# Project Fiche – IPA National programmes/Component I

## 1 IDENTIFICATION

<table>
<thead>
<tr>
<th><strong>Project Title</strong></th>
<th>Further alignment of food safety, veterinary and phytosanitary policies with EU requirements</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>CRIS Decision number</strong></td>
<td>2012/022-989</td>
</tr>
<tr>
<td><strong>Project no.</strong></td>
<td>10</td>
</tr>
<tr>
<td><strong>MIPD Sector Code</strong></td>
<td>8. Agriculture and Rural Development</td>
</tr>
<tr>
<td><strong>ELARG Statistical code</strong></td>
<td>03-12</td>
</tr>
<tr>
<td><strong>DAC Sector code</strong></td>
<td>31110</td>
</tr>
<tr>
<td><strong>Total cost</strong></td>
<td>2012: EUR 3,621,000</td>
</tr>
<tr>
<td><strong>EU contribution</strong></td>
<td>2012: EUR 2,999,950</td>
</tr>
<tr>
<td><strong>Management mode</strong></td>
<td>Decentralised</td>
</tr>
<tr>
<td><strong>Responsible Unit or National Authority/Implementing Agency</strong></td>
<td>The Central Financing and Contracting Department (CFCD) 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: Mrs. Radica Koceva (PAO) Central Financing and Contracting Department Ministry of Finance Tel: +389 2 3231 219 Fax: +389 2 3106 612 E-mail: <a href="mailto:radica.koceva@finance.gov.mk">radica.koceva@finance.gov.mk</a></td>
</tr>
<tr>
<td><strong>Implementation management</strong></td>
<td>Food and Veterinary Agency (FVA) Ms. Svetlana Tomeska-Mickova, Senior Programme Officer, Head of legislation unit Telephone: +389 23112 265 ext.313 E-mail: <a href="mailto:s.tomeska-mickova@fva.gov.mk">s.tomeska-mickova@fva.gov.mk</a></td>
</tr>
<tr>
<td><strong>Implementing modality</strong></td>
<td>Stand alone project</td>
</tr>
<tr>
<td><strong>Project implementation type</strong></td>
<td>1 Twinning contract, 1 supply contract</td>
</tr>
<tr>
<td><strong>Zone benefiting from the action(s)</strong></td>
<td>Nationwide</td>
</tr>
</tbody>
</table>
2 RATIONALE

2.1 PROJECT CONTEXT: ISSUES TO BE TACKLED AND NEEDS ADDRESSED

This project addresses the priorities of the National Programme for Adoption of the Acquis, as well as priorities described in other relevant strategic documents in terms of strengthening of capacities of the competent authorities regarding food safety, veterinary and phytosanitary policy, in order to bring them in line with and to fulfil EU requirements.

2.2 LINK WITH MIPD AND NATIONAL SECTOR STRATEGIES

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 modernisation 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 2011 in Chapter 12 Food safety, Veterinary and Phytosanitary Policy, General principles, comprises establishment of an integrated system for control of food safety and appropriate activity coordination, which will provide efficient implementation of the legal framework regarding food safety. In that order, the new Food Safety Law was adopted (Official Gazette, 157/2010) under which the new Food and Veterinary Agency was established by merging the former Veterinary Directorate within the Ministry of agriculture, forestry and water economy and the Food Directorate within the Ministry of health.

Government of the former Yugoslav Republic of Macedonia in September 2010 has adopted the National strategy for implementation of HACCP 2010-2014, with Action plan for implementation of the foreseen activities. The aim of this Strategy is to support the food business operators in establishment of the food safety systems, such as improvements in infrastructure, equipment, implementation of GPP, GHP and HACCP. The Action plan envisages trainings for official veterinarians, food inspectors and food business operators, as well as developing of guidelines.

Additionally, it is envisaged that in 2012, a new Strategy for transposition and implementation of EU Acquis regarding Food safety, veterinary and phytosanitary policy will be adopted, including the Multi-annual control programme for conducting an official controls, in accordance to the Regulation 882/2004. These activities are foreseen under IPA 2008 project “Capacity building of the veterinary service for implementation of EU Acquis”.

Regarding Veterinary policy, Programme for control and eradication of brucellosis in sheep and goats (Official Gazette, 46/2010) was adopted. With this Programme and in accordance with recommendations of EC, a new approach has been inducted: massive vaccination and disease control by monitoring of the movement of small ruminants. The Book of rule on Compulsory notifiable diseases was likewise adopted (Official Gazette, 110/2010).

The FVA is implementing annual programs for Animal health protection and Veterinary public health. The scope of the programmes and its implementation are dependent on the availability of funds.
Regarding Phytosanitary policy progress was made related to harmonisation of the national legislation with the EU Phytosanitary Acquis. The following framework laws have been adopted:

- Law on plant protection products (“Official Gazette” 110/2007, 20/2009);

In 2011 initial activities were undertaken, in order to establish a Register of plant protection products and Register of producers, processors and distributors of plants, plant products and other establishments and subjects (register of operators). Phytosanitary certificates for export, re-export and implementation of the List V Part B for import of consignments from third countries and establishing monitoring for agricultural primary products are as well under preparation.

Further strengthening of the administrative capacity of the Phytosanitary Directorate for surveillance and monitoring of harmful organisms and plant protection products will be improved with the planned activities under the IPA 2009 project “Capacity building of the competent authorities for food safety, veterinary and phytosanitary policy”.

In order to meet the objectives of previously addressed documents, programmes and strategies, this project will contribute towards:

- improvement of animal health status,
- eradication of zoonoses,
- improvement of food and feed hygiene standards, and
- efficient and effective phytosanitary control.

Regarding Europe 2020, a strategy for jobs and smart, sustainable and inclusive growth, this project addresses the following targets: Employment (75% of the 20-64 year-olds to be employed) and Poverty/social exclusion (at least 20 million fewer people in or at risk of poverty and social exclusion). Namely, 20 new employments in FVA and 5 new employments in PD are envisaged for 2012 and regarding poverty/social exclusion, this project will contribute towards its reduction by increasing the number of establishments approved for export in EU. Furthermore, the economic impact can also be identified in improvement of animal health status, as well as enhancing and enlarging of agriculture food production.

2.3 LINK WITH ACCESSION PARTNERSHIP (AP)/EUROPEAN PARTNERSHIP (EP)/STABILISATION AND ASSOCIATION AGREEMENT (SAA)/ANNUAL PROGRESS REPORT

The project will address the following Accession partnership priorities: Continuous alignment of legislation on veterinary and phytosanitary policy, focusing on framework 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; Assess the compliance of agri-food establishments with EU requirements, which will serve as a basis for a future upgrading plan of those establishments; Establishment of a properly staffed plant health authority; Further alignment of the phytosanitary legislation with the acquis; Adoption and implementation of a plan for upgrading of the agri-food establishments.
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.

Within the **EC Progress Report for 2011** the following weaknesses have been detected: The capacities of the competent authority remain insufficient to perform systematic controls in relation to transmissible animal diseases; The system for supervising the veterinary inspectors and veterinary stations has not yet been implemented; The number of food business operators that implement hazard analysis critical control point (HACCP)-based procedures has increased but the procedures are not always applied correctly; Evaluation of food processing establishments for compliance with EU standards and their upgrading programmes is not done always correctly; A plan for improving the quality of raw milk has not been implemented yet, due to the lack of available funding; Some progress was made on specific rules for feed. Legislative preparations in this area have started.

