

FINAL VERSION

1. Basic information

1.1 CRIS Number: 2009/021-665

1.2 Title: Capacity building of the competent authorities for food safety, veterinary and phytosanitary policy

1.3 ELARG Statistical code: 3.12

1.4 Location: Skopje

Implementing arrangements

1.5 Implementing Authority

The Central Finance 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, upon conferral of management. The Head of CFCD will act as the Programme Authorizing Officer (PAO) of the project.

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1.6 Beneficiary (including details of project manager/SPO):

The Veterinary Directorate, Phytosanitary Directorate and State Phytosanitary Laboratory, Seeds and Seedling Directorate within Ministry of agriculture, forestry and Water Economy (MAFWE) and Food Directorate within Ministry of Health (MoH), are the primary beneficiaries of the project.

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1.7 Overall costs (VAT excluded)¹: EUR 1 938 250

1.8 EU contribution: EUR 1 744 425

1.09 Final date for contracting

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

1.10 Final date for execution of contracts

Two years from the final date for contracting

1.11 Final date for disbursements

One year from the final date for execution of contracts

2. Overall Objective and Project Purpose

2.1 Overall Objective

The overall objective of the project is to improve the protection of human animal and plant health by strengthening institutional capacity of the food safety system.

2.2 Project purpose

Improve the institutional framework for food safety, in the country by strengthening the existing system of competent bodies and institutions in order to ensure an integrated multidisciplinary approach, covering all food chain stages.

2.3 Link with AP/NPAA/SAA

2.3.1 Accession Partnership

For food safety, veterinary and phytosanitary policy, the Accession Partnership outlines a series of priorities to be addressed. The AP stresses the importance of alignment of legislation with the relevant acquis and reinforcement of the capacity of the competent services at both central and local levels in order to put in place an EU-compatible control system, as well as strengthen the capacity of the laboratories involved.

2.3.2 Link with Stabilisation and Association Agreement

Stabilisation and Association Agreement the programme will contribute towards the implementation of the Article 100 - on gradual harmonisation of veterinary and phytosanitary legislation with Community standards and Article 97 on consumers' protection and institutional development of the administration for enforcement of the relevant legislation and market surveillance

2.3.3 Link with National Plan for Adoption of Acquis

¹ The total cost 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 (see Section 7.6)

The **National Plan for Adoption of Acquis** with regard to food safety, veterinary and phytosanitary policy reforms intends to further pursue legal development and further alignment of the legislation with the Acquis, its implementation, strengthen administrative capacities of the relevant services,.

2.4 Link with MIPD

The **Multi-Annual Indicative Planning Document** (MIPD) with regards to food safety, veterinary and phytosanitary policy indicates that support shall be given to the adoption of the acquis and its implementation particular as regards controls and laboratories.

2.5 Link with National Development Plan

The **National Development Plan** underlines the following:” 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”; This also underlines the priorities addressed in the project: provision of healthy and safe food to consumers

2.6 Link with national/ sectoral investment plans

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

- National strategy for food safety;
- National Action Plan for Food and Nutrition;
- Annual work plan 2009 of the Food Directorate;
- Strategic Plan 2007-2011 of the Food Directorate;
- Business plan in the Veterinary Directorate;
- International Animal Health Code of the OIE (International Office of Epizootics);
- Strategic Plan 2008-20010 of the Ministry of Agriculture, Forestry and Water Economy.

3. Description of Project

3.1 Background and justification:

The Ministry of Health and the Ministry of Agriculture, Forestry and Water Economy are the competent authorities for food safety control. The Food Directorate of the Ministry of Health, Veterinary Directorate, the Phytosanitary Directorate and the State Agriculture Inspectorate within the Ministry of Agriculture, Forestry and Water Economy are monitoring the application of national regulations, regulating the issues related to food in a wider context.

