

Project Fiche – IPA National programmes/Component I

1 IDENTIFICATION

Project Title	Further alignment of food safety, veterinary and phytosanitary policies with EU requirements
CRIS Decision number	2012/022-989
Project no.	10
MIPD Sector Code	8. Agriculture and Rural Development
ELARG Statistical code	03-12
DAC Sector code	31110
Total cost	2012: EUR 2,801,473
EU contribution	2012: EUR 2,251,400
Management mode	Decentralised
Responsible Unit or National Authority/Implementing Agency	<p>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.</p> <p><u>Contact:</u> Mrs. Radica Koceva (PAO) Central Financing and Contracting Department Ministry of Finance Tel: +389 2 3231 219 Fax: +389 2 3106 612 E-mail: radica.koceva@finance.gov.mk</p>
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Implementing modality	Stand alone project
Project implementation type	1 Twinning contract, 2 supply contracts
Zone benefiting from the action(s)	Nationwide

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 2014-2016 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 make approximation with 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 will be done with the IPA 2009 project,(currently under implementation) regarding the accreditation of the inspection services of the FVA according the EN 45004 or other relevant standard.

Food and Veterinary Agency has prepared the new Food safety strategy 2013-2018 The Second Food Safety Strategy is based on several basic principles as follows: (1) activities that cover whole food chain, from the primary production till the final consumer, (2) effective implementation of the relevant EU legislation, (3) principles of risk analysis, (4) priority given to major health risks, (5) implementation of the official controls in accordance to Regulation 882/2004.

The Macedonian Multi-annual National Control Plan (MANCP) was adopted by the Government of the former Yugoslav Republic of Macedonia and published in ("Official Journal of RM" 152/2012 from 27.08.2012) .

The overall objective of MANCP is to ensure effective implementation of relevant national legislation and other implementing documentation and to ensure that the Competent Authorities and other relevant stakeholders enforce and verify that relevant requirements are met, and that systems for official controls from "farm to fork", surveillance and monitoring activities covering all stages of productions, processing and distribution of food and feed as well as animal health and welfare and plant health, are maintained.

Furthermore, its specific objective is to ensure that the established comprehensive and integrated control system of official controls will contribute to protection of public and animal health and welfare and plant health and safeguard consumer interests.

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 health (“Official Gazette” 29/2005, 81/2008, 20/2009, 57/2010, 17/2011, 148/2011);
- Law on plant protection products (“Official Gazette” 110/2007, 20/2009);
- Law on fertilizers (“Official Gazette” 110/07, 20/09).

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 2013** as regards **general food safety**, a new food safety strategy (2013-2018), an internal audit plan (2012-2016) and a general crisis management plan were adopted by the Food and Veterinary Agency. The government established National Council for Food and Animal Feed Safety to perform an advisory function. Preparations in this area are on track.

In the area of **veterinary policy**, the Agency continued to provide regular updates on control systems of imports and import requirements for live animals and animal products. The system of reduced frequency of checks on consignments at the border inspection posts has yet to be implemented. As regards control measures for animal diseases, the Agency continues to implement the programme for oral vaccination of foxes against rabies and issued an eradication rulebook. The FVA also continues mass vaccination of domestic pigs against classical swine fever and will increase monitoring of the wild boar population from 2013. The quality of the rabies laboratory improved, allowing the Commission to authorise it to perform blood tests for rabies. Significant delays in payments to authorised private veterinary stations remain a problem for the implementation of the animal health programme. In the area of veterinary policy, preparations are advanced.

In the area of **food safety rules**, the annual monitoring programme for food safety is in place. Risk-based classification of food establishments dealing with food of non-animal origin and inspection planning has been established. The capacity of the food inspectorate remains insufficient.

In the area of **phytosanitary policy**, some implementing legislation was adopted on plant health and on quality of seeds and propagation material but no action was taken to implement international standards, in particular on surveillance, export certification and determining pest status. Control of marketing places of plant production products continues on a random basis only. Coordination between the competent authorities has not improved. The administrative capacity of the Phytosanitary Directorate remains weak.

The State Phytosanitary Laboratory remains under-used due to its undefined role in the food safety monitoring system and the lack of samples received on a regular basis. Preparations in the area are not very advanced.

The Conclusions of the above mentioned report are as follows: Good progress was made in the area of food safety and veterinary policy, in particular regarding the implementation efforts of the Food and Veterinary Agency and the introduction of the risk-based system for official controls. Preparations in the area of food safety and veterinary policy are well on track. Preparations in the phytosanitary area are at an early stage.

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 of food of animal origin as well as feed safety and residues of veterinary medicinal products.

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.

In order to raise the level of preparedness and to strengthen the capacity of animal health service training of official veterinarians and FVA officials at central level involved in the control of the diseases in animals is necessary.

Currently the FVA is implementing program for control of Rabies in domestic and wild animals including the oral vaccination of foxes against rabies and program for monitoring of Classical swine fever and Trichinellosis in wild boar. The program for monitoring of the brucellosis in wild boar will start in 2014.

At the moment, there are no surveillance programs for vector born and parasitological diseases in place. Certain diseases (West Nile, Leishmaniasis, Echinococcosis), are present in the human population but the epidemiological situation in animals is not clear. In order to have clear picture of the presence of the vector borne diseases and the presence of vectors and their movement the general survey of the presence of this disease and vectors as well need to be prepared and implemented with appropriate analysis of the results. The outcome of this activity will be used for defining the pathway of the FVA for combating this disease and vectors.