Progress can be reported in the area of phytosanitary policy. Implementing legislation was adopted in all areas, including on plant health, plant protection products, quality of seeds and propagation materials and plant variety rights. A new list of authorised active substances intended for plant protection products was adopted. No action was taken to implement the international standards for phytosanitary measures, in particular for surveillance, export certification and determining pest status in an area. Despite some recruitment, the administrative capacity of the phytosanitary directorate needs further strengthening.

Coordination among the various competent authorities in the area of phytosanitary policy has not been improved. The human resources, equipment and facilities for border controls are still inadequate. The improved capacity of the state phytosanitary laboratory remains under-used because its role in the national food safety monitoring system is undefined and samples are not received on a regular basis.

The Conclusions of the above mentioned report are as follows: The administrative capacity of the institutions, in terms of financial and human capacity, remains insufficient, in particular as regards the effectiveness of monitoring and control systems. Preparations in the area of food safety, veterinary and phytosanitary policy are well on track.

### 2.4 Problem Analysis

Food and Veterinary Agency is responsible for the protection of animal health by control/prevention of animal diseases, through border controls, vaccination, disease eradication programmes, internal movement controls, surveillance and monitoring etc). Food and Veterinary Agency is also a competent authority for official control on primary production of food of animal origin.

Disease control/prevention strategies are formulated annually and at the beginning of each year the FVA publishes an Annual Order that details the strategies and interventions, by type, number of animals and time period that must be undertaken that year.

Animal health services are delivered by the private Veterinary Stations which are implementing the Annual order programme. They are also responsible for initial detection and reporting of suspected outbreak of economically important diseases (such as foot and mouth disease, rabies, brucellosis, swine fever, etc).
As an obligation rose by the Law on veterinary health and the responsibilities given by the membership in the World animal health Organization (OIE), the country is obliged to define animal health status for animal diseases and particularly zoonoses that currently are not monitored or surveyed by the competent authority. At the moment, due to lack of knowledge and financial constrains there is no Strategy for monitoring and surveillance of certain diseases in the country and also a lack of epidemiological data.

As a candidate acquiring accession to EU, the country should have favourable animal health status for the diseases declared as free in most of the territory of EU. Having in mind all previously stated, the human capacity and the annual budget is insufficient to cover the screening of the whole territory for other zoonoses and infectious diseases for which FVA does not have field information and epidemiological surveys are needed in order to put in place effective disease control options and efficient annual control programmes.

In order to ensure satisfactory health status of pigs placed on market, as well as to reduce persistence and spreading of pig diseases, including Classical Swine Fever, improvement of bio security standards on farm and effective bio security system is of an utmost importance. Currently, there are 120 commercial (large capacity) pig farms with 100 pigs/per year. Regarding small capacity pig farms census has not been carried out yet. Establishment of the System for Identification of porcine animals and Registration of their movements (I&R system of pigs) is part of IPA 2008 project results. This system will contribute towards improvement of some bio security standards for example control of movement of animals, but there are still issues that need to be covered, such as: Control of movement of people, vehicles, protection from the contact with wild animals, control of the waste etc.

Activities related to procurement and application of the vaccines in wild foxes against rabies is part of the ongoing five year (2011-2015) programme for control and eradication of Rabies. This activity is established at the national level, but also as a regional programme among the Western Balkan countries and is financially supported by the EU IPA funds. Two vaccination campaigns in 2011 were implemented under IPA 2008 and the vaccination in 2012 and 2013 will be implemented under IPA 2010 national programme. Having in mind the importance of eradication of this disease in wild life, EU financial assistance in this area is further needed.

A development of Classical Swine Fever (CSF) strategy is part of IPA 2008 project. Whether vaccination against CSF in wild boar will be implemented on the territory of the country is still an open issue, a cost-benefit study is in the phase of preparation as an activity within IPA 2008 project and its outcome will provide data whether the oral vaccination against CSF will be needed.

With regards to the primary production of food of animal origin, the large number of small capacity farms which hardly fulfil hygiene requirements is an existing problem in the country. There is a lack of awareness and knowledge among the keepers and breeders of animals that produce primary products of the legislative requirements particularly Good hygienic practice GHP, Good manufacturing practice-GMP and also technology of producing safe primary product. In this respect, only 10% of raw milk farms meet the standards for raw milk according to Regulation 853/2004.

The administrative capacity of the competent authorities is still insufficient to overcome the deficiencies in the primary production process. Further improvement, especially regarding implementation is of the highest importance.
Phytosanitary Directorate are responsible for policy making in phytosanitary field and State Agriculture Inspectorate responsible for control of the implementation of relevant legislation regarding primary production for food of non-animal origin, respectively.

Some progress has been made in the area of phytosanitary policy but that is still no sufficient to bring in line with EU requirements. Namely, a new list of harmful organisms has been adopted and some implementing legislation on plant protection products has been adopted also, as well as establishment of a register of plant protection products.

Regarding adoption of the International Standards for Phytosanitary Measures (ISPM), 9 out of a total 34 standards, including those for export certification and determining pest status, have been adopted in 2011. In terms of ISPM standard for surveillance, it will be adopted till the end of 2012. In mid-term priorities indicated in NPAA 2011, the part of Chapter 12 - Phytosanitary field, is stated that all 34 ISPM standards will be adopted by the end of 2014. Nevertheless, regarding their proper implementation, EU assistance is crucial.

Having in regard that **surveillance** is covered by IPA 2009 project, further activities in phytosanitary area are needed in respect of overcoming **export certification** and **determination of pest status** in the country (3 high priority standards), as well as all other ISPM.

In 2011 Phytosanitary Directorate started with the registration of legal and natural entities in the registry for producers, processors, importers and distributors of plants, plant products and other objects and items in accordance with Directive 2000/29 EEC.


Official controls on border inspection posts are performed on the basis of the Law on plant health, Art. 74, 75 and 3 By-laws, namely: Book of Rules on the manner of performing phytosanitary inspection at import of consignments of the list V part B section 1 (“Official Gazette “ 131/2010); Book of Rules on the manner and procedure for performing phytosanitary inspection on plants, plant products and other objects and items at entry posts in the former Yugoslav Republic of Macedonia (“Official Gazette” 111/2010); and Book of Rules on time-frames and manner of performing the phytosanitary inspection on plants, plant products and other objects and items laid down in list V part A section 1 and list V part A section 2 (Official Gazette“ 131/2010); Still, because of lack of knowledge and training of the border phytosanitary inspectors, existing legislation is not properly and efficiently implemented. This project will contribute towards overcoming this issue.

Establishment of **Information system for plant health** is envisaged. This system will incorporate all data from different registers (register for producers, processors, importers and distributors of plants, plant products and other objects and items, register of certified natural and legal entities for plant passport issuance), results from annual programme for surveillance of harmful organisms, international communication and data exchange since this system would be part of International plant health information system etc.

By-laws regarding the previous are in preparatory stage and are to be adopted until the end of 2012.

### 2.5 Linked Activities and Donor Coordination

One of the main objectives of IPA 2008 (“Capacity building of the veterinary service for implementation of EU Acquis”) and IPA 2010 projects (“Strengthening of administrative and institutional capacity of the competent authorities regarding food safety, veterinary and
phytosanitary policy”) is to support the AHV to prevent the spread of Rabies in wild animals by implementation of a campaign of oral vaccination against Rabies in wild foxes.

In order to have sustainable results, the oral vaccination of wild animals has to be implemented for at least five years. Therefore, this project will be continuation of the system (oral vaccination, surveillance, diagnostic, other control measures required) established with the IPA 2008 and IPA 2010 projects.

