

Project Fiche 3.5: Capacity building of the veterinary service for implementation of EU Acquis

1. Basic information

1.1 CRIS Number: 2008/20-311

1.2 Title: Capacity building of the veterinary service for implementation of EU Acquis

1.3 ELARG Statistical code: 3.12

1.4 Location: Skopje

Implementing arrangements

1.5 Contracting Authority (EC)

European Commission, EC Delegation, on behalf of the beneficiary

1.6 Implementing agency

European Commission, EC Delegation, on behalf of the beneficiary

1.7 Beneficiary (including details of project manager):

The Veterinary Directorate is the primary beneficiary of the project.

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1.8 Overall costs (VAT excluded)¹: EUR 3.900.000

1.9 EU contribution: EUR 3.300.000

1.10 Final date for contracting

Two years from the date of the conclusion of the Financing Agreement

1.11 Final date for execution of contracts:

Two years from the final date for contracting.

1.12 Final date for disbursements

One year from the final date for execution of contracts.

¹ The total costs of the project should be net of VAT and/or other taxes. Should this not be the case, the amount of VAT and the reasons why it should be considered eligible should be clearly indicated.

2. Overall Objective and Project Purpose

2.1 Overall Objective

The overall objective of the project is to contribute to a further development of the livestock sector in the country.

2.2 Project purpose

To provide technical and material assistance to the Veterinary Directorate to improve its overall ability and capacity for implementation of the EU Acquis and Accession Partnership commitments, with specific reference to its capability to transpose and implement EU acquis into national law, appropriately implement its inspection services, control animal disease, organize animal waste disposal and expand the Animal Identification and Registration system to include pigs.

2.3 Link with AP/NPAA/EP/SAA

The programme will contribute towards the implementation of the **Stabilisation and Association Agreement** Article 100 on gradual harmonisation of veterinary legislation with Community standards and Article 103 on the protection of animals against man-made disasters.

For veterinary policy, the **Accession Partnership** outlines a series of priorities to be addressed. The AP stresses the importance of alignment of legislation with the veterinary acquis and reinforcement of the capacity of the veterinary service at both central and local levels in order to put in place an EU-compatible control system, particularly for import controls. It calls for ensuring operational character of the system for identification of bovines and registration of their movements and starting a system of identification of pigs, sheep and goats. Furthermore, the AP calls for strengthening the laboratory capacity in the veterinary domain and for assessment of the compliance of the agri-food establishments, which will serve as a basis for a future upgrading of those establishments.

The **National Plan for Adoption of Acquis** with regard to veterinary reforms intends to further pursue legal development and harmonisation with the Acquis, strengthen administrative capacities of the Veterinary Directorate through training, equipment and staffing.

2.4 Link with MIPD

The **Multi-Annual Indicative Planning Document** (MIPD) with regard to veterinary policy indicates that support shall be given to the adoption of the acquis and to upgrading the laboratory sector, including inspectors and staff.

2.5 Link with National Development Plan

The **National Development Plan** underlines the importance of veterinary protection and underlines the priorities of strengthening the veterinary mandate of the Ministry of Agriculture, establishment of national system for identification and registration of animals, professional training of the veterinary administration staff, and improvement of the regulatory, legislative and institutional structure in relation to the production, trade and use of veterinary-medical materials.

2.6 Link with national/ sectoral investment plans (where applicable)

The project directly links to the following key strategies and action plans in the sector (see for a more extensive list annex 3):

- Business plan in the Veterinary Directorate,
- International Animal Health Code of the OIE (International Office of Epizootics),
- Strategic Plan 2007-2009 of the Ministry of Agriculture, Forestry and Water Economy,

3. Description of Project

3.1 Background and justification:

The Veterinary Directorate (VD) in the Ministry of Agriculture, Forestry and Water Economy is the authority competent for safety of foodstuffs of animal origin throughout all stages of their production and marketing. The Directorate has the competence in the area of animal health, animal reproduction, animal feed, veterinary medicines and residue monitoring and animal welfare. The Directorate consists of four sectors – Border Veterinary Inspection, Animal Health, Public Health, and Legal and Administrative Affairs. Field activities (vaccinations, disinfection, etc.) are implemented by private veterinary clinics which have a contract with the Veterinary Directorate. The laboratory testing of animals is performed at the Faculty of Veterinary Medicine which is designated as a reference laboratory. The laboratories of the faculty are in their final phase of national and international accreditation for a number of tests that are performed.

The competencies of the Veterinary Directorate derive from the Law on Veterinary Health, Law on Safety of Foodstuffs, Products and Materials in Contact with Foodstuffs, Law on Animal Identification and Registration, Law on veterinary public health, Law on animal by-products, and the Law on animal protection and welfare.

The enforcement and execution of controls is carried out by the state veterinary inspectors assigned to the Regional Veterinary Offices, and the state veterinary inspectors assigned to the Border Inspection Posts. Regional Veterinary Offices and Border Inspection Points are directly subordinated to the Veterinary Directorate.

Commensurate with present capacities and development priorities, the Directorate has identified five areas where additional support is needed to make the required improvements:

- 1) Transposition of the EU Acquis
- 2) Strengthening of inspection services
- 3) Animal disease control
- 4) Animal waste disposal
- 5) Expansion of the Animal Identification and Registration system to include pigs

Concerning the transposition of the **EU Acquis**, the Veterinary Directorate is in the process to align the EU legislation and practices in the veterinary field into national legislation. Priority areas for legal harmonization include control measures for animal diseases, control systems in the internal market, intra community trade, rules for animal products and by-products.

Apart drafting new laws or amendments, keeping track of the constantly evolving EU *acquis* in the veterinary sector is essential. DG SANCO maintains a database with Tables of Correspondence between the EU Acquis and the national legislation. In close cooperation with DG SANCE, the Veterinary Department will develop and maintain an appropriate agenda of legislation that is to be harmonized.

While significant attention has been given to the harmonization of the legal instruments with the EU acquis, the Directorate intends to place equal weight on the actual implementation and enforcement of the legal instruments. This requires a strong and competent staff establishment to undertake or supervise official, effective and regular **inspections** in the fields of competence of the Directorate, including animal health and welfare, veterinary public health and food safety, veterinary drug products, animal by-products, feed hygiene and animal nutrition. Equally important is that a sound procedural structure for implementing the controls is established. Although some training activities have been performed, mainly in the safety and hygiene of food of animal origin, and the implementation of risk monitoring, further training in animal health and veterinary public health remains essential. The following elements require specific attention:

- Introduction of risk assessment principles and practices especially in the areas of imports;
- Establishing procedures for official controls in food and feed
- Animal welfare standards during slaughter and killing
- Establishing a system for feeding stuffs control

While overall the situation vis-à-vis the **disease control** is quite satisfactory, in two areas supplementary activities are necessary to comply with the EU standards: rabies and swine fever. A close cooperation with the regional initiative in this area is envisaged.

Rabies is a viral disease that affects predominantly carnivores (mainly wild foxes) but can occur sporadically also in all animal species and humans. The last case of human Rabies was recorded in 1976. The last case of Rabies in animals in the country was registered in a cat near Skopje in December 2000.

Concerning the control measures for domestic animals, the Veterinary Directorate is prescribing a compulsory vaccination of all dogs against Rabies. On annual basis 40.000-50.000 dogs are vaccinated. The costs of vaccination are born by the owner of animals. In 2007, 6 domestic animals (4 dogs and 2 cats) have been examined on Rabies with negative result.