The legal basis is the Law on Veterinary Health (OJ of the RM No.113/07, 24/11, 136/11, 123/12); and the relevant Book of rules on Compulsory notifiable diseases (OJ of the RM No.110/10); Program for control and eradication of Bluetongue (OJ of the RM No.104/07); and Program for control and eradication of contagious diseases in animals (OJ of the RM No.82/07).

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.

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 were 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 will provide data whether the oral vaccination against CSF will be needed.

Although the primary and secondary legislation in the area of animal welfare is adopted, the implementation and the awareness of the animal owners of the provisions, responsibilities and its tasks, is at low level.

Food and Veterinary Agency is responsible for protection of human and animal health from possible adverse reactions from veterinary medicinal products. For that reason, establishment of functional system for monitoring of adverse reactions as well as a system for antimicrobial resistance.

The Veterinary Information System within FVA is designed to provide data and reports from official controls. In order to provide a solid preventive and control system for food safety, development of additional modules for collection of data related to alimentary intoxications is necessary. Improvement of the capacity in application of measures to prevent alimentary intoxications is needed.

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.

According to Art. 19 of the Law on plant health (“Official Gazette” 29/2005, 81/2008, 20/2009, 57/2010, 17/2011, 148/2011), all registered legal and natural entities are obligated to notify the competent authority on any suspected occurrence of harmful organisms.

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.

Food and Veterinary Agency and Phytosanitary Directorate are responsible for the control of import and export of live animals, products and by-products of animal origin, plants, products of plant origin and plant protection product at the border crossing points, respectively.

The Government has adopted National Strategy for Integrated Border management. The Strategy is a comprehensive document addressing integrated border management in his full length. Chapter 22 of that Document is dedicated to the Veterinary and Phytosanitary border service.

At the moment there are 10 Border inspection post operating in the Country on the borders with Albania, Bulgaria, Serbia and Greece as below distributed:

- One at Skopje Airport;
- Five at Road crossings;
- Four at mixed Road/Railroad crossings.

In order to increase the level of the official controls closer to EU - standards and for entire envisaged personnel, additional financial support is essential,

For the purpose of the Measure 3, purchase of equipment for BIP Blace and Tabanovce is envisaged.

In addition, technical tools for execution of the official controls, both at the Border inspection posts as well as in land inspections. Currently FVA inspectors are not sufficiently equipped to perform the controls.

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; Increased capacity for surveillance and monitoring of harmful organisms and plant protection products. **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 official controls; The capacities at the central level and inspection units for veterinary issues and implementation of hygiene standards in primary production for food of animal origin are strengthened and implementation of the priority monitoring and surveillance programs; 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. Farm categorization scheme, with associated movement controls, adopted Bio security standards and codes of practice developed; The Phytosanitary border inspection control strengthened, as well as capacities for plant health and control of plant protection products

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, , animal welfare, , Contingency planning, feed safety, veterinary medicinal products alimentary intoxications , respectively, as well as strengthening the capacity of Phytosanitary system.

Results within Operation 1

- Further development of national legislation in line with the EUAcquis;
- Systematic preparation of operative documentation for implementation of the legislation

Measurable indicators:

- Number of prepared documents regarding implementing secondary legislation;
- Number of developed manuals, models, forms which will be used by official inspectors and/or FBO.

Results within Operation 2:

- The capacity of the official veterinarians is strengthened to perform official controls in animal welfare requirements

Measurable indicators:

- All official veterinarians are trained to use animal welfare equipment and perform inspection controls, as well as pose corrective measures;

Results within Operation 3:

- Priority vector borne and parasitic diseases of national importance defined;
- Cost benefit study for control of predefined vector borne and parasitic diseases prepared;
- Strategy plan for monitoring and surveillance for vector borne and parasitic diseases of national importance established;
- Appropriate legislation adopted;

- Procedures and check list for uniform application of the established surveillance and monitoring system developed;
- Monitoring and surveillance system for predefined vector borne and parasitic diseases established and implemented;
- Training of official veterinarians and other staff in performing official controls implemented.

Measurable indicators:

- Report presenting the risk and distribution of vectors and vector borne diseases and parasitic diseases prepared;
- Procedures and check list for the relevant programs are used;
- Monitoring and surveillance system for predefined vector borne and parasitic diseases implemented and maintained in the following years;
- All official veterinarians and staff involved in animal disease control trained.

Results within Operation 4:

- Capacity of the Food and Veterinary Agency with regards to contingency planning is strengthened
- Training of Official Veterinarians on measures in case of an outbreak of a disease subject to contingency planning implemented;
- ;
- Monitoring and surveillance programs for diseases subjected to contingency planning implemented;
- GIS modalities in aquaculture implemented;
- Laboratory capacities for diagnostics in aquatic health improved;
- Monitoring and surveillance programs for diseases in aquaculture implemented.

Measurable indicators:

- All official veterinarians trained in implementation of measures in case of outbreak of a disease;
- GIS modules in VIS implemented for aquaculture diseases;
- Monitoring and surveillance programs for aquatic diseases implemented and maintained.

Results within Operation 5:

- Improved system for feed safety;
- Application of the principles of risk analysis for feed safety

Measurable indicators:

- Prepared monitoring programme regarding feed safety and animal nutrition;
- Food and Veterinary Agency staff trained for the application of feed safety risk analysis

Results within Operation 6:

- Improved system for Veterinary medicinal products(VMP).

Measurable indicators:

- Developed programme for antimicrobial resistance;
- Introduced functional system/centre for adverse reaction

- Improvement of technical knowledge regarding VMP for the private veterinarians and producer of VMP, through development of manuals, operative documents etc.