Phytosanitary monitoring programme for plant health is also a follow up, namely under IPA 2009 Project fiche (project “Capacity building of the competent authorities for food safety, veterinary and phytosanitary policy”) is envisaged development of an operational monitoring programs of harmful organisms and plant protection products. This project would contribute to its further improvement and sustainability.

Regarding complementarity of this project with relevant results and activities of IPA 2008, 2009 and 2010, the list is as follows:

**IPA 2008 – Results:** Establishing an integrated food and feed control system throughout the food chain, based on a solid assessment of the existing situation; Assessment of the epidemiological situation for rabies and CSF in the whole territory of the country; A detailed plan and procedures for vaccination of wild animals is prepared and approved; Immunization of the wild fox, wild boar population (including farmed wild boar) and of domestic farmed pigs against Rabies and CSF respectively; Passive surveillance in wild life supported. Hunters are well informed about the importance of reporting and sending specimens for laboratory; I&R system for pigs is introduced, established and sustained

**Activities:** Establish an integrated food and feed control system throughout the food chain; Analysis of the epidemiological situation in the whole territory of the country related to rabies and CSF,; Develop detailed plan and procedures for vaccination of wild animals; Implement immunization of the wild fox, wild boar population (including farmed wild boar) and of domestic farmed pigs against Rabies and CSF respectively; Purchase vaccine for the farmed domestic pigs (approximately 700.000 doses for one year); Develop a sound coordination and cooperation system with hunters, concession holders, etc, to develop a passive surveillance system of wild life; Develop and introduce an I&R system for pigs;

**IPA 2009 – Results:** The food and veterinary and phytosanitary administration with regard to organisational structure, management, coordination and staff capacity is capable for executing food safety control and surveillance in line with EU standards; National legislation in line with the relevant EU food provisions is prepared and adopted; A risk analysis system in line with EC Regulation 178/2002 is established and operational; Risk oriented official control procedures and control plans including multi-annual control plan for food surveillance and control of establishments are prepared; Sector specific guides are prepared distributed and introduced; Methodology for data collection and evaluation is established;

**Activities:** Further approximation of the national legislation with Community legislation for food safety, veterinary and phytosanitary policy; Guidelines and manuals for implementation of the legislation developed and training provided; Implementation of the Acquis, training of staff for official controls in all sectors of the food chain including phytosanitary control; Development of detailed Operational Manual of procedures for risk assessment, risk management and risk communication; Development of Monitoring programmes for harmful organisms, and plant protection products; Development and
delivery of specific training activities (curricula and on the job training) for strengthening the capacity for conducting Phytosanitary controls.

IPA 2010 – Results: The capacities at the central level and inspection units of the competent bodies for food safety, veterinary and phytosanitary issues are strengthened; Trained staff engaged in import/export control; The architecture of a system for collection, processing and analysis of the data from official controls findings and data from monitoring and surveillance programmes is designed; Immunisation of the animal against rabies and classical Swine Fever.

Activities: Assist the relevant authorities in the further transposition of the EU implementing legislation; Assist the central level and inspection units of the competent bodies for food safety, veterinary and phytosanitary develop their capacity to enforce the legislation and to implement monitoring and surveillance programmes,

2.6 Lessons learned
The recommendations and lessons learned from previous EU projects have been taken into consideration while designing the project fiche. Project realisation is impaired by the long time gap between programme preparation and implementation. Therefore in this case the maximum amount of flexibility has been retained in order have room to manoeuvre later.

Former Veterinary Directorate within Ministry of Agriculture, Forestry and Water Economy and former Food Directorate within Ministry of Health - now incorporated in a new, independent authority, Food and Veterinary Agency - along with Phytosanitary Directorate as beneficiary institutions, were implementing institutions in numerous projects under PHARE, CARDS or other donor projects. Some of the projects were very complex, combining service and supply contracts.

The key challenges, including availability of funds and staff, involvement in tender procedures and project activities, have been translated into sustainability and assumptions and preconditions (see below).

Involvement of the main stakeholders and beneficiaries in the design and implementation of project activities will contribute to sustainable institutional capacity which enhances ownership and commitment, leads to improved results and facilitates acceptance of recommendations at the policy level.

An appropriate coordination of activities supporting the sector is essential to avoid overlap. For this purpose, a strong Steering Committee will be established under the project.

Learning from and cooperating with EU Member States and neighbouring countries generally yields good results. E.g. wildlife Rabies and CSF were eradicated from most areas in central and Western Europe through vaccination. In recent years similar programmes have been implemented in Member States with favourable results.

Inclusion and active participation of the National food safety bodies in the International and EU food safety schemas i.e. EFSA committees, IPPC committees, activities of the EU reference laboratories etc. will contribute to sustainability of the project results and faster integration of the country in the EU food safety programmes.

3 Description
3.1 **OVERALL OBJECTIVE OF THE PROJECT**

The overall objective of the project is further institutional and administrative capacity building, including development of the national competent authorities regarding food and feed safety, veterinary and phytosanitary policy.

3.2 **SPECIFIC OBJECTIVE(S) OF THE PROJECT**

Providing additional assistance to the Food and Veterinary Agency and Phytosanitary directorate in order to improve their overall ability for implementation of EU *Acquis* and obligations addressed in the other relevant documents, with specific reference on improvement of the animal disease control, field inspection services, food and feed safety, primary production control and plant health control systems.

3.3 **RESULTS**

**Measure 1:** Strengthening the capacity of animal health and veterinary public health services regarding disease surveillance and implementation of hygiene standards in primary production for food of animal origin, respectively, as well as strengthening the capacity of Phytosanitary Directorate

**Results within Operation 1:**

- Defined animal diseases and zoonoses of national importance for the country in addition of those currently implemented by the beneficiary;
- Specific control programmes prepared for the defined animal diseases of national importance for the country;
- Monitoring and surveillance of zoonoses on national level prioritised;
- Cost-effective disease control strategy prepared;
- Strategy and Road map designed for establishment of officially free status of certain animal disease in the country;
- Official veterinarians trained on the bases of epidemiological survey’s findings;
- Bio security standards and codes of practice developed with key stakeholders and approved by the competent authorities;
- Farm categorization scheme adopted, with associated movement controls;
- Bio security upgrading programme in place (linked to IPARD and/or funding schemes);
- Implementing measures are adopted in the national legislation.

**Measurable indicators:**

- Sustainable and comprehensive epidemiological data and laboratory results for certain animal and zoonotic diseases in competent authority data base developed;
- Cost-benefit study in terms of defining animal diseases and zoonoses of national importance prepared;
- Control programmes for the defined animal diseases adopted;
- Priority list of monitoring and surveillance of zoonoses developed;
- Strategy for disease control established;
- Officially free status strategy and road map of certain animal diseases established;
- Training delivered on the bases of epidemiological survey’s findings;
– Industry led bio security standards and codes of practice publicly available;
– Official monitoring in place and all pig holdings assessed;
– Funding scheme established and (subject to budget commitments) open to applications by pig producers and related businesses;
– New or amended national legislation adopted and published in the official journal.

Results within Operation 2:
– Capacity at the central level and inspection unit of the Veterinary Public Health Sector strengthened;
– Trained staff engaged in official controls, with the emphasis on primary production phase;
– The system for collection, processing and analysis of the data from official controls findings and data from monitoring and surveillance programmes improved.