Concerning control measures for wild animals, hunters, concessionaires of hunting grounds and National Parks are obliged to take all found dead animals to the Veterinary Institute for laboratory examination of Rabies. Only a limited number of samples (9 foxes, 6 wolves, 2 wild cats and 2 martens) have been examined in 2007. All samples (except the one sent to the Reference laboratory) claimed negative results. It is foreseen that in 2008 with TA provided by TAIEX, the Veterinary Directorate will perform a wide surveillance on Rabies in wild animals allowing an assessment of the extent of the problem per region, and consequently the control/eradication of the disease in wild foxes can be achieved by the immunization through vaccination of the susceptible population.

Currently, the laboratory is performing direct immunofluorescence. In order to ensure sustainable diagnosis, additional equipment for the laboratory and training of staff is needed.

Classical Swine Fever (CSF) is a transmissible disease of pigs. When the disease circulates in the wild boar populations it constitutes a threat for the farmed pigs where the disease causes economic losses and leads to trade restrictions. The CSF virus is present in the country. The Veterinary Directorate is prescribing a compulsory vaccination of all pigs. There are only sporadic outbreaks of the disease in pigs kept extensively - backyard pigs (7 outbreaks in

2006 and 2 in 2007). No outbreaks are recorded in commercial farms. In confirmed outbreaks stamping out measures are applied. Based on epidemiological evidence the virus is circulating also in wild boars.

Although the eradication of CSF from the farmed pigs requires additional measures to be taken, the control of the disease in wild boar is an important prerequisite for the achievement of this aim. It is foreseen that in 2008 with TA provided by TAIEX, the Veterinary Directorate will perform a wide surveillance on CSF in wild boars, evaluating the extent of the problem per region, and consequently the control/eradication of the disease in wild boars can be achieved by the immunization through vaccination of the susceptible population.

The Laboratory capacity is limited and needs further equipment, while the staff needs further training.

The fourth priority concerns the establishment of a system for **animal waste disposal**. Establishing appropriate levels of public and animal health protection related to treatment, use and trade of animal byproducts is very important, given that a new Law on animal by-products, transposing the EU Acquis, was recently adopted. In order to appropriately implement the new law, the existing situation concerning the animal waste treatment and control in the country needs to be assessed. Proposals need to be developed for establishing a system for separation, prohibition of recycling certain animal byproducts into the feed chain, safe disposal, processing and trade of animal byproducts in accordance with the EU legislative provisions.

The last priority concerns the expansion of the existing **Animal Identification and Registration** system to pigs. The Accession Partnership indicates that the country should start a surveillance system to register pigs. The implementation of the ear-tag system for identification and registration of pigs will contribute to the registration of pig holdings and individual identification of pigs. This will strengthen the country's livestock sector and secure its status as an exporter of live animals and animal products to the EU and other third country markets, while at the same time it will greatly support the eradication efforts of diseases in pigs.

3.2 Assessment of project impact, catalytic effect, sustainability and cross border impact

Transposition of the EU Acquis

In order to fulfill the requirements of the SAA and attain solid administrative capacity in the veterinary sector capable to respond in a prompt and efficient manner in conformity with the EU procedures, all veterinary legislation needs to be in line with the EU acquis.

Strengthening of inspection services

Effective implementation of the legislation and efficient veterinary surveillance service is a key priority in accomplishing successful results in the veterinary sector.

Training staff involved in performing official controls in the fields of animal health and welfare, veterinary public health and food safety, veterinary drugs, animal by-products, feed hygiene and animal nutrition, will enable them to undertake their duties competently and to carry out official controls in a consistent and uniform manner.

Effective food and feed inspection system operating in accordance with EU principles as well as upgrading of inspection system for food quality control is essential priority for implementation of EU relevant legislation.

Strengthening the administrative capacity to implement and maintain effective control in the livestock industry ensuring its compliance with EU animal welfare standards will enable the country to cope with the requirements necessary for the accession process to the EU.

The project will strengthen the capacity within Ministry to assess the guidelines of good hygiene practice in primary production and report it to EU as well as to assess the dossiers for additives in animal nutrition.

All the above is not only important in the accession process as such, it also is essential in the development of the livestock market in the country, safeguard public health and stimulate exports and foreign direct investments in the sector.

Animal disease control

Rabies is typically introduced in the country via wildlife. Concerning that there are no confirmed cases of Rabies in the country, it is of utmost importance that the introduction of the disease is prevented. Immunization of wildlife is the only sustainable approach to this end.

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.

The control/eradication of the two diseases in wildlife will contribute to similar activities taking place in the other countries of the region, as will be supported through the regional IPA 2008 project in these fields. It will also reduce the risk of introduction of these two very important diseases to the European Union.

Establishing a system for animal waste disposal

In order to fulfil the requirements necessary for EU accession, an appropriate animal byproducts disposal system will be established. This will contribute to safeguard public health as well as economic development in the sector.

Expansion of the Animal Identification and Registration system

Expansion of the Animal Identification and Registration system will not only be essential to implement a sound system of disease control, it also will be very important to stimulate exports.

The combined impact of the different components may lead to increased foreign direct investment in the sector, as the conditions for production will be very similar to the Member States.

3.3 Results and measurable indicators²:

The project has five components:

- 1) Transposition of the EU Acquis
- 2) Strengthening of inspection services
- 3) Animal disease control
- 4) Establishing a system for animal waste disposal

² Please note that some of the indicators have not yet been quantified or been given a benchmark. This will be done during the development of the detailed Terms of Reference.

- 5) Expansion and Improvement of the Animal Identification and Registration system to include pigs

Component 1: Transposition of the EU Acquis

The expected results are:

- Further transposition of the prioritized EU Acquis into the national legislation
- Established road map for further transposition of EU Acquis in veterinary field

The measurable indicators are:

- 100% of the national legislation aligned with EU Acquis assessed and evaluated;
- Prioritized laws have been harmonized with the EU Acquis;
- A methodology for full transposition of relevant EU Acquis is established.

Component 2: Strengthening of inspection services

The expected results are:

- A professional Human Resource Development system is established, including:
 - a. Training needs assessment,
 - b. Training action planned and implemented
 - c. New re-training courses for veterinary inspectors
 - d. Study materials (e.g. good hygiene practices, EU legislation, food safety, etc.)
 - e. Training of Trainers (TOT) on different disciplines of food hygiene and veterinary public health
- Establishing an integrated food and feed control system throughout the food chain, based on a solid assessment of the existing situation and including:
 - a. Upgraded inspection systems for quality control of food and feed, risk monitoring and analysis, animal welfare during slaughter and killing, and animal waste in compliance with EU Regulations;
 - b. Inspection manuals for inspectors are prepared;
 - c. Target group definitions
 - d. Public campaigns and information materials
 - e. Reporting requirements (internal, national and international)
- Revised current situation on competences of institutions for certification and control and evaluation of certification system.

The measurable indicators are:

- The new Human Resource Development system is approved
- Training is taking place according to the agreed upon plan
- Training course and course materials are produced
- Satisfaction rates of trainees, measured through after training survey
- Integrated food and feed control system is developed and approved
- Operational mechanisms are developed and in operation (e.g. manuals, guidance notes, public campaign materials, etc.)
- Reports are produced in time

Component 3: Animal Disease Control

The expected results are:

- Assessment of the epidemiological situation 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.
- A detailed concept, system design and implementation plan is prepared to introduce electronic identification³.
- Laboratory development:
 - Required equipment is purchased.
 - Accredited for performing laboratory diagnosis.
 - Personnel are trained in performing prescribed tests.

The measurable indicators are:

- The process of vaccination has been done according to the detailed plan
- Number of vaccine baits distributed. Number of samples collected and tested and results of the tests. Number of domestic pigs vaccinated.
- Laboratory is included in proficiency tests with favorable results.
- Establishment of sustainable cooperation with the hunters, National parks, concessionaires of hunting grounds. Required number of samples (as arranged with the TAIEX activity) collected and tested.
- A series of informative workshops are performed and leaflets are distributed.