Results within Operation 7:

- Developed system for management zoonosis and alimentary intoxications.

Measurable indicators:

- Established rapid alert system regarding alimentary intoxications;
- Established system for monitoring outbreaks of alimentary intoxications.
- Established measures to prevent alimentary intoxication occurrence

Results within Operation 8:

- Harmonized national legislation regarding plant health and plant protection products;
- Strengthened capacities within the Phytosanitary System (Phytosanitary Directorate, State Agriculture Inspection, in particular Phytosanitary Inspectors and State Phytosanitary Laboratory);
- Developed and update Phytosanitary Information System;
- Developed institutional structure for proper implementation of a National Plant Passport System;
- Established a system for reporting, diagnostic and forecasting of harmful organisms in the country;
- Sustainable use of plant protection products.

Measurable indicators:

- Number of adopted legislation on plant health and plant protection products, as well as inspection control procedures;
- Proper implementation of national legislation and ISPM, that contributes to decreased number of positive findings regarding plant health and use of plant protection products;
- Functional Phytosanitary Information System;
- Functional National Plant Passport System;
- Increased number of inland official controls achieving decreased number of disease notifications for harmful organisms;
- Decreased use of PPPs and introduced a principles of Integrated Pest Management.

Measure 2: Follow up of oral vaccination against Rabies

Results:

- Procurement of Rabies vaccines and immunization of the wild fox against rabies;
- Samples collected by the hunters for laboratory analysis, in order to obtain more comprehensive and consequently more reliable data regarding presence/absence of the disease in question.

Measurable indicators:

- Rabies vaccines supplied and immunization of the wild fox 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.

Measure 3: Supply of equipment for official controls and for the border inspection facilities at BIP Blace and BIP Tabanovce

Results:

- Procurement of equipment for inspection services to perform official controls
- ;
- Equipped and operational BIP facilities for Food, Veterinary and Phytosanitary control.

Measurable indicators:

- Efficient performance of the official controls both in the territory of the country and at the border
- .

3.4 MAIN ACTIVITIES

Measure 1: Strengthening the capacity of animal health and veterinary public health services regarding disease surveillance, animal welfare, Contingency planning, feed safety, veterinary medicinal products, alimentary intoxications respectively as well as strengthening the capacity of Phytosanitary system

Operation 1:

- Drafting a legislation (primary/secondary) in line with the EU legislation including last amendments
- Systematic approach and drafting of operative implementing secondary legislation ;
- Preparation of documentation relevant for the implementation of adopted new legislation.
- Drafting of supporting implementing documents: guidelines, procedures etc. aimed for the official controls and/or Food/feed business operators;

Operation 2:

- Organization and delivery of trainings for official veterinarians as regards animal welfare requirements

Operation 3:

- Preparation of analysis for priority vector borne and parasitic diseases of national importance for RM;
- Preparation of cost benefit study for control of predefined vector borne and parasitic diseases;
- Preparation of Strategy plan for monitoring and surveillance for vector borne and parasitic diseases of national importance;
- Development of relevant legislation;
- Preparation of Procedures and check list for uniform application of the established surveillance and monitoring system;
- Preparation of Monitoring and surveillance system for predefined vector borne and parasitic diseases;
- Conducting trainings for official veterinarians and other staff in performing official controls.

Operation 4:

- Preparation, where applicable revision of different contingency plans;
- Conducting trainings for official veterinarians regarding measures in case of an outbreak of a disease subject to contingency planning;
- Preparation of Monitoring and surveillance programs for diseases subjected to contingency planning;
- Preparation of GIS modalities in aquaculture;
- Preparation of Monitoring and surveillance programs for diseases in aquaculture.

Operation 5:

- Preparation of monitoring programme regarding feed safety and animal nutrition;
- Development of a system for feed safety risk analysis;
- Conducting trainings for FVA staff regarding the application of feed safety risk analysis.

Operation 6:

- Preparation of a programme for antimicrobial resistance;
- Preparation of functional system/centre for adverse reaction;
- Development of operative documentation for supporting the implementation of relevant legislation;
- Drafting of guidelines, manuals and other documents for relevant stakeholders;
- Organization and delivering training to FVA relevant personnel to improve the knowledge as regards VMP.

Operation 7:

- Development a rapid alert system regarding alimentary intoxications ;
- Development of monitoring system for occurrence of alimentary intoxications;
- Development of IT module for reporting and data collection related to alimentary intoxications;
- Development of system for prevention of occurrence of alimentary intoxications.

Operation 8:

- Preparation of documents regarding plant health and plant protection products;
- Conducting trainings for Phytosanitary Directorate, State Agriculture Inspection and State Phytosanitary Laboratory staff regarding proper implementation of national legislation and ISPM;
- Analysis, development, if applicable update of Phytosanitary Information System;
- Development of institutional structure for proper implementation of a National Plant Passport System;
- Development of system for reporting, diagnostic and forecasting of harmful organisms in the country;

Measure 2: Follow up of oral vaccination against Rabies Purchasing of vaccine baits and implementation of the oral rabies vaccination campaign (twice per year);

- Collection of samples for laboratory analysis.

Measure 3: Supply of equipment for official controls and for the border inspection facilities at BIP Blace and BIP Tabanovce

- Equipping the inspection services for performance of official controls;
- Equipping of facilities for food, veterinary and phytosanitary inspection at BIP Blace and Tabanovce.