Measurable indicators:
– Number of official controls based on risk analysis conducted;
– Number of monitoring and surveillance programmes implemented;
– Training delivered to the staff performing official controls and the staff engaged in primary production phase;
– Annual reports of conducted official controls in accordance with provisions set up in Regulation 882/2004;
– Increased number of farms that comply with the standards according to Regulation 853/2004.

Results within Operation 3:
– Strengthened phytosanitary border control in accordance with established border control procedures;
– Strengthened capacity of inland phytosanitary inspectors in order to implement relevant national legislation;
– ISPM standards implemented;
– Establishment of Information system for plant health.

Measurable indicators:
– Number of conducted border control checks of consignments by the staff in accordance with established border control procedures;
– Decreased number of disease notification by producers of plant and plant products;
– Decreased number of positive findings regarding harmful organisms from samples taken by phytosanitary inspectors;
– Information system for plant health established and operational.

Measure 2: Follow up of oral vaccination against Rabies and CSF (if needed)
Results:
– Procurement of Rabies and CSF vaccines and immunization of the wild fox and wild boar population (including farmed wild boar) against CSF;
− Samples collected by the hunters for laboratory analysis, in order to obtain more comprehensive and consequently more reliable data regarding presence/absence of the diseases in question.

**Measurable indicators:**
− Rabies and CSF vaccines supplied and immunization of the wild fox and wild boar population (including farmed wild boar) carried out according to the scheduled time-plan (number of baits per km²);
− Number of samples collected and tested according to the corresponding surveillance and monitoring programmes.

### 3.4 Main activities

**Measure 1:** Strengthening the capacity of animal health and veterinary public health services regarding disease surveillance and implementation of hygiene standards in primary production for food of animal origin, respectively, as well as strengthening the capacity of Phytosanitary Directorate

**Operation 1:**
− Conducting a wide sero survey in order to define animal diseases and zoonoses of national importance for the country (in addition of those currently implemented by the beneficiary);
− Cost-benefit analysis;
− Conducting a series of epidemiological surveys targeting selected animal diseases and zoonoses;
− Economic analysis of disease control options;
− Organising and conducting of competency-based training for official veterinarians based on the findings of the epidemiological surveys;
− Preparation of strategies and a road map for establishment of free status for certain diseases in the country;
− To engage with key stakeholders (pig producers, meat processors, livestock dealers and transporters, veterinary practitioners, feed suppliers, NGO’s) and promote development and adoption of sector-driven bio security standards and codes of practice covering all phases of production;
− To establish official bio security monitoring programme to categorise farms according to the standards in place;
− To develop further scheme, in conjunction with state agencies for rural support and development, to which pig producers and other related businesses may apply for support in improving bio security standards (structural and operational);
− To develop/amended national legislation with particular emphasis on links to requirement concerning identification and movement of animals, controls on animal by-products (dead animal, catering waste), cross-compliance with subvention scheme and disease.

**Operation 2:**
Development of the capacities at central level and of the inspection unit of the Veterinary Public Health Sector in order to implement monitoring and surveillance programmes, notably through:

- Elaboration of various inspection procedures (including practical implementation) and corresponding technical documentation i.e. guidelines, checklists, reports, etc;
- Elaboration of various monitoring procedures (including data collection) and corresponding technical documentation;
- Elaboration of methodology for data processing and analysis and risk assessment;
- Reporting (Annual reports/Multi-annual Control plan, Monitoring and Surveillance reports, etc);
- Development of corrective measures;
- Development of Guidelines for implementation of the new legislation (end users);
- Development of communication capacity in the competent authority to undertake public awareness campaigns;
- Organizing and conducting training for official veterinarians, as well as for primary food producers.

**Operation 3:**
- Organization and delivering of training for the border phytosanitary inspectors:
  - Preparation of manuals and guidelines on performing phytosanitary controls for phytosanitary inspectors at BIP, as well as for internal phytosanitary inspectors;
  - Organization and delivering of training for the relevant staff on implementation of ISPMs (Phytosanitary Directorate and Phytosanitary Inspection within State Agricultural Inspectorate);
- Assistance in establishment of Information system for plant health, notably through:
  - Record keeping;
  - Data-base collection and update;
  - Data processing;
- Organization and delivering of training for primary agricultural producers on:
  - Proper usage of plant protection products;
  - Biological plant protection.

**Measure 2: Follow up of oral vaccination against Rabies and CSF (if needed)**
- Purchasing of vaccine baits and implementation of the oral rabies and CSF vaccination campaign (twice per year);
- Collection of samples for laboratory analysis.

**3.5 ASSESSMENT OF PROJECT IMPACT, CATALYTIC EFFECT AND CROSS BORDER IMPACT**
Different activities under Measure 1 are underlined with the common goal that will reflect on overall improvement of public health through the improvement of implementation of food hygiene standards in primary food production as well through the improvement in the areas of animal and plant health.
Furthermore, the impact of improvement of hygiene standards in primary production phase is increased number of establishments approved for export in EU. The economic impact can also be identified in improvement of animal health status, as a direct impact of implementation of the adopted control programmes and disease control strategy. Designed Strategy and road map for establishment of officially free status of certain animal disease is of a great national significance, since this is a step forward towards fulfilling the OIE requirements.

Plant health activities and expected results under this project will contribute towards enhancing and enlarging of agriculture food production, as well as its quality improvement, reduce plant production expenses and consequently, better market competitiveness.

Regarding Measure 2 and taking into consideration that in 2011 there were nine confirmed cases (4 in foxes and 4 in wolves) of Rabies, in the samples taken from wild animals, as an ongoing activity under IPA 2008, Animal Disease Control Component, it is of an utmost importance that the immunization of wildlife against Rabies must continue.

Control/eradication of Classical Swine Fever in the wild boar population will reduce the incidence and facilitate the complete control/eradication in the pig farming industry of the country with clear economic benefits both in terms of reduction of losses and by enabling external trade of pigs and pig meat. So far, there are 13 confirmed cases of existing antibodies against CSF virus in wild pigs, according to laboratory analysis in the framework of IPA 2008 project implementation activities.

The control/eradication of the two diseases in wildlife will contribute to similar activities taking place in the other countries of the region. It will also reduce the risk of introduction of these two very important diseases to the European Union.

3.6 SUSTAINABILITY
The beneficiary institutions have competences and established structural framework required to continue and improve the results of this project. The beneficiary institutions will continue to work towards further promotion of project results in regard to fulfil EU requirements without delay in forthcoming period.

In terms of the administrative capacity to ensure sustainability, in 2010 competent authorities were significantly strengthened with new employments of staff involved in EU integration issues, in particular for implementation of EU Acquis: 15 new employments in Veterinary Directorate and 6 new employments in Food Directorate, as well as 5 employments in Phytosanitary Directorate. The Food and Veterinary Agency administrative capacity was strengthened with 16 new employments and Phytosanitary Directorate with 3 new employments in 2011. This trend of human resources strengthening will continue in future. Namely, 20 new employments in FVA and 5 new employments in PD are envisaged for 2012.

A number of personnel will be dedicated towards fulfilment of the project activities, achievement of project results and all further activities in this regard in order to achieve its sustainability. Additionally, the establishment of the National disease surveillance system, the trainings provided for the staff engaged on issues related to the area of food safety, veterinary and phytosanitary policy, the preparation and adoption of the of the legal framework, including guidelines, procedures, methodologies), as well as the successfully implemented
Communication strategy will be the main pillars of the project that will likewise secure the sustainability of the activities once the project is completed.