Component 4: Establishing a system for animal waste disposal

The expected results are:

- A system of separate collection, processing, use, trade of and disposal of the animal by-products is developed and starts to be implemented;
- Legislative provisions developed in line with EU acquis concerning (a) health rules for animal by-products not intended for human consumption and (b) ban on use of processed animal proteins in animal nutrition.

The measurable indicators are:

- Assessment of current state concerning the animal waste treatment and control;
- Evaluation of existing animal waste processing plants (rendering plants) and capacities;
- Drafted operational guidelines on health rules concerning animal byproducts not intended for human consumption and feed ban and SRM's (Specified Risk Material);
- A program for processing of different categories of animal by-products is prepared, including and if necessary the requirements for possible new plants (i.e. low risk processing establishments, incinerators...).

Component 5: Animal Identification and Registration

The expected results are:

- An I&R system for pigs is introduced, established and sustained.
- I&R+VIS IT systems are further developed and integrated, and interfaces needed for the total chain control of the sectors and to develop the production level of farm animals.

The measurable indicators are:

³ This activity will build further upon the Animal I&R activities undertaken.

- 90% of holdings and pigs are identified in first year.
- The country is implementing EU regulations on I&R of cattle, sheep and goats, and pigs.
- An information flow in animal health and food safety is further developed.

3.4 Activities

The project has five components:

- 1) Transposition of the EU Acquis
- 2) Strengthening of inspection services
- 3) Animal disease control
- 4) Animal waste disposal
- 5) Expansion of the Animal Identification and Registration system to include pigs.

Component 1: Transposition of the EU Acquis

- Analysis of the national legislation vis-à-vis transposition of the EU Acquis
- Development of a methodology for further fully transposition of the veterinary EU Acquis
- Harmonizing prioritized laws.

Component 2: Strengthening of inspection services

- Develop a professional Human Resource Development system, including:
 - a. Implement training needs assessment;
 - b. Develop training action plan, including Training of Trainers (TOT), re-training courses for veterinary inspectors;
 - c. Implement training;
 - d. Develop study materials (e.g. good hygiene practices, EU legislation, food safety, etc.)
- Establish an integrated food and feed control system throughout the food chain
 - a. Implement an assessment of the existing situation;
 - b. Develop upgraded inspection systems for quality control of food and feed, animal welfare during slaughter and killing, and animal waste in compliance with EU Regulations;
 - c. Develop inspection manuals for inspectors are prepared;
 - d. Develop target group definitions
 - e. Develop Public campaigns and information materials
- Assess the current situation on competences of institutions for certification and control and evaluation of certification system and propose amendments as appropriate.

Component 3: Animal Disease Control

- Analysis of the epidemiological situation in the whole territory of the country, based on surveys implemented with TAIEX assistance;
- 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 a detailed concept, system design and implementation plan to introduce electronic identification;
- Purchase required Laboratory equipment;

- Develop and implement training plan for laboratory personnel to perform prescribed tests.

Component 4: Establishing a system for animal waste disposal

- Assess current state concerning the animal waste treatment and control;
- Evaluate existing animal waste processing plants (rendering plants) and capacities;
- Develop legislative provisions in line with EU acquis concerning (a) health rules for animal by-products not intended for human consumption and (b) ban on use of selected processed animal proteins in animal nutrition;
- Draft operational guidelines on health rules concerning animal by-products not intended for human consumption and feed ban and SRM's (Specified Risk Material);
- Prepare a program for processing of different categories of animal by-products, including and if necessary the requirements for possible new plants (i.e. low risk processing establishments, incinerators...).

Component 5: Animal Identification and Registration

- Develop and introduce an I&R system for pigs;
- Further develop and integrate I&R+VIS IT systems, develop interfaces for the total chain control of the sectors;
- Prepare to implementation plan for EU regulations on electronic I&R of animals;

Management and contracting arrangements

Although the project contains 5 individual components, these components are inter-related. Therefore, the project will be implemented through a strong coordination mechanism. A steering committee will be established chaired by the Director of the Veterinary Directorate. The Delegation of the European Union and the Secretariat for European affairs shall be invited to participate with observer status. The Steering Committee shall meet not less than once per three months.

Advisory services will be provided to the beneficiary. As the different components are strongly interlinked, one service contract will be engaged to provide the technical assistance for the total project. The TA contract will provide next to a team leader additional expertise to assist in key tasks, e.g. in the field of administrative capacity building, training, animal disease control, animal waste management, animal identification and registration, legal development and others. Some of these experts will address the cross-cutting issues.

The core project team – consisting of the team leader and other expertise will be placed within the Veterinary Department. The team leader will be responsible for the overall management, representation (co-ordination with the EU and other international bodies) as well as reporting. The co-ordination of activity development in the different components of the activity is significantly important. The team leader is responsible for an appropriate management of resources. During the inception phase of the project, a detailed deployment plan will be developed under the coordination of the Steering Committee in which each co-operating national institution will be represented to ensure appropriate inclusion.

The expected contracting arrangements are:

Financed through IPA:

- 1 Service contract will be concluded following an international restricted tender procedure to support the project with duration of 18 to 24 months. Implementation is expected to start in 2nd quarter 2010, one month after the signature of the contract and the contract value will be approx. EUR 2.0 Million.
- 1 Supply contract for the purchase of vaccines. Implementation is expected to start in 2nd quarter 2011, one month after the signature of the contract. The contract has an expected implementation period of 4 to 8 months, and a subsequent defect liability period of 12 months, bringing the total duration to 16 – 20 months. The contract value will be approx. EUR 1.3 Million.

Financed through the national contribution:

- 1 Supply contract for the delivery and installation, as well as associated training, of the laboratory equipment. Implementation is expected to start in 2nd quarter 2011, one month after the signature of the contract. The contract has an expected implementation period of 4 to 8 months, and a subsequent defect liability period of 12 months, bringing the total duration to 16 – 20 months. The contract value will be approx. EUR 300.000.
- 1 Supply contract for the purchase of software module for Identification and Registration of pigs. Implementation is expected to start in 2nd quarter 2011, one month after the signature of the contract. The contract has an expected implementation period of 4 to 8 months, and a subsequent warranty period of 12 months, bringing the total duration to 16 – 20 months. The contract value will be approx. EUR 200.000.
- 1 Supply contract for the purchase of ear tags for pigs for the I&R system. Implementation is expected to start in 2nd quarter 2011, one month after the signature of the contract. The contract has an expected implementation period of 4 to 8 months, and a subsequent defect liability period of 12 months, bringing the total duration to 16 – 20 months. The contract value will be approx. EUR 100.000.

3.5 Conditionality and sequencing:

The projects should further include the following conditions in the preparation phase:

1. Endorsement by all key stakeholders of the Terms of Reference, specifications for the individual contracts to be engaged;
2. Appointment of counterpart personnel by the beneficiary before the launch of the tender process;
3. Allocation of working space and facilities by the beneficiary for technical assistance before the launch of the tender process;
4. Participation by the beneficiary in the tender process as per EU regulations;
5. Organisation, selection and appointment of members of working groups, steering and coordination committees, seminars by the beneficiary as per work plan of the project;
6. Appointing the relevant staff by the beneficiaries to participate in training activities as per work plan;
7. Availability of funds for co-financing.
8. Laboratories capable of properly performing the necessary tests should exist in the country otherwise foreign laboratories should be contracted to undertake these activities.
9. The current I&R system for cattle, sheep and goats is functional, including number of modules developed i.e. sample management, bovine brucellosis and tuberculosis workflow application, subsidy crosscheck module etc.

In the event that conditions are not met, suspension or cancellation of projects will be considered.