Having in mind the current state of supervision and control in some areas of the food chain, as well as a certain overlapping in the competences of the responsible authorities, the food safety system in the country needs to be reorganised. This includes adaptation of the methods of control, preparation and implementation of the legislation, application of the EU approach to the official controls and redefining the role of laboratories. The reorganisation is required in order to ensure adequate coordination within the framework of the "from stable to table" control system, improving the efficiency by applying risk assessment throughout the whole system, optimising the budget and improve transparency, not only by fulfilling the continuous

responsibility for food safety, but also to respond to future requirements in an efficient and prompt manner. The approach is supported by the EC, as pointed out in a number of reports and comments given to the competent national authorities.

As a candidate country it is necessary to enforce EU requirements in animal feed and food law, animal health and animal welfare rules and monitor and verify that relevant requirements are fulfilled by all relevant actors at all stages of production, processing and distribution. Animal health and welfare are important factors which contribute to the quality and safety of food, to the prevention of the spreading of animal diseases and to the humane treatment of animals. Rules covering these matters are laid down in several EU acts. It is appropriate to establish a harmonised framework of EU rules for the organisation of such controls. This can include routine surveillance checks and more intensive controls such as inspections, verifications, audits, sampling and the testing of samples. Proper implementation of those techniques requires training. Training is also required in order to ensure that the competent authorities take decisions in a uniform way.

Appropriate procedures should be available for the cooperation of the competent authorities in the country, in particular when official controls reveal that feed and food problems extend to more than one factor, and also to more than one country. It is an obligation, that competent authorities in the country notify and cooperate between each other and with authorities from other countries.

For a number of activities related to official controls, the European Committee for Standardisation (CEN) has developed European Standards (EN Standards). These Standards relate to the operation and accreditation of control bodies. International standards have also been drawn up by the International Organisation for Standardisation (ISO) and the International Union of Pure and Applied Chemistry (IUPAC). These standards are appropriate for the purposes of official controls, taking into account that performance criteria are laid down in feed and food law, in order to ensure flexibility and cost effectiveness.

Development of a feasibility study for establishment a sustainable system for the safe disposal of animal by products has been completed. Its main objective is an analysis and evaluation of current situation as well as recommendation for establishment of most appropriate and economically feasible system for the country intended for animal by products and animal waste management.

At present ABPs are buried in landfill sites for which municipalities are responsible. This practice is contrary to best practice and EU legislation. It is planned to discontinue this at the earliest opportunity.

Two main options are considered for the development of ABP disposal facilities, either a single Category 1 rendering plant established in the Skopje region or two small plants located in two other regions close to main animal production areas. The main advantage of option 1 is the reduced capital cost, and there would be only one planning application. It is estimated that the equipment for this plant would cost in the region of EUR 5 000 000 at 2009 prices, with a further EUR 1 500 000 for buildings and land. The main advantage of option 2 is reduced transport costs but, the capital costs would be in the order of EUR 10 000 000. In view of these factors it was argued that option 1 be adopted.

The options were presented to a stakeholders and a full discussion took place without negative comments.

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

- Administrative and institutional Strengthening of the competent authorities of food safety , veterinary and phytosanitary policy:
- Implementation of Animal By-products (ABP) strategy:
- Monitoring programme for plant health:
- ISO 17020 and preparation for accreditation of inspection services.

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

In order to fulfil the requirements of the SAA and achieve solid administrative capacity in food safety system in the country, avoiding the mistakes and improving the current situation, establishment of an efficient integrated system for food safety is inevitable. The latter will

- Ensure implementation of the holistic approach of the food safety system by priorities in order to achieve further alignment of the Acquis in the food safety area;
- Safeguard the interest of consumers, ensuring that the food complies with requirements for food safety, by strengthening food safety control through risk assessment, risk management and risk communication procedures and procedures for crisis management;
- Ensure animal health and welfare;
- Ensure veterinary and hygiene control at all stages of food and feed handling;
- Ensure phytosanitary protection and health; and promote the entry of the country into the EU food, veterinary and phytosanitary sector;
- Strengthening the capacity of the State Phytosanitary Laboratory, as a provider of laboratory services in the phytosanitary area.