3.7 ASSUMPTIONS AND PRE-CONDITIONS

Assumptions: Commitment of national authorities; appropriate cooperation with all stakeholders; political commitment; vaccination of wildlife is successfully applied in neighbouring countries; the Government provides financial resources for implementation of surveillance and monitoring programmes, so the costs of actual implementation of the disease screening exercise on the whole territory of the country i.e., collection of samples, laboratory tests/ procurement of laboratory kits and reagents etc, will be provided by the Government. Software and IT equipment for establishment of Information system for plant health procured.

Preconditions: Endorsement by all key stakeholders of the twinning work plan and technical specifications for the individual contracts; organisation, selection and appointment of members (sufficient number and competency) of working groups, steering and coordination committees, seminars by the beneficiary as per work plan of the projects; appointing the relevant staff by the beneficiaries to participate in training activities as per work plan; availability of funds for national contribution;
  - The trainings under the individual activities will be carried out in the national training premises (for ex. EU/IPA Training and Support Facility);
  - In areas where there is evident expertise with the final beneficiary, the trainings will delivered by the civil servants, as part of their job description, without any compensation and/or with the assistance of key/short term experts;
4 IMPLEMENTATION ISSUES
The project will be implemented under DIS, and the Central Financing and Contracting Department (CFCD) will be the contracting authority for the following contracts under this project:

- **One Twinning contract** will be concluded, in total amount of approximately 1,421,000 EUR (EUR 1,349,950 from IPA and EUR 71,050 national co-financing);

- **One Supply contract** will be concluded (and one supply contract for CSF vaccines, if needed), in total amount of approximately EUR 2,200,000 (EUR 1,650,000 from IPA and EUR 550,000 national co-financing).

The overall coordination of the activities of the project will be carried out by the Food and Veterinary Agency, while the relevant departments within FVA and PD will have the responsibility for project execution and overall monitoring during its implementation.

For the Twinning arrangement, a Steering committee will be established to oversee the implementation process of the project activities. The twinning arrangement will also allow for administrative capacity building, training, integrity, legal development and addressing the cross-cutting issues. The project leaders will be responsible for the overall management, representation (co-ordination with the EU and other international bodies) as well as reporting to the Contracting Authority. The contact persons and details for this contract would be developed in the process of preparation of the actual Twinning Fiche, prior to the submission to the MSs.
4.1 **INDICATIVE BUDGET**

**Indicative Project budget 2012 (amounts in EUR)**

<table>
<thead>
<tr>
<th>PROJECT TITLE</th>
<th>TOTAL EXPENDITURE</th>
<th>TOTAL PUBLIC EXPENDITURE</th>
<th>IPA CONTRIBUTION</th>
<th>NATIONAL PUBLIC CONTRIBUTION</th>
<th>PRIVATE CONTRIBUTION</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>EUR (a)=(b)+(e)</td>
<td>EUR (b)=(c)+(d)</td>
<td>EUR (c)</td>
<td>% (2)</td>
<td>EUR (e) % (3)</td>
</tr>
<tr>
<td>IB (1)</td>
<td>INV (1)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Measure 1</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Twining</td>
<td>x</td>
<td>1,421,000</td>
<td>1,349,950</td>
<td>95</td>
<td>71,050</td>
</tr>
<tr>
<td>Supply</td>
<td>x</td>
<td>2,200,000</td>
<td>1,650,000</td>
<td>75</td>
<td>550,000</td>
</tr>
<tr>
<td>contract</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>TOTAL IB</td>
<td>1,421,000</td>
<td>1,349,950</td>
<td>71,050</td>
<td></td>
<td></td>
</tr>
<tr>
<td>TOTAL INV</td>
<td>2,200,000</td>
<td>1,650,000</td>
<td>550,000</td>
<td></td>
<td></td>
</tr>
<tr>
<td>TOTAL PROJECT</td>
<td>3,621,000</td>
<td>2,999,950</td>
<td>621,050</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**NOTE: DO NOT MIX IB AND INV IN THE SAME ROW. USE SEPARATE ROWS.**

Amounts net of VAT

1. In the Activity row, use "X" to identify whether IB or INV
2. Expressed in % of the Public Expenditure (column (b))
3. Expressed in % of the Total Expenditure (column (a))
4.2 **INDICATIVE IMPLEMENTATION SCHEDULE (PERIODS BROKEN DOWN BY QUARTER)**

<table>
<thead>
<tr>
<th>Contracts</th>
<th>Start of Tendering/Call for proposals</th>
<th>Signature of contract</th>
<th>Project Completion</th>
</tr>
</thead>
<tbody>
<tr>
<td>Twinning contract</td>
<td>Q1 2015</td>
<td>Q4 2015</td>
<td>Q4 2017</td>
</tr>
<tr>
<td>Supply contract</td>
<td>Q1 2014</td>
<td>Q2 2014</td>
<td>Q4 2014</td>
</tr>
</tbody>
</table>

4.3 **CROSS CUTTING ISSUES**

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

The mainstreaming of the cross cutting issues is two folded: (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.

4.3.1 **Equal Opportunities 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.

4.3.2 **Environment and climate change**

The training activities and the process of vaccination and numbering of animals will include a specific component to train beneficiary staff in the different aspects of mainstreaming environment in programme and project development.

4.3.3 **Minorities 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.

4.3.4 **Civil Society/Stakeholders involvement**

Relevant stakeholders (partners) of the this project that will benefit and cooperate with the beneficiary institutions are the *Macedonian Hunting Association*, the Private Enterprise *Macedonian Forestry*, which are already part of the implementation activities of the oral vaccination against rabies and classical swine fever in accordance with IPA Project fiche 2008, and as such are familiarised and well informed about the project purpose and their significant role regarding project implementation and effective project fulfilment. Also the primary food producers will benefit from the project activities.
ANNEXES
Documents to be annexed to the Project fiche

1. Log frame

2. Description of Institutional Framework

3. Reference list of relevant laws and regulations only where relevant

4. Details per EU funded contract(*) where applicable

5. Project visibility activities
ANNEX 1: Logical framework matrix in standard format (Logical framework matrix should be modified accordingly)

<table>
<thead>
<tr>
<th>LOGFRAME PLANNING MATRIX FOR Project Fiche</th>
<th>Project title and number</th>
<th>Further alignment with EU requirements of the competent authorities in the area of food safety, veterinary and phytosanitary policy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Contracting period expires two years from the date of the conclusion of the Financing Agreement</td>
<td>Execution period expires two years from the final date for contracting</td>
<td></td>
</tr>
<tr>
<td>Total budget</td>
<td>EUR 3,621,000</td>
<td></td>
</tr>
<tr>
<td>IPA budget:</td>
<td>EUR 2,999,950</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Overall objective</th>
<th>Objectively verifiable indicators</th>
<th>Sources of Verification</th>
</tr>
</thead>
<tbody>
<tr>
<td>The overall objective of the project is further institutional and administrative capacity building, including development of the national competent authorities regarding food and feed safety, veterinary and phytosanitary policy.</td>
<td>Comprehensive advancement towards fulfilling EU requirements regarding food safety, veterinary and phytosanitary policy (Chapter 12)</td>
<td>- Documentation: - Government progress reports; - EU assessment and progress reports.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Specific objective</th>
<th>Objectively verifiable indicators</th>
<th>Sources of Verification</th>
<th>Assumptions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Providing additional assistance to the Food and Veterinary Agency and Phytosanitary directorate in order to improve their overall ability for implementation of EU Acquis and obligations addressed in the other relevant documents, with specific reference on improvement of the animal disease control, field inspection services, food and feed safety, primary production control and plant health control systems.</td>
<td>Institutional development and increased capacity over ability to assume EU Acquis and substantiate EU priorities addressed in EP.</td>
<td>- Documentation: - Government progress reports; - EU assessment and progress reports.</td>
<td>-Commitment of national authorities; -Political commitment; - The Government provides financial resources for implementation of surveillance and monitoring programmes - Follow up on EU priorities.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Results</th>
<th>Objectively verifiable indicators</th>
<th>Sources of Verification</th>
<th>Assumptions</th>
</tr>
</thead>
</table>
**Measure 1:** Strengthening the capacity of animal health and veterinary public health services regarding disease surveillance and implementation of hygiene standards in primary production for food of animal origin, respectively as well as strengthening the capacity of Phytosanitary Directorate