3.6 Linked activities

Regarding Animal Health, several activities in terms of legal approximation have been delivered and EU funded:

- Project “Strengthening the Veterinary Services in the former Yugoslav Republic of Macedonia” running from 22 June to 28 July 2003. In brief, the Final Report demonstrates that the situation is unattainable in the VD/MAFWE and in the field due to shortages in terms of staff, facilities, infrastructure and equipment. As a consequence, all sectors of administrative and field veterinary activity need to be strengthened and, to this end, certain priorities must be set.
- Project “Strengthening the Veterinary Services in the former Yugoslav Republic of Macedonia– Harmonization of veterinary legislation with the Community *acquis*” running from 27 November 2003 to 26 November 2004. The purpose of this project was to explore various scenarios of law-making approaches and recommending, through a broad consultation procedure leading to consensus, the one most suitable and feasible under the local circumstances, and proposing a scheme and timetable for subsequent legislative work towards full transposition of the entire EU veterinary *acquis*. The first version of the Framework Veterinary Health Law was drafted.
- The project “MAFWE Structural and Legal Reform”, veterinary component, running from 20 January 2005 to 30 June 2006, mainly dealing with Legal approximation with the EU *acquis* in the fields of animal health, veterinary public health, animal welfare and protection, veterinary drugs, veterinary border controls and feed.

Several projects support the required investments for Identification and registration of animals.

- National Animal Identification System (phase 1) (€1.55 million: €0.72 million – Phare 1999; €0.83 million – CARDS 2001). The project strengthened the country’s livestock sector and secured its status as an exporter of live animals and animal products to the EU and other third country markets through the development and implementation of a National Animal Identification and Registration (I&R) System for cattle, and by the approximation of relevant legislation to EU directives. The project has been completed in December 2004. The full implementation of the I&R system for cattle is completed under the phase 2 of the project in 2005.
- National Animal Identification System (phase 2) (1.3 million – CARDS 2003). The project aimed to complete and consolidate the establishment of a bovine I&R system initiated the above Phare 1999/CARDS 2001 project. It also developed a concept for the establishment of an EU-consistent ovine and caprine I&R system, as well as integrates these I&R information features with a wider animal health and veterinary information system. The project has been completed 30 April 2007.
- National Animal Identification System (phase 3) (CARDS 2006 – 0.47 million). The objectives are to complete the establishment of an integrated animal identification, holding registration and movement control system for small ruminants, in compliance with EU requirements; prepare a concept for the expansion of animal I&R to pigs and continue to develop an integrated I&R and VIS with interfaces and components relevant to the MAFWE IT system including Food Safety software for both, veterinary and Food Agency inspectors. The present project for I&R will further build upon this project.

- Software for Veterinary Sample Management (€44,000 – CARDS 2003). The purpose of the contract is the delivery, installation, putting into operation, training, warranty, support of additional “Software for Veterinary Sample Management” for the National Animal Identification and Registration System.
- Supply of Ear tags and Pliers for Cattle (€149,000 – CARDS 2003) The purpose of the contract is the delivery of Ear tags and pliers for Cattle.
- PDAs for the National Animal Identification System (€36,285 – CARDS 2003). The purpose of the contract is the delivery, installation, putting into operation, training, warranty, support of additional PDAs for the National Animal Identification and Registration System. The project has commenced his activities second half of September 2007.

3.7 Lessons learned

So far EU technical support played important role in alignment of the National legislation with the EU Acquis, as well as in the effective preparation for its implementation and strengthening the overall capacities of the Veterinary Department. However, during the implementation of the project several challenges emerged. The key challenges, including availability of funds and staff, involvement in tender procedures and project activities, have been translated into conditions (see above).

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

Although the various activities will in the medium and long term have a strong beneficial impact on the sector, it remains important that a solid communication campaign accompanies the activities. Especially in the case of disease control, it is important to realize a large nationwide coverage as well as cross-border cooperation to avoid slippage in the system.

As with many ‘development activities’ in the farming sector, there is a definite male bias in most communications. Especially in the field of farm sanitation, it remains important to reach out to the total farming family, including the women. For this purpose specific attention will be paid to gender (see further below under cross cutting issues).

Learning from and cooperating with EU Member States and neighboring 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 favorable results.

4. Indicative Budget (amounts in €Million)

			SOURCES OF FUNDING									
			TOTAL EXP.RE	IPA COMMUNITY CONTRIBUTION		NATIONAL CONTRIBUTION					PRIVATE CONTRIBUTION	
ACTIVITIES	IB (1)	INV (1)	EUR (a)=(b)+(c)+(d)	EUR (b)	%(2)	Total EUR (c)=(x)+(y)+(z)	% (2)	Central EUR (x)	Regional/ Local EUR (y)	IFIs EUR (z)	EUR (d)	% (2)
Contract 1 - TA Contract	X		2.0	2.0	100							
Contract 2- Supply Software		X	0.2			0.2	100	0.2				
Contract 3 - Supply laboratory		X	0.3			0.3	100	0.3				-
Contract 4- Supplies Vaccines		X	1.3	1.3	100							-
Contract 5- Supplies ear tags		X	0.1			0.1	100	0.1				
.....												
TOTAL IB			2.0	2.0	100							
TOTAL INV			1.9	1.3	68	0.6	32	0.6				
TOTAL PROJECT			3.9	3.3	85	0.6	15	0.6				

Amounts net of VAT

- (1) In the Activity row use "X" to identify whether IB or INV
- (2) Expressed in % of the **Total** Expenditure (column (a))

5. Indicative Implementation Schedule (periods broken down per quarter)

Contracts (financed by IPA)	Start of Tendering	Signature of contract	Project Completion
<u>Contract 1 – TA Contract</u>	Qu4 2009	Qu2 2010	Qu2 2012
<u>Contract 2 – Supplies Vaccines</u>	Qu4 2010	Qu2 2011	Qu4 2012
Contracts (financed by National Contribution)	Start of Tendering	Signature of contract	Project Completion
<u>Contract 3 – Supplies Software</u>	Qu4 2010	Qu2 2011	Qu4 2012
<u>Contract 4 – Supplies Laboratory</u>	Qu4 2010	Qu2 2011	Qu4 2012
<u>Contract 5 – Supplies ear tags</u>	Qu4 2010	Qu2 2011	Qu4 2012

6. Cross-cutting issues

The cross-cutting issues will be addressed throughout the project. Up to 10% of the budget of the individual service contracts for capacity building – through short term expertise - may be allocated to assist the different beneficiaries to comply with European standards and best practices, implement relevant existing Government strategies and develop internal measures to ensure each cross-cutting issue is appropriately mainstreamed.

The mainstreaming of the cross cutting issues is regarded on two different levels:

- 1) 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.
- 2) 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.

Throughout the project cycle, in particular when developing project ToR, state actors specifically addressing (one of) the cross cutting issues shall be consulted. Specific attention will be paid to transfer knowledge to trainees on mainstreaming the cross cutting issues into future IPA plans. The following cross-cutting issues should be addressed:

- Equal opportunities and non-discrimination;
- Support to minority and vulnerable groups;
- Environmental protection;
- **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.

- **Support to minority and vulnerable groups**

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

- **Environment**

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, especially with regard to animal waste disposal.