3.5 ASSESSMENT OF PROJECT IMPACT, CATALYTIC EFFECT AND CROSS BORDER IMPACT

Different activities in the project are underlined with the common goal that will reflect on overall improvement of public health through the improvement of implementation of feed hygiene standards, animal health and welfare as well through the improvement in the area of plant health.

Furthermore, the impact of improvement of feed hygiene standards is an increased number of establishments approved for export in EU. The economic impact can also be identified in improvement of animal health and welfare status, as a direct impact of implementation of the adopted control programmes and disease control strategy and animal welfare principles. Designed Strategy and establishment of system for adverse reaction of Veterinary medicinal products as well as rapid alert system for alimentary intoxications is of a great national significance, and protection of human health and life.

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 activity under IPA 2008, as well as IPA 2010, it is of an utmost importance that the immunization of wildlife against Rabies must continue.

Measure 3 will contribute to improve the quality of performing the official controls in the area of food safety, animal health and welfare of animals, conducted by official inspection services into the country and in particular provide effective protection of the whole territory, and neighbouring countries against the introduction of contagious diseases of animal and plant origin and their products and for the protection of public health between the borders of the neighbouring countries due to proper implementation of veterinary and phytosanitary check at BIPs. .

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 has continued. Namely, 20 new employments in FVA and 5 new employments in PD are envisaged for 2012. In the 2013, 23 new employments were accomplished in the Food and Veterinary Agency.

A number of newly employed personnel is 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 and feed 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 recourses 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 time frame of the projects; appointing the relevant staff by the beneficiaries to participate in training activities identified in the project; availability of funds for national contribution;

- ;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 Twining contract** will be concluded, in total amount of approximately 751,499 EUR (EUR 713,900 from IPA and EUR 37,599 national co-financing);
- **One Supply contract** will be concluded (and one supply contract for CSF vaccines, if needed), in total amount of approximately EUR 1.000.000 (EUR 750.000 from IPA and EUR 250.000 national co-financing);
- **One Supply contract** will be concluded to cover the equipment of the BIPs and the specialised equipment for official controls, under measure 3. The budget is approximately EUR 1.050.000 (IPA funds will be EUR 787.500 and the national co-financing EUR 262.500). The project duration is expected to be of 6-8 months, followed by warranty period of 12 months

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 contract arrangement, a Steering committee will be established to oversee the implementation process of the project activities. The twinning contract 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 as well as reporting to the Contracting authority. The contact persons and details for this contracts 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)

PROJECT TITLE			SOURCES OF FUNDING										
			TOTAL EXPENDITURE	TOTAL PUBLIC EXPENDITURE	IPA CONTRIBUTION		NATIONAL PUBLIC CONTRIBUTION						PRIVATE CONTRIBUTION
	IB (1)	INV (1)	EUR (a)=(b)+(e)	EUR (b)=(c)+(d)	EUR (c)	% (2)	Total EUR (d)=(x)+(y)+(z)	% (2)	Central EUR (x)	Regional/Local EUR (y)	IFIs EUR (z)	EUR (e)	% (3)
Measure 1													
Twining contract	x		751,499	751,473	713,900	95	37,573	5					-
Measure 2													
Supply contract		x	1.000.000	1.000.000	750.000	75	250.000	25					-
Measure 3													
Supply contract		x	1.050.000	1.050.000	787.500	75	262.500	25					
TOTAL IB			751,473	751,473	713,900		37,573						
TOTAL INV			2,050,000	2,050,000	1,537,500		512,500						
TOTAL PROJECT			2,801,473	2,801,473	2,251,400		550,073						

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)

Contracts	Start of Tendering/ Call for proposals	Signature of contract	Project Completion
Twining contract	Q1 2016	Q4 2016	Q2 2018
Supply contract vaccines	Q2 2016	Q4 2016	Q4 2017
Supply contract of equipment	Q1 2016	Q3 2016	Q3 2017

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)

LOGFRAME PLANNING MATRIX FOR Project Fiche		Project title and number	Further alignment with EU requirements of the competent authorities in the area of food safety, veterinary and phytosanitary policy	
		Contracting period expires two years from the date of the conclusion of the Financing Agreement	Execution period expires two years from the final date for contracting	
		Total budget	EUR 2,801,473	
		IPA budget:	EUR 2,251,400	
Overall objective	Objectively verifiable indicators	Sources of Verification		
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.	Comprehensive advancement towards fulfilling EU requirements regarding food safety, veterinary and phytosanitary policy (Chapter 12)	<ul style="list-style-type: none"> - Documentation; - Government progress reports; - EU assessment and progress reports. 		
Specific objective	Objectively verifiable indicators	Sources of Verification		Assumptions
Providing additional assistance to the Food and Veterinary Agency and Phytosanitary directorate in order to improve their overall ability for implementation of EU <i>Acquis</i> 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.	Institutional development and increased capacity over ability to assume EU <i>Acquis</i> and substantiate EU priorities addressed in EP.	<ul style="list-style-type: none"> - Documentation; - Government progress reports; - EU assessment and progress reports. 		<ul style="list-style-type: none"> -Commitment of national authorities; -Political commitment; - The Government provides financial resources for implementation of surveillance and monitoring programmes - Follow up on EU priorities.
Results	Objectively verifiable indicators	Sources of Verification		Assumptions