**Results within Operations1:**

- Defined animal diseases and zoonoses of national importance for the country in addition of those currently implemented by the beneficiary;
- Specific control programmes prepared for the defined animal diseases of national importance for the country;
- Monitoring and surveillance of zoonoses on national level prioritised;
- Cost-effective disease control strategy prepared;
- Strategy and Road map designed for establishment of officially free status of certain animal disease in the country;
- Official veterinarians trained on the bases of epidemiological survey’s findings;
- Bio security standards and codes of practice developed with key stakeholders and approved by the competent authorities;
- Farm categorization scheme adopted, with associated movement controls;
- Bio security upgrading programme in place (linked to IPARD and/or funding schemes);
- Implementing measures are adopted in the national legislation.

- Sustainable and comprehensive epidemiological data and laboratory results for certain animal and zoonotic diseases in competent authority data base developed;
- Cost-benefit study in terms of defining animal diseases and zoonoses of national importance for country prepared;
- Control programmes for the defined animal diseases adopted;
- Priority list of monitoring and surveillance of zoonoses developed;
- Strategy for disease control established;
- Officially free status strategy and road map of certain animal diseases in the country established;
- Training delivered on the bases of epidemiological survey’s findings;
- Industry led bio security standards and codes of practice publicly available;
- Official monitoring in place and all pig holdings assessed;
- Funding scheme established and (subject to budget commitments) open to applications by pig producers and related businesses.
- New or amended national legislation adopted and published in the official journal.

- Reports from the passive surveillance system.
- Disease reports;
- Project documents and reports;
- FVO reports;
- EU Annual progress report;
- Monitoring end surveillance reports;
- National control plan annual report.

- Vaccination of wildlife is successfully applied also in neighbouring countries;
- Technical specification and ToR prepared in time;
- Cooperation arrangements with other stakeholders are appropriately established;
- Supply of software and IT equipment for Information system for plant health.
**Results within Operation 2:**
- Capacity at the central level and inspection unit of the Veterinary Public Health Sector strengthened;
- Trained staff engaged in official controls, with the emphasis on primary production phase;
- The system for collection, processing and analysis of the data from official controls findings and data from monitoring and surveillance programmes improved.

**Results within Operation 3:**
- Strengthened phytosanitary border control in accordance with established border control procedures;
- Strengthened capacity of inland phytosanitary inspectors in order to implement relevant national legislation;
- ISPM standards implemented;
- Establishment of Information system for plant health

**Measure 2: Follow up of oral vaccination against Rabies and CSF (if needed)**
- Number of official controls based on risk analysis conducted;
- Number of monitoring and surveillance programmes implemented;
- Training delivered to the staff performing official controls and the staff engaged in primary production phase;
- Annual reports of conducted official controls in accordance with provisions set up in Regulation 882/2004
- Increased number of farms that comply with the standards according to Regulation 853/2004
- Number of conducted border control checks of consignments by the staff in accordance with established border control procedures;
- Decreased number of disease notification by producers of plant and plant products;
- Decreased number of positive findings regarding harmful organisms from samples taken by phytosanitary inspectors;
- Information system for plant health established and operational
- Rabies and CSF vaccines supplied and immunization of the wild fox and wild boar population (including...
- Procurement of Rabies and CSF vaccines and immunization of the wild fox and wild boar population (including farmed wild boar) against CSF
- Samples collected by the hunters for laboratory analysis, in order to obtain more comprehensive and consequently more reliable data regarding presence/absence of the diseases in question.

<table>
<thead>
<tr>
<th>Activities to achieve results</th>
<th>Means / contracts</th>
<th>Costs (in EUR)</th>
<th>Assumptions</th>
</tr>
</thead>
</table>
| **Measure 1:** Strengthening the capacity of animal health and veterinary public health services regarding disease surveillance and implementation of hygiene standards in primary production for food of animal origin, respectively as well as strengthening the capacity of Phytosanitary Directorate | 1 Twining Contract | Total budget: 1,421,000  
IPA contribution: 1,349,950  
National contribution: 71,050 |  |
| **Operation 1:** | 1 Supply contract (supplies vaccines) | Total budget: 2,200,000  
IPA contribution: 1,650,000  
National contribution: 550,000 |  |
| - Conducting a wide sero survey in order to define animal diseases and zoonoses of national importance for the country (in addition of those currently implemented by the beneficiary); | | |  |
| - Cost-benefit analysis; | | |  |
| - Conducting a series of epidemiological surveys targeting selected animal diseases and zoonoses; | | |  |
| - Economic analysis of disease control options; | | |  |
| - Organising and conducting of competency-based training for official veterinarians based on the findings of the epidemiological surveys; | | |  |
| - Preparation of strategies and a road map for establishment of free status for certain diseases in the country. | | |  |
| - To engage with key stakeholders (pig producers, meat processors, livestock dealers and transporters, veterinary practitioners, feed suppliers, NGO’s) and promote development and adoption of sector-driven bio security standards and codes of practice covering all phases of production; | | |  |
| - To establish official bio security monitoring | | |  |
programme to categorise farms according to the standards in place;
- To develop further scheme, in conjunction with state agencies for rural support and development, to which pig producers and other related businesses may apply for support in improving bio security standards (structural and operational);
- To develop/amended national legislation with particular emphasis on links to requirement concerning identification and movement of animals, controls on animal by-products (dead animal, catering waste), cross-compliance with subvention scheme and disease.

**Operation 2:**
- Development of the capacities at central level and of the inspection unit of the Veterinary Public Health Sector in order to implement monitoring and surveillance programmes, notably through:
  - Elaboration of various inspection procedures (including practical implementation) and corresponding technical documentation i.e. guidelines, checklists, reports, etc;
  - Elaboration of various monitoring procedures (including data collection) and corresponding technical documentation;
  - Elaboration of methodology for data processing and analysis and risk assessment;
  - Reporting (Annual reports/ Multi-annual Control plan, Monitoring and Surveillance reports, etc);
  - Development of corrective measures;
  - Development of Guidelines for implementation of the new legislation (end
users);

- Development of communication capacity in the competent authority to undertake public awareness campaigns;
- Organizing and conducting training for official veterinarians, as well as for primary food producers.

Operations 3:
- Organization and delivering of training for the border phytosanitary inspectors;
- Preparation of manuals and guidelines on performing phytosanitary controls for phytosanitary inspectors at BIP, as well as for internal phytosanitary inspectors;
- Organization and delivering of training for the relevant staff on implementation of ISPMs (Phytosanitary Directorate and Phytosanitary Inspection within State Agricultural Inspectorate);
- Assistance in establishment of Information system for plant health, notably through:
  ▪ Record keeping
  ▪ Data-base collection and update
  ▪ Data processing
- Organization and delivering of training for primary agricultural producers on:
  ▪ Proper usage of plant protection products
  ▪ Biological plant protection

Measure 2: Follow up of oral vaccination against Rabies and CSF (if needed)
- Purchasing of vaccine baits and implementation of the oral rabies and CSF vaccination campaign (twice per year);
- Collection of samples for laboratory analysis.
ANNEX II - Description of Institutional Framework

I. FOOD AND VETERINARY AGENCY

Food and Veterinary Agency has been established in accordance with the Law on Food Safety (“Official Journal of RM” No.157/2010, 53/2011, 1/2012).