ANNEXES

1 - Log Frame in Standard Format

2 - Amounts contracted and Distributed per Quarter over the full duration of Programme

3 - Description of Institutional Framework

4 - Reference to laws, regulations and strategic documents

- Reference list of relevant laws and regulations
- Reference to AP/NPAA/EP/SAA
- Reference to MIPD
- Reference to National Development Plan
- Reference to national/sectoral investment plans

5 – Details per EU funded contract (*) where applicable:

- *For TA contracts*: account of tasks expected from the contractor
- *For Twinning covenants*: account of tasks expected from the team leader, resident twinning advisor and short term experts
- *For Grant schemes*: account of components of the scheme
- *For Investment contracts*: reference list of feasibility study as well as technical specifications and cost price schedule + section to be filled in on investment criteria
- *For works contracts*: reference list of feasibility study for the constructing works part of the contract as well as a section on investment criteria (**); account of services to be carried out for the service part of the contract

(*) non standard aspects (in case of derogation to PRAG) also to be specified

(**) section on investment criteria (applicable to all infrastructure contracts and construction works):

- Rate of return
- Co-financing
- Compliance with state aids provisions
- Ownership of assets (current and after project completion)

ANNEX -Log frame in standard format

LOGFRAME PLANNING MATRIX FOR Project Fiche: Capacity building of the veterinary service for implementation of EU Acquis	Programme name and number: Capacity building of the veterinary service for implementation of EU Acquis	
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	Disbursement period expires one year from the final date for execution of contracts.
	Total budget : 3.9 Million Eur	IPA budget: 3.3 million EUR

Overall objective	Objectively verifiable indicators	Sources of Verification
The overall objective of the project is to contribute to a further development of the livestock sector in the country.	- SAA progress requirements - Progress Report follow up	Documents from the Government and the Commission

Project purpose	Objectively verifiable indicators	Sources of Verification	Assumptions
To provide technical and material assistance to the Veterinary Directorate to improve its overall ability and capacity for implementation of the EU Acquis and Accession Partnership commitments, with specific reference to its capability to transpose EU acquis into national law, appropriately implement its inspection services, control animal disease, organize animal waste disposal and expand the Animal Identification and Registration system to include pigs.	- SAA progress requirements - Progress Report follow up - Timely contracting of support project	Documents from the Government and the Commission Project Progress Report	Commitment of national authorities Cooperation between different stakeholders

Results	Objectively verifiable indicators	Sources of Verification	Assumptions
Component 1: Transposition of the EU Acquis - Transposition of the prioritized EU Acquis into national legislation - Established road map for transposition of EU Acquis in veterinary field	- 100% of the national legislation aligned with EU Acquis assessed and evaluated; - Prioritized laws have been harmonized with the EU Acquis; - A methodology for full transposition of relevant EU Acquis is established.	National Gazette Project reports	Political commitment remains

Results	Objectively verifiable indicators	Sources of Verification	Assumptions
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<p>Component 2: Strengthening of inspection services</p> <ul style="list-style-type: none"> - A professional Human Resource Development system is established, including: <ul style="list-style-type: none"> a.. Training needs assessment, b. Training action plan and implemented c. New re-training courses for veterinary inspectors d. Study materials (e.g. good hygiene practices, EU legislation, food safety, etc.) e. Training of trainers (TOT) on different disciplines of food hygiene and veterinary public health - Establishing an integrated food and feed control system throughout the food chain, based on a solid assessment of the existing situation and including: <ul style="list-style-type: none"> a. Upgraded inspection systems for quality control of food and feed, animal welfare during slaughter and killing, and animal waste in compliance with EU Regulations; b. Inspection manuals for inspectors are prepared; c. Target group definitions d. Public campaigns and information materials e. Reporting requirements (internal, national and international) - Revised current situation on competences of institutions for certification and control and evaluation of certification system 	<ul style="list-style-type: none"> • The new Human Resource Development system is approved • Training is taking place according to the agreed upon plan • Training course and course materials are produced • Satisfaction rates of trainees, measured through after training survey • Integrated food and feed control system is developed and approved • Operational mechanisms are developed and in operation (e.g. manuals, guidance notes, public campaign materials, etc.) • Reports are produced in time. 	<p>Project Reports Monthly progress reports Publications from the Directorate or/and the Ministry</p>	<p>Cooperation between stakeholders is established. Trainees willing and stimulated to put lessons learned into practice. Politically motivated intervention in HR Development system is low.</p>
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Results	Objectively verifiable indicators	Sources of Verification	Assumptions
Component 3: Animal Disease Control	- The process of vaccination has been	Project documents	Appropriate and fruitful cooperation

<ul style="list-style-type: none"> - Assessment of the epidemiological situation 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. - A detailed concept, system design and implementation plan is prepared to introduce electronic identification in the country. - Laboratory development: <ul style="list-style-type: none"> o Required equipment is purchased. o Accredited for performing laboratory diagnosis. o Personnel are trained in performing prescribed tests. 	<p>done according to the detailed plan</p> <ul style="list-style-type: none"> - Number of vaccine baits distributed. Number of samples collected and tested and results of the tests. Number of domestic pigs vaccinated. - Laboratory is included in proficiency tests with favorable results. - Establishment of sustainable cooperation with the hunters, National parks, concessionaires of hunting grounds. Required number of samples (as arranged with the TAIEX activity) collected and tested. - A series of informative workshops are performed and leaflets are distributed. 	<p>Disease reports</p>	<p>with all stakeholders is established. TAIEX support projects takes place and produces expected results.</p>
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Results	Objectively verifiable indicators	Sources of Verification	Assumptions
<p>Component 4: Establishing a system for animal waste disposal</p> <ul style="list-style-type: none"> - A system of separate collection, processing, use, trade of and disposal of the animal by-products is developed and start to be implemented. - Legislative provisions developed in line with EU acquis concerning (a) health rules for animal by-products not intended for human consumption and (b) ban on use o 	<p>The measurable indicators are:</p> <ul style="list-style-type: none"> - Assessment of current state concerning the animal waste treatment and control; - Evaluation of existing animal waste processing plants (rendering plants) and capacities; - Drafted operational guidelines on health rules concerning (a) animal by-products not intended for human consumption and (b) feed ban and SRM's; <p>A program for processing of different</p>		

- f selected processed animal proteins in animal nutrition.	- categories of animal by-products is prepared, including and if necessary the requirements for possible new plants (i.e. low risk processing establishments, incinerators...).	Project documents Official Gazette	Funds are or will be made available to finance likely investments.
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Results	Objectively verifiable indicators	Sources of Verification	Assumptions
Component 5: Animal Identification and Registration - An I&R system for pigs is introduced, established and sustained. - I&R+VIS IT systems are further developed and integrated, and interfaces needed for the total chain control of the sectors and to develop the production level of farm animals.	The measurable indicators are: - 90% of holdings and pigs are identified in first year. - The country is prepared to implement EU regulations on electronic I&R of animals. - An information flow in animal health and food safety is further developed.	Project documents Reports from I&R system.	Farmers willing to cooperate

Activities	Means	Costs	Assumptions
Component 1: Transposition of the EU Acquis - Analysis of the national legislation vis-à-vis transposition of the EU Acquis - Development of a methodology for further fully transposition of the veterinary EU Acquis - Harmonizing prioritized laws.	Technical Assistance Supplies vaccines Supplies Software Supplies laboratory Supplies Ear tags	IPA: 2.0 Million EUR 1.3 Million EUR National Contribution: 200.000 EUR 400.000 EUR 200.000 EUR TOTAL 3.9 Million EUR , of which 3.3 Million IPA Support.	- Vaccination of wildlife is successfully applied also in neighboring countries - Technical specification and ToR prepared in time. - Cooperation arrangements with other stakeholders are appropriately established.
Component 2: Strengthening of inspection services - Develop a professional Human Resource Development system, including: a. Implement Training needs assessment; b. Develop Training action plan, including TOT, re-training courses for veterinary inspectors; c. Implement training; d. Develop study materials (e.g. good hygiene practices, EU legislation, food safety, etc.)			