<p>Measure 1: Strengthening the capacity of animal health and veterinary public health services regarding disease surveillance, animal welfare, Contingency planning, feed safety, veterinary medicinal products alimentary intoxications , respectively, as well as strengthening the capacity of Phytosanitary system</p> <p>Results within Operations 1:</p> <ul style="list-style-type: none"> - Development of legislation which will be implemented after entering of the former Yugoslav Republic of Macedonia into EU; - Systematic preparation of operative documentation for implementation of the legislation <p>Results within Operation 2:</p> <ul style="list-style-type: none"> - The capacity of the official veterinarians is strengthened to perform official controls in animal welfare requirements 	<ul style="list-style-type: none"> - Number of prepared documents regarding implementing secondary legislation; - Number of developed manuals, models, forms which will be used by official inspectors and/or FBO; - In the first year of implementation surveillance system is implemented and comprehensive epidemiological data and laboratory results for priority diseases in wildlife are available from 10 pilot hunting grounds. - In the second year, all hunting grounds are involved in the surveillance system; - All official veterinarians are trained to use animal welfare equipment and perform inspection controls, as well as pose corrective measures; - Report presenting the risk and distribution of vectors and 	<ul style="list-style-type: none"> - 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. 	<ul style="list-style-type: none"> - 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
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<p>Results within Operation 3 :</p> <ul style="list-style-type: none"> - Priority vector borne and parasitic diseases of national importance defined; - Cost benefit study for control of predefined vector borne and parasitic diseases prepared; - Strategy plan for monitoring and surveillance for vector borne and parasitic diseases of national importance established; - Appropriate legislation adopted; - Procedures and check list for uniform application of the established surveillance and monitoring system developed; - Monitoring and surveillance system for predefined vector borne and parasitic diseases established and implemented; - Training of official veterinarians and other staff in performing official controls implemented; <p>Results within Operation 4 :</p> <ul style="list-style-type: none"> - Capacity of the Food and Veterinary Agency with regards to contingency planning is strengthened - Training of Official Veterinarians on measures in case of an outbreak of a disease subject to contingency planning implemented; - Monitoring and surveillance programs for diseases 	<p>vector borne diseases and parasitic diseases prepared;</p> <ul style="list-style-type: none"> - Procedures and check list for the relevant programs are used; - Monitoring and surveillance system for predefined vector borne and parasitic diseases implemented and maintained in the following years; - All official veterinarians and staff involved in animal disease control trained. <ul style="list-style-type: none"> - All official veterinarians trained in implementation of measures in case of outbreak of a disease; - - GIS modules in VIS implemented for aquaculture diseases; - Monitoring and surveillance programs for aquatic diseases implemented and maintained. <ul style="list-style-type: none"> - Prepared monitoring programme regarding feed safety and animal nutrition; - Food and Veterinary Agency staff trained for the application of feed safety risk analysis 		
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<p>subjected to contingency planning implemented;</p> <ul style="list-style-type: none"> - GIS modalities in aquaculture implemented; - Laboratory capacities for diagnostics in aquatic health improved; - Monitoring and surveillance programs for diseases in aquaculture implemented. <p>Results within Operation 5 :</p> <ul style="list-style-type: none"> - Improved system for feed safety; - Application of the principles of risk analysis for feed safety - Improved awareness of feed business operators in relation to feed safety <p>Results within Operation 6 :</p> <ul style="list-style-type: none"> - Improved system for Veterinary medicinal products(VMP). <p>Results within Operation 7 :</p> <ul style="list-style-type: none"> - Developed system for management zoonosis and 	<ul style="list-style-type: none"> - Developed programme for antimicrobial resistance; - Introduced functional system/centre for adverse reaction - Improvement of technical knowledge regarding VMP for the private veterinarians and production of VMP, through training; development of manuals, operative documents etc. <ul style="list-style-type: none"> - Established rapid alert system regarding alimentary intoxications - Established system for monitoring outbreaks of alimentary intoxications. - Established measures to prevent alimentary intoxication occurrence <ul style="list-style-type: none"> - Number of adopted legislation on plant health and plant protection products, as well as inspection control procedures; - Proper implementation of national legislation and ISPM, that contributes to decreased number of positive findings regarding plant health and use of plant protection products; - Functional Phytosanitary Information System; - Functional National Plant Passport System; - Increased number of inland official 		
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<p>alimentary intoxications.</p> <p>Results within Operation 8 :</p> <ul style="list-style-type: none"> - Harmonized national legislation regarding plant health and plant protection products; - Strengthened capacities within the Phytosanitary System (Phytosanitary Directorate, State Agricultural Inspection, in particular Phytosanitary Inspectors and State Phytosanitary Laboratory); - Developed and update Phytosanitary Information System; - Developed institutional structure for proper implementation of a National Plant Passport System; - Established a system for reporting, diagnostic and forecasting of harmful organisms in the country; - Sustainable use of plant protection products. <p>Measure 2: Follow up of oral vaccination against Rabies</p> <ul style="list-style-type: none"> - Procurement of Rabies vaccines and immunization of the wild fox against rabies. - Samples collected by the hunters for laboratory analysis, in order to obtain more comprehensive and consequently more reliable data regarding presence/absence of the disease in question. <p>Measure 3: Supply of equipment for official controls and for th</p>	<p>controls achieving decrease number of disease notifications for harmful organisms;</p> <ul style="list-style-type: none"> - Decreased use of PPPs and introduced a principles of Integrated Pest Management. <ul style="list-style-type: none"> - Rabies vaccines supplied and immunization of the wild fox 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. <ul style="list-style-type: none"> - Efficient performance of the official controls both in the territory of the country and at the border; 		
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border inspection facilities at BIP Blace and BIP Tabanovce Results: <ul style="list-style-type: none"> - Procurement of equipment for inspection services to perform official controls Equipped and operational BI facilities for Food, Veterinary and Phytosanitary control. 			
Activities to achieve results	Means / contracts	Costs (in EUR)	Assumptions
<p>Measure 1: Strengthening the capacity of animal health and veterinary public health services regarding disease surveillance, animal welfare, , Contingency planning, feed safety, veterinary medicinal products alimentary intoxications , respectively, as well as strengthening the capacity of Phytosanitary system</p> <p>Operation 1:</p> <ul style="list-style-type: none"> - Drafting a legislation (primary/secondary) applicable after the entry of the former Yugoslav Republic of Macedonia into EU - Systematic approach and drafting of operative implementing secondary legislation ; - Preparation of documentation relevant for the implementation of adopted new legislation. <p>Drafting of supporting implementing documents: guidelines, procedures etc. aimed for the official controls and/or Food business operators</p> <p>Operations 2 :</p> <ul style="list-style-type: none"> - Organization and delivery of trainings for official veterinarians as regards animal welfare requirements <p>Operation 3 :</p> <ul style="list-style-type: none"> - Preparation of analysis for priority vector borne and parasitic diseases of national importance for RM; - Preparation of cost benefit study for control of predefined vector borne and parasitic diseases; - Preparation of Strategy plan for monitoring and surveillance for vector borne and parasitic diseases of national importance; 	<p>1 Twining Contract</p> <p>1 Supply contract (supplies vaccines)</p> <p>1 Supply contract (equipment)</p>	<p>Total budget: 751,473</p> <p>IPA contribution: 713,900</p> <p>National contribution: 37,573</p> <p>Total budget: 1.000.000</p> <p>IPA contribution: 750.000</p> <p>National contribution: 250.000</p> <p>Total budget: 1.050.000</p> <p>IPA contribution: 787.500</p> <p>National contribution: 262.500</p> <p>TOTAL BUDGET: 2,801,473</p> <p>IPA CONTRIBUTION: 2,251,400 NATIONAL CONTRIBUTION: 550,073</p>	