Equally, improving the current situation regarding disposal of animal waste will contribute significantly to general public health as well as protection of the environment.

Phytosanitary Monitoring Programmes for plant health will also play an important role by controlling the spread of harmful organisms on plants

The EN 45004 accreditation of inspection services will improve the quality and technical competences of the inspection service for carrying out official controls and other checks.

These different results will help the competent authorities to grow as an organisation in terms of skills and expertise, thereby helping them carry out their role far more effectively. In addition through that strengthening, it should equally enable them to maintain closer and increasingly vital contacts with colleagues in neighbouring, other EU and international states. The impact on the society will focus on

- Increased public confidence in the food safety system
- Increased consumption of locally produced food

- Increased food export opportunities and overall economic growth of the country
- By applying a flexible and proportional risk based approach in the official control the authorities will:
 - reduce the unnecessary burden and inconvenience to the food business operators
 - reduce costs by improving the cost-effectiveness of the food safety system, reducing the number of checks, and improving the effectiveness of the laboratories etc.

3.3 Results and measurable indicators²:

The project has the following components:

- Administrative and Institutional strengthening of the competent authorities for food safety veterinary and phytosanitary policy;
- Implementation of the ABP strategy;
- Phytosanitary Monitoring Programme for plant health;
- Preparation for Accreditation of inspection services.

Component 1: Administrative and Institutional strengthening of competent authorities for food, veterinary and phytosanitary policy

The expected results under Component 1 are:

- The food, 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;
- Crisis management system is established;
- Traceability enforcement is established;
- RASFF (notification and information) is established and operational.

Information systems and platforms for food control authorities upgraded and linked with food and feed business operators self control data collection, as well as interested consumers complains notification

Measurable indicators under Component 1 are:

- Functional analysis and business plan of the food safety system developed;
- Operational Manual of procedures for communication between competent authorities developed and adopted;
- Number of fully Transposed relevant EU acts in to a national legislation and correlated application texts adopted;

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.

- Guidelines and manuals for implementation of legislation developed and training provided;
- Developed methodology procedures for Risk Assessment;
- Developed procedures for, risk management based on the results of risk assessment;
- Developed methodology procedures for Risk communication (involved operators, media and consumers);
- Methodology for data collection and evaluation is established;
- Training delivered in performing Risk Assessment, Risk Communication, Risk management to staff of the competent authorities and relevant stakeholders;
- Plan and working procedures for food crisis management – revised and upgraded
- Trained staff in performing Crisis Management within the competent authorities.

Component 2: Implementation of ABP strategy

A feasibility study for establishment of an efficient and economically feasible animal by product system in the country has been prepared. The outcome of the study is that a construction of a rendering plant would be the most suitable solution.

The expected results under Component 2 are:

- Designed work plan for transport, storage and disposal of animal-by products;
- Layouts for construction of rendering plant developed.

Measurable indicators under Component 2 are:

- Work plan for transport, storage and disposal of animal-by products is prepared;
- Layouts for rendering plant for disposal of animal-by products are developed.

Component 3: Phytosanitary Monitoring Programme for plant health

The expected results under Component 3 are:

- Strengthening of surveillance and monitoring of harmful organisms and plant protection products.

Measurable indicators under Component 3 are:

- Monitoring programs for harmful organisms, and plant protection products developed and operational

Component 4: Preparation for Accreditation of inspection services in accordance with adequate EU standard - EN 45004 or another standard if more relevant for the tasks in question)

The expected results under Component 4 are:

- Competent inspection services are performing reliable official controls according to international standards;
- Documented quality system for inspection performance is established.

Measurable indicators under Component 4 are:

- Inspection services within the competent authorities for veterinary, phytosanitary policy and food safety are EN 45004 prepared for accreditation.

3.4 Activities:

- Administrative and Institutional strengthening of the competent authorities for food safety, veterinary and phytosanitary policy;
- Implementation of ABP strategy;
- Phytosanitary monitoring programmes for harmful organisms and plant protection products;
- Accreditation of inspection services.

