak<br/>of a disease subject to<br/>contingency planning.</li> </ul>   |  |
|---|--|--|
| 3.1 Improvement of the system for feed<br>safety and application of the<br>principles of risk analysis for feed<br>safety | <ul> <li>Prepared monitoring programme<br/>regarding feed safety and anima<br/>nutrition;</li> <li>Prepared of National Control Plan<br/>for control of undesirable<br/>substances in feed;</li> <li>Improved implementation o<br/>Good Feeding Practices and<br/>Animal Nutrition;</li> <li>Food and Veterinary Agency<br/>staff trained for the application<br/>of feed safety risk analysis.</li> </ul> |  |
| 3.2 Improvement of the system for   |  |  |
| Veterinary medicinal products (VMP)   | <ul> <li>Developed programme fo<br/>antimicrobial resistance;</li> <li>Developed national action plan<br/>against the rising threats from<br/>antimicrobial resistance;</li> <li>Introduced functiona<br/>system/centre for adverse</li> </ul>   |  |

| [                                  | 1  |  |
|------------------------------------|--|--|
|                                    | reaction;  |  |
|                                    | -Developed manuals, operative                                      |  |
|                                    | documents which include  |  |
|                                    | improved Good Veterinary   |  |
|                                    | Practices regarding prescribing                                    |  |
|                                    | practices for VMP and  |  |
|                                    | respecting of dosages by the                                       |  |
|                                    | private veterinarians;   |  |
|                                    |  |  |
|                                    | -Control system on overuse and                                     |  |
|                                    | misuse of antimicrobial  |  |
|                                    | medicines in the veterinary field                                  |  |
|                                    | is operational;  |  |
|                                    | - Official system for monitoring                                   |  |
|                                    | of adverse reaction of veterinary                                  |  |
|                                    | medicinal products is  |  |
|                                    | established.   |  |
| 3.3 Development of system for      |  |  |
| management zoonosis and alimentary |  |  |
| intoxications                      | -Established rapid alert system or                                 |  |
| IntoAreadons                       | occurrence of zoonosis and   |  |
|                                    | alimentary intoxications;  |  |
|                                    | -Established system for monitoring                                 |  |
|                                    | of trends and sources of zoonosi                                   |  |
|                                    | and alimentary intoxications;<br>- Established measures to prevent |  |
|                                    | zoonosis and alimentary  |  |
| Component 4: Strengthening of the  | intoxication occurrence.   |  |
|                                    |  |  |

| <ul> <li>Phytosanitary system</li> <li>4.1 National legislation regarding plant<br/>health and plant protection products,<br/>seed and seedling material developed in<br/>compliance with the relevant EU<br/>legislation</li> <li>4.2 Strengthening the capacities within<br/>the Phytosanitary System and further<br/>development of the Phytosanitary<br/>Information System</li> </ul> | <ul> <li>Prepared assessment report<br/>based on reviewed<br/>phytosanitary legislation in<br/>force, gaps identified and<br/>relevant legislation and<br/>inspection control procedures<br/>adopted in line with the new<br/>Plant Health Regime and<br/>legislation for sustainable use<br/>of pesticides;</li> <li>Monitoring and inspection<br/>control, prevention,<br/>administrative control, urgency<br/>and other types of measures<br/>regularly and properly<br/>implemented.</li> </ul> | <ul> <li>New legislation<br/>developed</li> <li>Flow of information<br/>within PIS</li> <li>Control Plans</li> <li>Reports for realization<br/>of Monitoring<br/>Programmes</li> </ul> |  |
|--|---|--|--|
|  | - Trained administration<br>inspectors, and laboratory staf<br>in identification and forecasting<br>of harmful organisms tha<br>contributes to decreased numbe<br>of positive findings regarding<br>plant health;   |  |  |

| n                                       |                                    |
|---|------------------------------------|
|   | - Trained administration           |
|   | inspectors, and laboratory staf    |
|   | for proper implementation of the   |
|   | legislation related to sustainable |
|   | use of pesticides;                 |
|   | - Trained administration           |
|   | inspectors, and laboratory staf    |
|   | for proper implementation of the   |
|   | legislation related to seed and    |
|   | seedlings;                         |
|   | - Increased number of inland       |
|   | official controls achieving        |
|   | decreased number of disease        |
|   | notifications for harmful          |
|   | organisms;                         |
|   | - Developed, unified and           |
|   | operative Registers                |
|   | (Phytoregister, Register for       |
|   | producers, Processors, Traders     |
|   | of plant and plant products and    |
|   | other objects; Registers for       |
|   | importers, traders and             |
|   | distributors of plant protection   |
|   | products and fertilizers etc.);    |
|   | - Improved information exchange    |
|   | and Coordination between the       |
|   | competent authorities in the       |
|   | Phytosanitary system and othe      |
|   | institutions and stakeholder       |
| 4.3 Further Development of the National | involved in the Phytosanitary      |
| Plant Passport System                   | System.                            |
|   | •                                  |

| <ul> <li>Established and functional<br/>National Plant Passport System<br/>for all nurseries in the country,<br/>including forestry seedlings;</li> <li>Trained administration,<br/>inspectors and laboratory staff<br/>and other stakeholders capable<br/>to properly carry out tasks and<br/>duties regarding the National<br/>Plant Passport System.</li> </ul> |  |  |
|--|--|--|
|--|--|--|

| Activities   | Means            | Costs  | Assumptions   |
|--|------------------|--|---|
| The Twinning assistance will be<br>provided in the form of know-how<br>transfer, and will be delivered through:<br>- Advice and coaching sessions;<br>- Sharing of experience<br>- Tailor made training programme;<br>- Seminars, workshops and conferences:<br>- Legal acts, Guidelines, Manuals,<br>procedures and check-lists:<br>- Development, enforcement and<br>implementation;<br>- Study Visits;<br>- Assessment. | Twining Contract | Total EUR <b>751 473</b><br>(EUR 713 900 from IPA and<br>EUR 37 573 national<br>contribution); | Input from EU MS<br>partner<br>Continuing<br>commitment of<br>staff and<br>management |