<ul style="list-style-type: none"> - Establish an integrated food and feed control system throughout the food chain <ul style="list-style-type: none"> a. Implement an assessment of the existing situation; b. Develop upgraded inspection systems for quality control of food and feed, animal welfare during slaughter and killing, and animal waste in compliance with EU Regulations; c. Develop inspection manuals for inspectors are prepared; d. Develop target group definitions e. Develop Public campaigns and information materials - Assess the current situation on competences of institutions for certification and control and evaluation of certification system and propose amendments as appropriate. 			
Component 3: Animal Disease Control			
<ul style="list-style-type: none"> - Analysis of the epidemiological situation in the whole territory of the country, based on surveys implemented with TAIEX assistance; - 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 a detailed concept, system design and implementation plan to introduce electronic identification; - Purchase required Laboratory equipment; - Develop and implement training plan for laboratory personnel to perform prescribed tests. 			
Component 4: Establishing a system for animal waste disposal			
<ul style="list-style-type: none"> - Assess current state concerning the animal waste treatment and control; - Evaluate existing animal waste processing plants (rendering plants) and capacities; - Develop legislative provisions in line with EU acquis concerning (a) 			

<p>health rules for animal by-products not intended for human consumption and (b) ban on use of selected processed animal proteins in animal nutrition;</p> <ul style="list-style-type: none"> - Draft operational guidelines on health rules concerning animal by-products not intended for human consumption and feed ban and SRM's; - Prepare a program for processing of different categories of animal by-products, including and if necessary the requirements for possible new plants (i.e. low risk processing establishments, incinerators...). 			
Component 5: Animal Identification and Registration			
<ul style="list-style-type: none"> - Develop and introduce an I&R system for pigs; - Further develop and integrate I&R+VIS IT systems, develop interfaces for the total chain control of the sectors; - Prepare to implementation plan for EU regulations on electronic I&R of animals; 			

Pre-conditions:

1. Endorsement by all key stakeholders of the Terms of Reference, specifications for the individual contracts to be engaged;
2. Appointment of counterpart personnel by the beneficiary before the launch of the tender process;
3. Allocation of working space and facilities by the beneficiary for technical assistance before the launch of the tender process;
4. Participation by the beneficiary in the tender process as per EU regulations;
5. Organisation, selection and appointment of members of working groups, steering and coordination committees, seminars by the beneficiary as per work plan of the project;
6. Appointing the relevant staff by the beneficiaries to participate in training activities as per work plan;
7. Available funds for co-financing;
8. Laboratories capable of properly performing the necessary tests should exist in the country otherwise foreign laboratories should be contracted to undertake these activities.
9. The current I&R system for cattle, sheep and goats is functional, including number of modules developed i.e. sample management, bovine brucellosis and tuberculosis workflow application, subsidy crosscheck module etc.

In the event that these conditions are not met, suspension or cancellation of tendering projects will be considered

ANNEX 2 - Amounts (in million EUR) contracted and Distributed per Quarter over the full duration of Programme (only IPA funds)

	2010				2011				2012				2013			
Contracted	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
TA contract		2.0														
Supply Vaccines						1.3										
Cumulated		2.0				3.3										
Disbursed																
TA contract		0.4			0.4	0.3			0.3		0.3	0.3				
Supply Vaccines						0.4		0.4			0.3	0.2				
Cumulated		0.4			0.8	1.5		1.9	2.2		2.8	3.3				

ANNEX 3 - Description of Institutional Framework

1. Introduction

The Veterinary Directorate under the Ministry of Agriculture, Forestry and Water Economy is the competent authority responsible for:

- animal protection of diseases, zoonoses (diseases communicable from animals to humans and vice versa);
- sanitary and hygiene wholeness of food of animal origin;
- assuring animal welfare;
- veterinary health and promotion environment and nature promotion.
- providing the highest standards for health of citizens and animals by consistent application of veterinary provisions/regulations.
- providing expert opinions to the Government related to issues of veterinary area;
- providing services to appropriate/relevant subjects and citizens.

2. Departments and their tasks and duties:

2.a. Department of animal health and animal welfare:

- Promotes standards and efficiency of disease controls in animals as well as zoonoses;
- Planning, organization 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.

2.b. Department of 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 authorized drugs, approved wholesale distributors for veterinary medicinal products;
- Control of import and production for feeding-stuff;
- Establishment of centre for pharmaco-vigilance.

2.c. Department for normative-legal affairs:

- Drafting the national veterinary legislation (laws) harmonised to the relevant EU legislation;
- Drafting secondary legislation harmonized to relevant EU legislation;
- Transposition of new adopted legal acts relevant to veterinary area from EU acquis.
- Regular duties such as:
 - inter-departmental coordination regarding framework law and by law governing veterinary area;

- issues regarding farmers and manufacturers;
- project and foreign aid coordination.

2.d. Department of border veterinary inspection:

- Supervision and control import/transit of animals and products, raw materials and by products of animal origin. Therefore, Veterinary Directorate have complete insight for quantity, dynamics and health and safety status of food of animal origin, allowing rapid and efficient implementation of competency and guarantee a health status of consignments of 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 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:

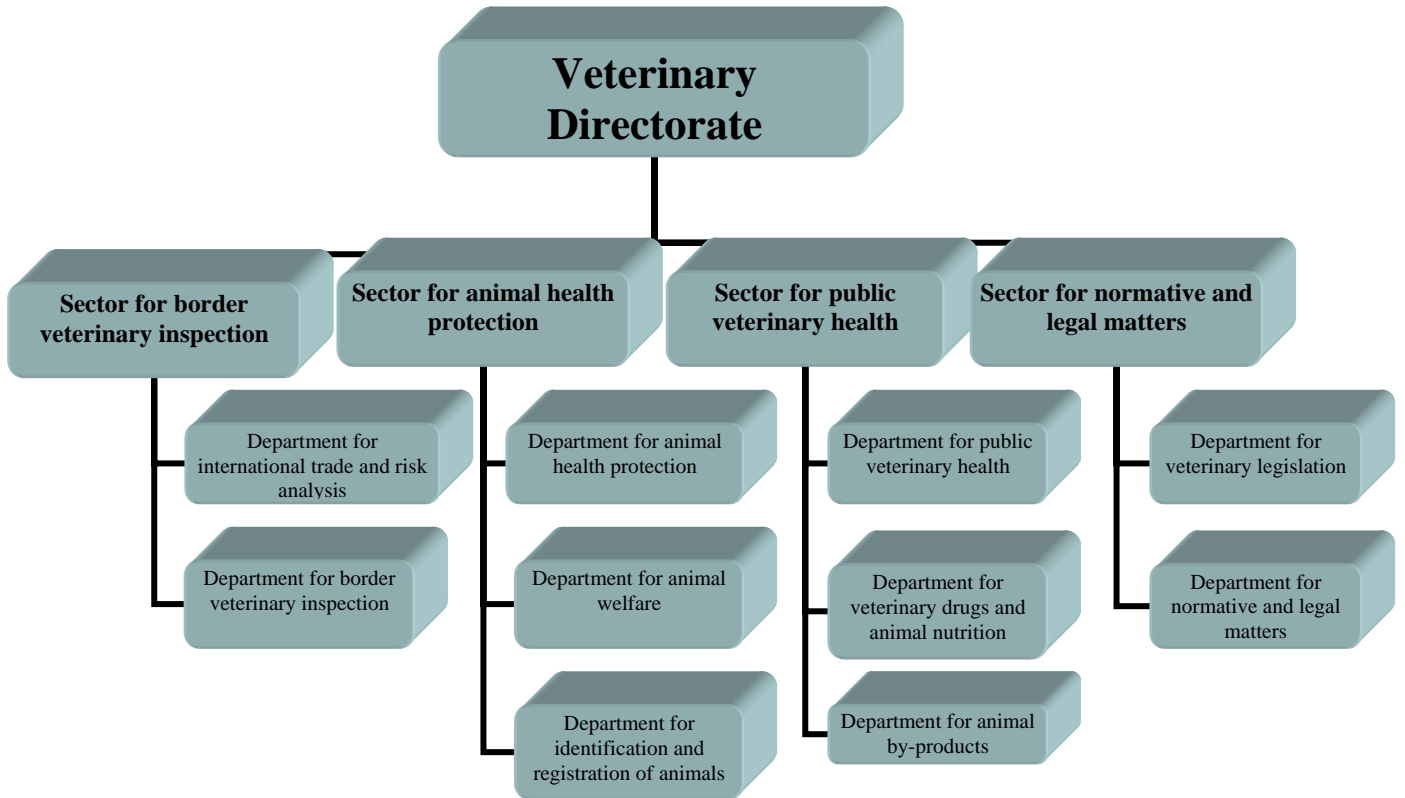
- Signature and ratification of the Stabilisation and Association Agreement;
- Participation to EU instruments/mechanisms, such as CARDS.
- Access to European and regional agreements and mechanisms on promotion of border management and
- Signature and ratification of international conventions.