1. Administrative and Institutional strengthening of the competent authorities for food safety, veterinary and phytosanitary policy

- Building up a sustainable business plan, functional analysis and division of responsibilities;
- Preparation of official procedures for communication between the responsible bodies for food safety;
- Assistance in capacity building of the staff in the competent authorities for food safety, veterinary and phytosanitary policy;
 - 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.
- Risk assessment, risk communication and risk management;
 - Development of communication tools to facilitate effective communication with the public and the authorities;
 - Development of detailed Operational Manual of procedures for risk assessment, risk management and risk communication;
 - Delivery of training for procedures for risk communication (informing consumers about product recall);
 - Revising and upgrading the Plan, trainings of Procedures for food crisis management;
 - Design and for Crises Units in the area of food and feed safety;
 - Training of staff on procedures for risk assessment methodology, statistical data collection for risk assessment;
 - Training of staff on risk assessment procedures for food contaminants;
 - Training of staff on procedures for risk communication;
 - Training of staff on procedures for risk management
 - Training of staff for identification of emerging risks;
 - Assistance in development operating procedures on food control based on risk assessment and used for the inspectors' daily work.

2. Implementation of ABP strategy

- Analysis of the current situation with regards to location, transportation and disposal of ABP;
- Design the work plan and layouts for rendering of the plant.

3. Phytosanitary Monitoring Programmes for plant health

- Monitoring programmes for harmful organisms, and plant protection products developed;
- Phytosanitary controls strengthened and relevant staff trained.

4. Accreditation of inspection services

- Prepare the inspection services for EN 45004 accreditation;
- Set up general accreditation guidelines and procedures for accreditation;
- Design and define writing procedures, methods and protocols;
- Establish a system for internal quality audit and a system for control of documentation and keeping records.

Management and contracting arrangement

A steering committee will be established chaired by the directors of the competent authorities. The EC Delegation and the Secretariat for European Affairs shall be invited to participate with observer status. The Committee shall meet not less than once every 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, phytosanitary issues, animal waste management, legal development and others. Some of these experts will address cross-cutting issues.

The core project team – consisting of the team leader and other expertise will be placed within the competent authority(ies). 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 Senior Programming Officer and the Steering Committee in which each co-operating national institution will be represented to ensure appropriate inclusion.

The expected contracting arrangements are:

- 1 Service contract will be concluded following an international tender procedure to support the project with a contract that has an expected duration of 18 – 24 months. It is expected to start at Q4 2011, and have a budget of approximately EUR 1 938 250 (IPA funds will be EUR 1 744 425 and the national co-financing EUR 193 825)

3.5 Conditionality and sequencing

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

1. The Government will ensure coordination between the competent authorities involved in the food safety system ;
2. Coordination with IPA 2008 project activities will be ensured;

3. Sufficient number of appropriately educated staff is available, with language skills that will allow proper functioning of the institution and efficient participation in the corresponding international and EU bodies and represent the interest of the institution and the country.
4. Endorsement by all key stakeholders of the Terms of Reference and any related specifications;
5. Appointment of counterpart personnel by beneficiary before launch of tender process;
6. Allocation of working space and facilities by the beneficiary for technical assistance before the launch of the tender process;
7. Participation by the beneficiary in the tender process as per EU regulations;
8. Organisation, selection and appointment of members of working groups, steering and coordination committees, seminars by beneficiary as per project work plan ;
9. Appointing the relevant staff by the beneficiaries to participate in training activities as per work plan;
10. Availability of funds for co-financing;
11. Laboratories capable of properly performing necessary tests (which should exist in the country) otherwise foreign laboratories should be contracted to undertake these activities.

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

3.6 Linked activities

Regarding veterinary and food safety issues, several activities have been delivered and EU funded:

- The 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 unsustainable 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;
- The 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 Macedonian 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. The project “Strengthening the Food safety and quality control”, running from 02 April 2007 to 03 April 2008. The aim of this project is to assist the Government to the legal and institutional development of the food safety system of the country, in compliance with the EU *Acquis*. The Project focuses on five

principal components relating to the food safety control system, namely legislation, institutional, training, information management and laboratories.