<ul style="list-style-type: none"> - Development of relevant legislation; - Preparation of Procedures and check list for uniform application of the established surveillance and monitoring system; - Preparation of Monitoring and surveillance system for predefined vector borne and parasitic diseases; - Conducting trainings for official veterinarians and other staff in performing official controls. <p>Operation 4 :</p> <ul style="list-style-type: none"> - Preparation, where applicable revision of different contingency plans; - Conducting trainings for official veterinarians regarding measures in case of an outbreak of a disease subject to contingency planning; - Preparation of Monitoring and surveillance program for diseases subjected to contingency planning; - Preparation of GIS modalities in aquaculture; - Preparation of Monitoring and surveillance program for diseases in aquaculture. <p>Operation 5 :</p> <ul style="list-style-type: none"> - Preparation of monitoring programme regarding feed safety and animal nutrition; - Development of a system for feed safety risk analysis - Conducting trainings for FVA staff regarding the application of feed safety risk analysis; <p>Operation 6 :</p> <ul style="list-style-type: none"> - Preparation of a programme for antimicrobial resistance; - Preparation of functional system/centre for adverse reaction; - Development of operative documentation for supporting the implementation of relevant legislation - Drafting of guidelines, manuals and other documents for relevant stakeholders - Organization and delivering training to FVA relevant 			
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<p>personnel to improve the knowledge as regards VMP</p> <p>Operation 7</p> <ul style="list-style-type: none"> - Development a rapid alert system regarding alimentary intoxications ; - Development of monitoring system for occurrence of alimentary intoxications. - Development of IT module for reporting and data collection related to alimentary intoxications - Development of system for prevention of occurrence of alimentary intoxications <p>Operation 8</p> <ul style="list-style-type: none"> - Preparation of documents regarding plant health and plant protection products; - Conducting trainings for Phytosanitary Directorate, State Agriculture Inspection and State Phytosanitary Laboratory staff regarding proper implementation of national legislation and ISPM; - Analysis, development, if applicable update of Phytosanitary Information System; - Development of institutional structure for proper implementation of a National Plant Passport System; - Development of system for reporting, diagnostic and forecasting of harmful organisms in the country; <p>Measure 2: Follow up of oral vaccination against Rabies</p> <ul style="list-style-type: none"> - Purchasing of vaccine baits and implementation of the oral rabies vaccination campaign (twice per year); - Collection of samples for laboratory analysis. <p>Measure 3: Supply of equipment for official controls and for the border inspection facilities at BIP Blace and BIP Tabanovce</p> <ul style="list-style-type: none"> - Equipping the inspection services for performance of official controls - Equipping of facilities for food, veterinary and phytosanitary inspection at BIP Blace and Tabanovce 			
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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 of 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