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.

Currently, the total number of civil servants employed in state veterinary service (veterinary Directorate and veterinary inspection) is 167.

Veterinary Directorate for 2008, as budget beneficiary disposes of *381.413.300,00 MKD* under financial resources provided by the national Budget.

Organigram of the Veterinary Directorate



ANNEX 4- Reference to laws, regulations and strategic documents

3.a) Reference list of relevant laws and regulations

Key laws and regulations on the sector:

- Law on Veterinary Health, 1998
- Law on Food Safety and Products and Materials in Contact with Food, 2002
- Law on Medicinal Drugs, Supplementary Treatment Substances and Medical Devices, 1998
- Law on Animal Identification and Registration, 2004
- Law on Livestock Breeding, 1997
- Rulebook on sheep and goats identification and registration
- Law on Public Veterinary Health,
- Law on Animal Welfare,
- Law on Waste and By-products of Animal Origin
- Law on Animal Feeding,
- Law on Veterinary Medicinal Products
- Law on Animal By-Products

3.b) Reference to AP/NPAA/EP/SAA

Reference to **SAA** (2001): The program will contribute towards the implementation of the SAA Article 100 on gradual harmonisation of veterinary legislation with Community standards and Article 103 on the protection of animals against man-made disasters.

Reference to **Accession Partnership** (2007-2008): The program will address the following AP priorities: “Continue to align legislation with the veterinary and phytosanitary acquis, focusing on framework legislation compatible with the acquis”; “Continue to reinforce the capacity of the veterinary service at both central and local levels in order to put in place an EU-compatible control system, particularly for import controls”; “Ensure the operational character of the system for identification of bovines and registration of their movements and start a system of identification of pigs, sheep and goats”; “Further align animal disease and animal health control systems with the 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”; “Further align the legislation with the acquis regarding transmissible spongiform encephalopathies (TSE) and animal by-products, implement and control its enforcement and set up the necessary collection and treatment system”; “Strengthen the laboratory capacity in the food safety, veterinary and phytosanitary domain”.

Reference to the **Progress Report** (2007): The latest progress report makes the following evaluation: “There has been modest progress in the area of food safety, veterinary and phytosanitary policy, mainly in the area of food safety. The level of legislative preparedness is moderate. The administrative capacity, in terms of both number and competence of staff, is not adequate to ensure proper implementation of the acquis. Overall, alignment remains at an early stage”; “In the area of veterinary policy, alignment of the legislation with the veterinary acquis has continued. The Law on Veterinary Health was enacted. It sets the framework for five other specific laws. The legislation on control systems in the internal market and on control systems for imports is partially aligned. The implementing legislation on veterinary border controls has not yet been adopted. The amended animal identification and registration legislation provides for identification and registration of sheep and goats. The operational character of the system for the identification of bovines and registration of their movements

remains to be confirmed. The Veterinary Directorate adopted general measures for the control of avian influenza and bluetongue diseases, as well as the multi-annual programmes for surveillance of transmissible spongiform encephalopathies (TSE), for prevention of bovine and ovine brucellosis and for prevention of bovine tuberculosis. Transposition of the TSE acquis is at an early stage. The acquis on trade in live animals and on the import requirements for live animals has been partially transposed; alignment remains to be confirmed. Implementing legislation transposing the acquis on trade in semen, ova and embryos, and on import requirements for animal products has yet to be issued. The Law on Animal Welfare and Protection was enacted. It transposes the acquis on non-commercial movement of pet animals and animal welfare; alignment has not yet been confirmed. The Veterinary Directorate adopted the monitoring programme for prohibition of substances and residues control. The budgetary allocations for veterinary expenditures have been increased from just under €4m in 2006 to just over €5 million in 2007; all of the increase relates to subsidies to farmers. The capacity of the veterinary laboratory, which is part of the veterinary faculty, to provide reliable results is not satisfactory. The capacity of the veterinary service at both central and local levels to put in place an EU-compatible control system has not been sufficiently strengthened. Despite recent recruitments, there are not enough veterinary inspectors, and their management and training is not yet adequate. Overall, preparations in the veterinary policy field are moderately advanced”.

Reference to **National Plan for Adoption of Acquis** (2007): The Plan has following priorities with regard to veterinary policy: “Adoption of relevant laws and bylaws; Strengthening the Veterinary Directorate capacities: Training (The training of the employees of the Veterinary Directorate will be carried out in the field of the harmonised EU legislation, implementation of the official control procedures included in the new package of laws in the field of veterinary. Training of the veterinary inspectors for the introduction of a system for control of the production, circulation and the use of the veterinary medicinal preparations, of a system for control of production, circulation and use of feed, continuing the training on eradication/control of other infectious diseases, plans for urgent activities in case of occurrence of infectious diseases, safety of food of animal origin: Introducing of position-authorized veterinarian, Upgrading the system for animal registration and identification with IT equipment and training on data base management, Establishing a system for collection and treatment of animal by-products), Equipment (Development of an IT system for network connection and exchange of information and establishing databases is planned, including introduction of the systems compatible with the EU IT systems foreseen with the third phase of the I and R Project, which is to start in May 2007), Human Capacities Strengthening of the Veterinary Directorate (The Veterinary Directorate will be strengthened with new employees. In the period from 2008 to 2010 the employment of approximately 50 persons is required in the Veterinary Directorate for accomplishing the foreseen systematisation in the units, and in particular in the Unit for veterinary inspection as veterinary inspectors in the regional offices and border veterinary inspectors)”.

3.d) Reference to MIPD

Multi-Annual Indicative Planning Document (2008-2010) refers to: “With regard to veterinary policy, support will be given to the adoption of the acquis and to upgrading the laboratory sector, including inspectors and staff”.

3.e) Reference to National Development Plan

The proposed project has reference in following assessments of the **National Development Plan** (2007): “To ensure health protection of the animals against diseases that can be

transferred to people, health and hygienic safety of the animal originated food, welfare of animals, veterinary protection and advancement of the environment and the nature”; “Veterinary development consists of: health protection of the animals against diseases that can be transferred to people, health and hygienic safety of the animal originated food, welfare of animals, veterinary protection and advancement of the environment and the nature. The main programmes in this activity are the following: (i) veterinary component of the Project for structural and legal reforms of MAFWE, (ii) national system for identification and registration of animals: II phase, (iii) education and professional training of the veterinary administration staff, (iv) programme for enhancement and improvement of the regulatory, legislative and institutional structure (the programme aims at improving the regulatory, legislative and institutional structure in the country in relation to production, trade and use of animal feed and the production, trade and use of veterinary-medical materials), (v) programme for health protection of animals (the programme for health protection of animals will have as a constituent part the preparation of the programme for epidemiologic studies for zoonoses and economical important diseases in the preparation of recommendations for preparation of programs for prevention/control), (vi) monitoring of residues of certain substances, veterinarian medicines, and contaminants in live animals and in animal originated food, and (vii) strengthening the regulatory, legislative and institutional structure of the country in relation to production, trade and use of animal feed”.