This Law lays down the general principles governing food and feed safety in general, general and specific hygiene requirements for food, organizational structures of the food safety system and the official controls on food and feed. Hence in Chapter IV Competent Authority Article 15 it is stipulated that:

- For performing the activities related to food and feed safety, implementation, control, surveillance and monitoring of the veterinary activities in the field of animal health, their welfare, veterinary public health, as well as control on laboratories, according to this and other law from the field of veterinary health, is established Food and Veterinary Agency, as an independent body of the public administration in the role of legal person.
- The full name of the Agency is: Food and veterinary Agency
- The name of the Agency in the international-legal trade is: Food and Veterinary Agency.
- The Headquarters of the Agency is in Skopje.

The Agency performs the activities under its competence in accordance with the international agreements ratified by country, International Standards of the World Animal Health Organization (OIE), Codex Alimentarius as well as with other acts and standards to which the country has obligated with.

The Agency performs the activities under its competence on the basis of the principles of legitimacy, competence, professionalism, responsibility, efficiency and transparency.

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, usage, 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; and
- Other activities significant for the veterinary health, food and feed safety.

The Agency is managed by director who is nominated and revoked of duty by the Government. The director has a mandate of four years, with possible re-nomination.

Within the framework of his competences, the director of the Agency is responsible for effective functioning of the Agency and coordination of the inter-sectorial activities. Expert,
administrative-technical, auxiliary and other activities are performed by the professional services of the Agency.

**Sector for animal health and welfare:**
- Promotes standards and efficiency in disease controls in animals as well as zoonoses;
- Planning, organisation and implementation of activities for surveillance, performs monitoring and control/eradication of animal diseases in the territory of the country;
- Collection, keeping and analyses of data concerning diseases occurrence and preparing the information;
- Monitoring of worldwide animal health situation by regular communications and consultation of International Office of Epizooties (OIE) and prescribes relevant import provisions;
- Providing Animal welfare and protection;
- Establishing the National System for Animal Identification, including bovine animals and other domestic animal species;
- Monitoring and control the movement of any animal by means of the appropriate database.

**Sector for veterinary public health**
- Responsibility for food control of animal origin following the concept “from stable to table”;
- Providing confidence to citizens by consistent application of standards at national and international level;
- Support and education of producers for quality and safety production;
- Access to foreign markets;
- Control of production, import, distribution and use of veterinary medicinal products (vmp);
- Records keeping of approved manufacturing establishments, marketing authorised drugs, approved wholesale distributors for veterinary medicinal products;
- Control of import and production for feeding-stuff;
- Establishment of centre for pharmaco-vigilance;
- Control of the quality of food of animal origin.

**Sector for food of non-animal origin**
- Responsibility for food of non-animal origin, approval before introducing on the market of different type of food of non-animal origin in relation with its specificity and effect on human health;
- Control of food of non-animal origin and food contact materials;
- Preparing, tracking and management of monitoring programme for food safety;
- Communication with different Competent Authorities in EU and third countries responsible for food safety;
- Control of food for special nutritional use, enriched food and food supplements;
- Control of GMO, novel food and ionizing radiation, other food types and products.

**Sector for border inspection:**
- Supervision and control import/transit of animals and products, raw materials and by products of animal origin and also food of non-animal origin. Therefore, Food and Veterinary Agency has complete insight for quantity, dynamics and health and safety status of food of animal and non-animal origin, allowing rapid and efficient
implementation of competency and guarantee a health status of consignments of animal and non-animal origin with minimum risks for humans, animals and environment;
- Upgrading the capacities at Border Inspection Posts-BIPs and introducing the procedures for veterinary controls of live animals and products of animal origin and also food controls, during their import/export in accordance with EU standards.

**Integrated Border Management** – National Strategy on Integrated Border Management, aiming at integration and approximation to EU standards and preserving of national and regional peace and stability, is created pursuant to recommendations and liability transposed by the country stipulating from:
- Signature and ratification of the Stabilisation and Association Agreement;
- Participation to EU instruments/mechanisms, such as CARDS;
- Access to European and regional agreements and mechanisms on promotion of border management; and
- Signature and ratification of international conventions.

Future border management is based on integrated system for border management in whole, closely related to implementation of laws at national level and increased control for humans and livestock intended for import in and transit through and export from the territory of the country. Integrated concept for protection of borders, by improvement of methodology for intelligence data collection and more efficiently coordination activities and internal inter-agencies and international collaboration will provide better assurance focused to annul the risks originating from internal and international crime and terrorism. At same time, the future system will be focused to permanent improvement of border control system efficiency and augmentation of movement/circulation of people and goods.

**Sector for EU and international cooperation**
- Development and consolidation of policies in relation with approximation and transposition of national legislation with EU Acquis;
- Preparing of progress reports for EU integration for Chapter 12- Food safety, veterinary and phytosanitary policy;
- Preparing of activities related with EU negotiation;
- Project and foreign aid coordination.

**Sector for legal and administrative affairs**
- Coordination of all Legal matters related with the Food and Veterinary Agency;
- Coordination of all Financial matters related with the Food and Veterinary Agency;
- Coordination of all matters related with maintenance of all IT systems which are part of the Food and Veterinary Agency;
- Coordination of all archive and office matters in the Food and Veterinary Agency.

**Sector for professional support**
- Risk assessment and risk communication related to food safety;
- Contact point with the RASFF system;
- Implementation of ISO standards, coordination and control of laboratories which are pursue activities with national interest;
- Implement and coordinate activities regarding approval and registration of legal and physical persons according with acts for food safety, veterinary health and veterinary medicinal products.
The Regional Units of the Agency and the BP are in Annex 1 and 2.
II PHYTOSANITARY DIRECTORATE
Phytosanitary Directorate within Ministry of Agriculture, Forestry and Water Economy is competent authority for:
- Plant health;
- Overall plant protection;
- Production, usage and marketing of fertilisers.

The Phytosanitary Directorate is consisted of the following departments:

**Sector 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.

**Sector for Agro-chemistry** responsible for authorization, placing on the market, use and control of the plant protection products, placing on the market and control of active substances which are products, maximum residue levels, equipment for application, exchange of information about the products, production of the products, evidence of legal and single entities and persons involved in production and placing on the market, provisions for authorization of the entrusted authorities responsible for implementation, monitoring and control.

**Unit for fertilizers** within this Sector is responsible for the provisions for production, placing on the market, import, use of fertilizers, types of fertilizers, identification, quality, composition, sampling, packing, marking, examination, declaration, monitoring, registration and other issues regarding the fertilizers.

**Sector for Phytosanitary Legislation and Management** responsible for phytosanitary legislation, translation of EU regulations, international cooperation and communication, analysis and management.
ANNEX III - Reference list of relevant laws and regulations:
- Food Safety Law, 2010
- Veterinary Health Law, 2007;
- Animal By-products Law, 2007;
- Animal Welfare Law, 2007;
- Identification and Registration of Animals Law, 2004;
- Veterinary Medicinal Products Law, 2010;
- Feed Law, 2010;
- Quality of Agricultural Products Law, 2010;
- Plant Health Law, 2005;
- Plant Protection Products Law, 2007;

ANNEX IV - Details per EU funded contract

The overall coordination of the activities of the project will be carried out by the Food and Veterinary Agency, while the relevant departments within FVA and PD will have the responsibility for project execution and overall monitoring during its implementation.