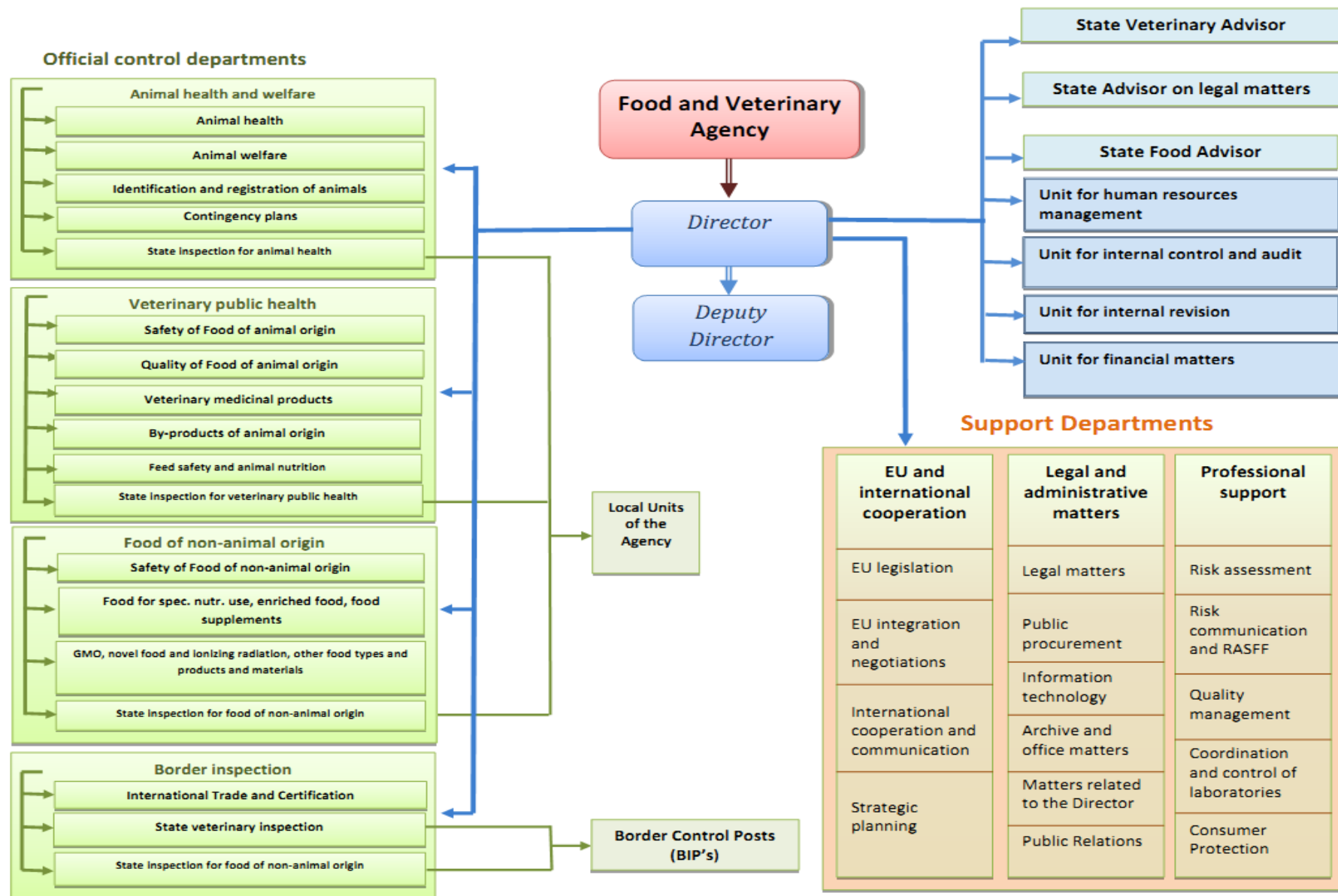
- Development and consolidation of policies in relation with approximation and transposition of national legislation with EU Acquis;
- Preparing of progress reports for EU integration for Chapter 12- Food safety, veterinary and phytosanitary policy;
- Preparing of activities related with EU negotiation;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



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.

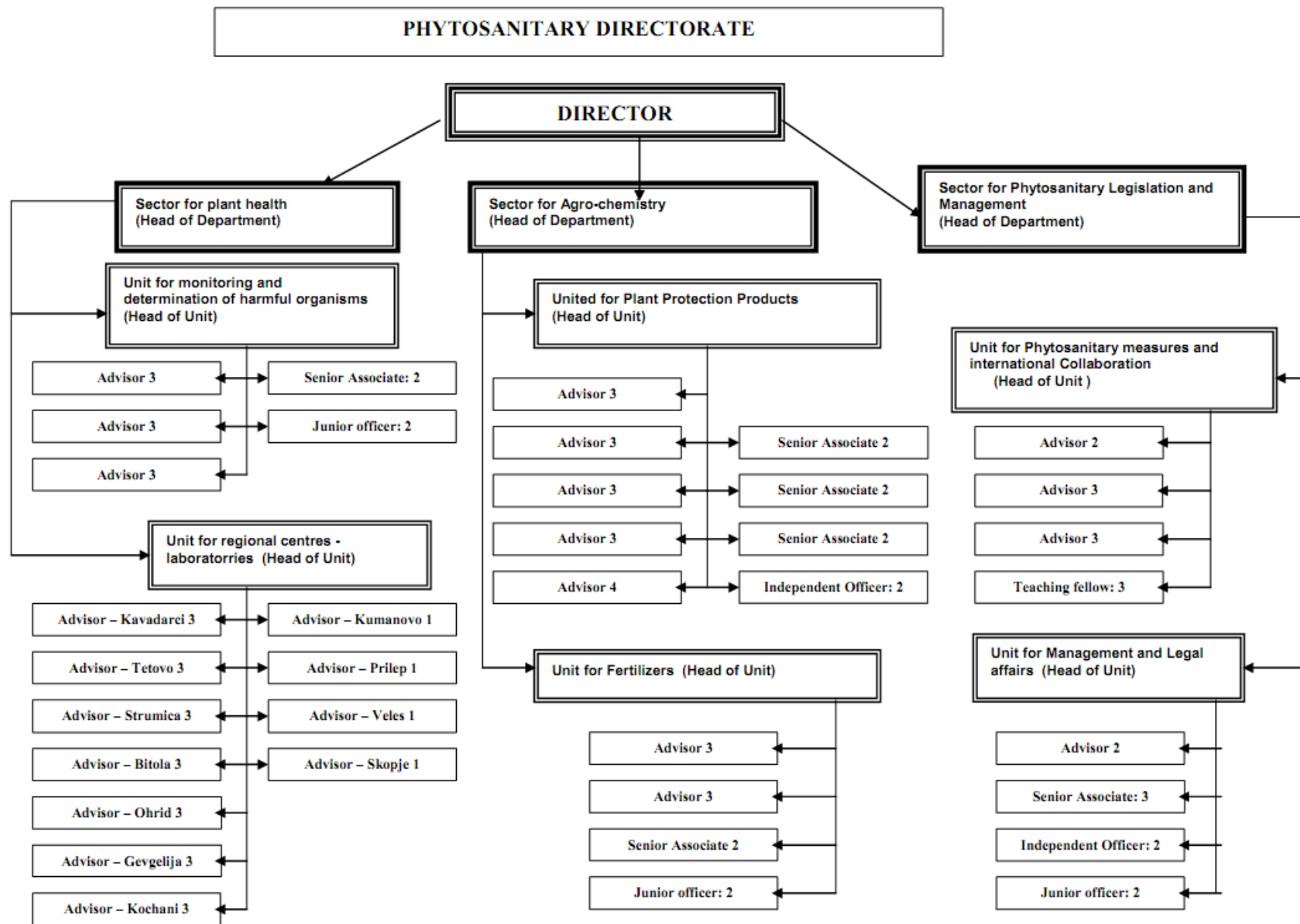
The Phytosanitary Directorate is consisted of the following departments:

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;
- Fertilisers 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 contract arrangement, a Steering committee will be established to oversee the implementation process of the project activities. The twinning contract 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 as well as reporting to the Contracting authority. The contact persons and details for this contracts 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

Rabies

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

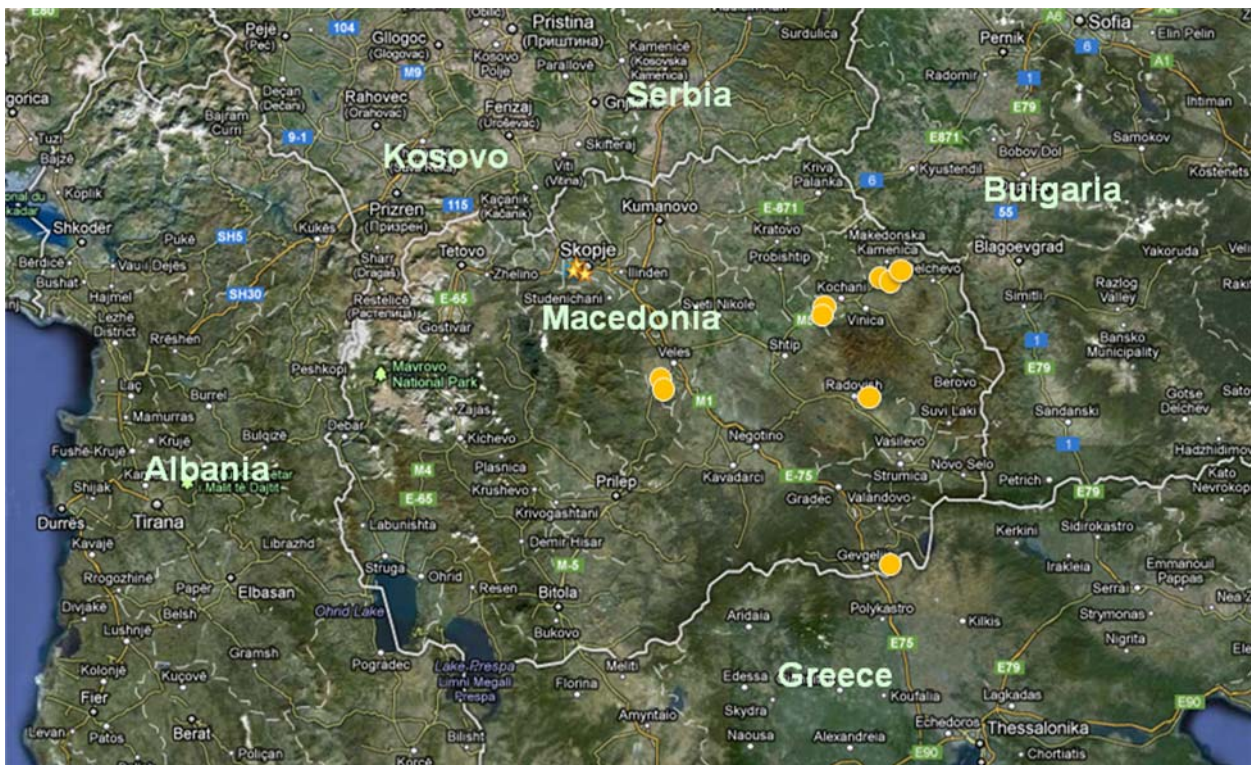
Definition and size of the area to be vaccinated

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 assess 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 0,5 Euro per distributed vaccine bait following calculation may be made:

Number of years for ORV	Number of campaigns/year	Number of baits/campaign	Price estimate per distributed bait	Total price
2	2	500,000	0.5 Euro	EUR 1, 000,000

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.