3.f) Reference to national / sectoral investment plans

The project directly links to the following strategies and action plans in the sector:

- Business plan in the Veterinary Directorate,
- International Animal Health Code of the OIE (International Office of Epizootics),
- Strategic Plan 2007-2009 of the Ministry of Agriculture, Forestry and Water Economy,
- Working Programme 2006-2010 of the Government

ANNEX 5 - Details per EU funded contract

Management and contracting arrangements

Although the project contains 5 individual components, these components are inter-related. Therefore, the project will be implemented through a strong coordination mechanism. A steering committee will be established chaired by the Director of the Veterinary Directorate.. The Delegation of the European Union and the Secretariat for European affairs shall be invited to participate with observer status. The Steering Committee shall meet not less than once per three months.

Advisory services will be provided to the beneficiary. As the different components are strongly interlinked, one service contract will be engaged to provide the technical assistance for the total project. The TA contract will provide next to a team leader additional expertise to assist in key tasks, e.g. in the field of administrative capacity building, training, animal disease control, animal waste management, animal identification and registration, legal development and others. Some of these experts will address the cross-cutting issues.

The core project team – consisting of the team leader and other expertise will be placed within the Veterinary Department.

The team leader will be responsible for the overall management, representation (co-ordination with the EU and other international bodies) as well as reporting. The co-ordination of activity development in the different components of the activity is significantly important. The team leader is responsible for an appropriate management of resources. During the inception phase of the project, a detailed deployment plan will be developed under the coordination of a Steering Committee in which each co-operating national institution will be represented to ensure appropriate inclusion.

The expected contracting arrangements are:

Financed through IPA:

- 1 Service contract will be concluded following an international restricted tender procedure to support the project with duration of 18 to 24 months. Implementation is expected to start in 2nd quarter 2010; one month after the signature of the contract and the contract value will be approx. EUR 2.0 Million.
- 1 Supply contract for the purchase of vaccines. Implementation is expected to start in 2nd quarter 2011, one month after the signature of the contract. The contract has an expected implementation period of 4 to 8 months, and a subsequent defect liability period of 12 months, bringing the total duration to 16 – 20 months. The contract value will be approx. EUR 1.3 Million.

Financed through the national contribution:

- 1 Supply contract for the delivery and installation, as well as associated training, of the laboratory equipment. Implementation is expected to start in 2nd quarter 2011, one month after the signature of the contract. The contract has an expected implementation period of 4 to 8 months, and a subsequent defect liability period of 12 months, bringing the total duration to 16 – 20 months. The contract value will be approx. EUR 300.000.

- 1 Supply contract for the purchase of software module for Identification and Registration of pigs. Implementation is expected to start in 2nd quarter 2011, one month after the signature of the contract. The contract has an expected implementation period of 4 to 8 months, and a subsequent warranty period of 12 months, bringing the total duration to 16 – 20 months. The contract value will be approx. EUR 200.000.
- 1 Supply contract for the purchase of ear tags for pigs for the I&R system. Implementation is expected to start in 2nd quarter 2011, one month after the signature of the contract. The contract has an expected implementation period of 4 to 8 months, and a subsequent defect liability period of 12 months, bringing the total duration to 16 – 20 months. The contract value will be approx. EUR 100.000.

Concerning the supply contract for laboratory equipment:

The supply contract will include a module for training of the staff, following the installation of the equipment.

Laboratory capacity for rabies

Currently, the laboratory is performing direct immunofluorescence.

The required equipment to be purchased is:

- Biocontainment cabinet
- Fluorescent microscope
- One humidified and one dry CO₂ incubator on 37°C
- Centrifuge and vortex
- Refrigerator from +4 to -30°C
- Equipment for section and opening of the head
- Microtitre plates etc.
- Positive and negative controls (tissue smears and sera) from Reference Laboratories
- Cell culture flasks
- Human protection equipment
- Laboratory water bath

Laboratory capacity for swine fever

Current capacities for CSF laboratory are:

PCR lab:

- Conventional PCR machine (Perkin Elmer 480) and Real Time Bio Rad IQ5
- Separate rooms for a) extraction; b) preparation and aliquoting of the master mixes; c) addition of samples to the master mixes; d) electrophoresis and real time reading.
- Implemented procedures for detection of CSF virus in 5'NTR and E2 regions (conventional PCR) and in 5'NTR region for Real Time.
- The procedures have been overtaken from the EU reference laboratory for CSF at Ti-Ho, Hannover, Germany.

However, the PCR laboratory is used also for Avian Influenza, Brucellosis and other diseases.

Serology:

- Implemented ELISA protocols for antibody and antigen detection.
- Direct IF for detection of the virus in nasal swabs and organ smears.

For PCR and serology results have been submitted (except IF) for the official Ring trial 2008, organized by EU reference laboratory at Ti-Ho Hannover. Evaluation of the results is still in progress.

Virus isolation is still in preparation, and is not active at the moment. Current situation:

- Obtained cell cultures, monoclonal antibodies labeled with POD for detection of viruses: a) pan-pesti (all pesti viruses); b) CSF specific (only CSF) and c) BVDV specific.
- The antibodies have been obtained from the EU reference laboratory for CSF at Ti-Ho, Hannover, Germany.

The required equipment to be purchased is:

- Real Time machine.
- Conventional PCR machine with more independently programmable heating bodies, preferably compatible with both, the microtitar format PCR tubes and conventional (0,5 ml) PCR tubes.
- Homogenizers for the parenchymal organs (spleen, tonsillas, kindeys and other lymph nodes) with appropriate tubes filled with cheramic pellets.
- Centrifuge for the real time PCR microtitar strips (or whole plates).

Concerning the vaccination strategy

Table 1. Estimated number of wild carnivores in the country

Species	Estimated number of animals
Boar	200-250
Fox	10 000-11 000
Wolf	600-800
Badger	2500-3000
Polecat	1500-2000
Marten	4500-5000
Lynx	25-30
Wild cat	2500-3000

Source : Hunter's Association

The vaccination strategies for rabies control will consist of using commercial baits formulated for oral consumption by the mentioned animals. All of the baits have incorporated the antibiotic Oxytetracyclin. The vaccination against Rabies will be done by manual distribution of the baits and by plane in density of 20-25 baits per. km². The estimated number of baits for a single vaccination is 350.000. Estimated area to be covered is 15.000 km². The vaccination needs to be performed twice a year.

Vaccination against CSF will be performed in farmed wild boars with a vaccine used for domestic pigs. Wild boars that roam freely will be vaccinated using oral baits. Based on experiences from other MS countries, the number of oral baits per km² should be 11-15. The estimated number of baits for a single vaccination is 150.000. Estimated area to be covered is 10.000 km². The vaccination needs to be performed twice a year.

Estimated number of sows in the country is 30.000. Therefore the number of vaccines required for vaccination of domestic pigs (including farmed wild boars) in one year is approximately 700.000. The application of the vaccine will be performed by veterinary clinics

that have contract with the Veterinary Directorate for performing preventive measures. The costs for application will be born by Veterinary Directorate. Other anticipated costs (compensation for killed animals, disinfection, etc.) will be borne by Veterinary Directorate. TA provided by TAIEX for development of national legislation for eradication of CSF and development of CP is foreseen for 2008.

Monitoring of the immunization and of the infection through sampling and laboratory testing (cooperation between authorities, hunters and laboratories)

After each distribution of the vaccines for wild animals, a validation of the success of the vaccination campaign will be performed by testing hunted and dead animals. Tests will be performed at the national laboratory. Samples will be provided by hunters, National parks, Concessionaires of hunting grounds and Hunter associations.