For the Twinning arrangement, a Steering committee will be established to oversee the implementation process of the project activities. The twinning arrangement will also allow for administrative capacity building, training, integrity, legal development and addressing the cross-cutting issues. The project leaders will be responsible for the overall management, representation (co-ordination with the EU and other international bodies) as well as reporting to the Contracting Authority. The contact persons and details for this contract would be developed in the process of preparation of the actual Twinning Fiche, prior to the submission to the MSs.

Indicative list of items/cost estimate

**Classical Swine Fever (CSF)**

Please find below a preliminary estimation of the likely cost of running a **CSF vaccination programme**.

*Context:* This estimation is given taking account of the principles established in the EFSA Scientific Opinion (SO) on the control and eradication of Classic Swine Fever in wild boar. In particular, it takes account of the following principles:

- Once a decision is taken to commence vaccination, it should be performed frequently (3 campaigns per year – Spring, Summer & Autumn; vaccination distributed twice (14-28 days apart) during each campaign) and continued for several years (e.g. the strategy in France was to continue for at least 8 years (2004-2011); Germany has been vaccinating since 2002).
- The baiting density depends to an extent on the density of the wild boar population (baiting density must be increased as competition for baits increases). However, in sparsely populated areas, the baiting density must be sufficient in order ensure that wild boar have the opportunity to consume a bait. The EFSA SO recommends baiting densities of 20-40 baits per campaign in each feeding area, with 1-2 feeding areas per square kilometre.
The data used in the analysis were provided by the Member States (BG, DE, FR, RO) that received EC funding for CSF vaccination of wild boar during 2011.

**Analysis** - The attached spread sheet presents three vaccination scenarios, which are used to estimate the likely costs of vaccination. Scenario 1 presents the most extensive programme, using the least favourable cost estimates. Scenario 3 presents a ‘light touch’ programme using the most optimistic cost estimates – it is far from certain that such a campaign would have any positive effect and it is included here mainly for illustrative purposes. Scenario 2 presents the ‘middle ground’. Details of the sources of data used and the assumptions made in the model are presented as comments inserted into the cells in column B.

**Conclusion:** - The estimates provided in the attached spread sheet are quite rigid and based on a number of assumptions: in practice the vaccination plan is likely to be a hybrid, based on elements drawn from each scenario. The cost estimates are based on data prepared by Member States during 2010 – inflationary effects have not been accounted for. Additional costs (e.g. for laboratory equipment, training of hunters etc.) are certain to arise. Therefore, it is probably best to estimate the cost of vaccination each year as Scenario 2 estimates – i.e. EUR 200,000. Further consideration must be given to the number of years over which the programme is likely to extend. It is considered that IPA 2012 project will cover 2 consecutive years. A vaccination strategy lasting less than 5 years is unlikely to have a significant positive impact on the incidence of disease. Therefore, further consideration will be given to assure secure funding for the following years.

Finally, no decision to commence vaccination should be made before the likely costs, benefits and associated risks are considered. It is far from certain that the conditions justifying the implementation of emergency vaccination of wild boar exist in the former Yugoslav Republic of Macedonia. These factors will be examined in detail as part of the study being undertaken within the framework of the technical assistance project.

Summary: - If ‘middle ground’ approach is used, an estimation of appr. EUR 200,000 will be required per year for two years.

**Rabies**

The estimation of the costs for the oral vaccination of foxes against Rabies was done having in consideration following:

**Definition and size of the area to be vaccinated**

Experience from programs that have successfully eradicated wildlife rabies from several European countries provides fundamental guidelines for definition of the minimal size of the vaccination zone, which should ideally include:

- the entire infected area, or at least a large part of it. The area should be as large as possible (5,000 km² at least). Elimination of wildlife rabies from a small area that is not defined by natural or artificial fox-proof barriers would be impossible, or only temporary, due to contamination of the non-immunized young foxes of the area by rabid individuals from bordering zones. Every year more than half of the fox population is replaced by young individuals.
a buffer zone, i.e. a strip at least 50 km wide that extends ahead of the front into the supposedly non-infected areas. This precautionary step is advisable because 1) it is essentially impossible to precisely determine the exact position of the advancement of the front, and 2) the front is likely to advance during the time between definition of the vaccinated areas and implementation of the vaccination campaigns.

In 2011/2012 a total of eight outbreaks of Rabies have been recorded in the country:

Recent examination on the genetic characterization of the virus isolated from the positive cases in the former Yugoslav Republic of Macedonia reveals perfect nucleotide similarity with 100% identity with the Serbian isolate (First reported cases of rabies in the national Veterinary Record; T.Kirandjiski et al 2011).

According to the above, and taking into account the last confirmed rabies case in a cow in Albania recorded appr. 10 km from the border with the former Yugoslav Republic of Macedonia in 2010, it was concluded that the total territory of the country except the lakes and mountains with attitude of more than 1,800 m should be covered with the bait distribution i.e. appr. 25,000 km². Same approach was accepted in the vaccination campaign implemented in 2011.

Vaccine bait - Several night-counts of foxes were conducted in various geographic locations and habitat types in June-July 2010 to access the relative abundance of foxes across the country. Results of these investigations indicated that the abundance of foxes does not differ from (i.e., is not greater than) that reported elsewhere in Europe. Thus, the distribution of 20 vaccine baits per km² is considered conservatively sufficient for all parts of the territory.

Therefore, a total of 500,000 vaccine baits are required per vaccination campaign. Two vaccination campaigns (Spring/Autumn) are required per year.
Given the price estimate of 0.9 Euro per distributed vaccine bait following calculation may be made:

<table>
<thead>
<tr>
<th></th>
<th>Number of years for ORV</th>
<th>Number of campaigns/year</th>
<th>Number of baits/campaign</th>
<th>Price estimate per distributed bait</th>
<th>Total price</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>2</td>
<td>2</td>
<td>500,000</td>
<td>0.9 Euro</td>
<td>EUR 1,800,000</td>
</tr>
</tbody>
</table>

**Intended beneficiary** - Food and Veterinary Agency

**Technical specification** - The detailed technical specification will be prepared by FVA officials.

**Maintenance** - Having in regard the specific supply type – vaccines, the maintenance is not required.
ANNEX V - Project visibility activities

All requirements to ensure the visibility of EU financing will be fulfilled in accordance with the Commission Regulation (EC) No. 718/2007 of 12 June 2007 Implementing the Council Regulation (EC) No 1085/2006 Establishing an Instrument for Pre-accession Assistance (IPA IR).

During the implementation of the Project the necessary measures will be taken to ensure the visibility of the EU financing or co-financing. Such measures must be in accordance with the applicable rules on the visibility of external action laid down and published by the Commission. The Project must observe the latest Communication and Visibility Manual for EU External Actions concerning acknowledgement of EU financing of the project (see http://ec.europa.eu/europeaid/work/visibility/index_en.htm). Particular attention should be given to ensuring the sustainability and dissemination of project results. The visibility issues must be addressed in all types of communications, written correspondence and preparation of deliverables (brochures, posters, new letters pamphlets and other type of promotion material). All the deliverables to be published / issued will respect and comply with visibility guidelines.