Several activities of the Food Directorate have been supported by EU:

- The project „Quality and Regulatory Infrastructure Development for Food safety and Quality in South East Europe,, will be implemented in a period between 01 February 2008 and 31 December, 2011 based on Memorandum of Understanding signed between Ministry of Health of the former Yugoslav Republic of Macedonia and consortium consist of Swedish Accreditation Board and Swedish National Food Administration. The aim of the project is training of state food inspectors in performing of official food control according of HACCP principles;
- The project CARDS 2006 ‘Strengthening food safety and quality control’; began May 2007. Equipment for quick lab tests for field work will be provided in 2009;
- The project “Western Balkan Consumer Protection Network” has been started on 08 May 2007 based on Memorandum of Cooperation signed between the Ministry of Health (Food Directorate) and Ministry of Development of Greece;
- The project related creation matrix for use of pesticide/ active substances of pesticides by region and by product supported by GTZ has finished and was a base for creating Monitoring Programme of pesticide residues.

Phytosanitary policy

The Project “National Integrated Phytosanitary System” running from the June 2004 until July 2006. The aim of the project was to established National integrated phytosanitary system including set up of State Phytosanitary Laboratory, harmonisation of phytosanitary legislation with the Community *acquis*. Implementation of the Directives 2000/29 EEC and 91/414 EEC

3.7 Lessons learned

EC technical support has played an important role in the alignment of the National legislation with the EU Acquis. It has been key for the effective preparation for its implementation and strengthening the overall capacities of the competent authorities responsible for veterinary and food related activities. Veterinary Directorate, Phytosanitary Directorate and Food Directorate as beneficiary institutions, were or currently are an 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 recommendations and the 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.

The key challenges, including availability of funds and staff, involvement in tender procedures and project activities, have in this case been incorporated into the above conditionalities. Local ownership of the reform process underlines that capacity development is a process that should be led by the government. When designing future interventions, it is recommended to involve the main stakeholders and beneficiaries fully in the design and implementation of project activities. This will contribute to sustainable institutional capacity

which enhances ownership and commitment, leads to improved results and facilitates acceptance of recommendations at the policy level. The beneficiary institutions' staff

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.

Although the various activities will in the medium to long term have a beneficial impact on the sector, it remains important that a communication campaign accompanies the activities. Especially in the case of animal waste disposal, it is important to realise nationwide coverage as well as cross-border cooperation.

Learning from and cooperating with EU Member States and neighbouring countries has yielded good results. It is noted that in recent years similar programmes have been implemented in Member States with favourable results.

4. Indicative Budget (amounts in €)

		SOURCES OF FUNDING											
		TOTAL EXP.RE	TOTAL PUBLIC EXP.RE	IPA COMMUNITY CONTRIBUTION	NATIONAL PUBLIC CONTRIBUTION			PRIVATE CONTRIBUTI ON					
ACTIVITIES	IB (1)	IN V (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)	IFI s EU R (z)	EUR (e)	% (3)
Activities													
Service contract	x		1 938 250	1 938 250	1 744 425	90	193 825	10	193 825				-
TOTAL IB			1 938 250	1 938 250	1 744 425	90	193 825	10	193 825				
TOTAL INV			-	-	-	-	-	-	-				
TOTAL PROJECT			1 938 250	1 938 250	1 744 425	90	193 825	10	193 825				-

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

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))

In case of local or foreign training the project will fund from incidentals – whenever necessary - the renting of training rooms and equipment, the printing of training material and accessories as well as per diems/allowances for participants in the way and to the level normally financed by the government, but never higher than the per diem rates published by the EU Commission.

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

Contracts	Start of Tendering	Signature of contract	Project Completion
TA Contract	Q3 2010	Q4 2011	Q4 2013

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:

- 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.
- 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:

6.1 Civil Society development and dialogue

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

6.2 Environmental considerations

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.

6.3 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.

6.4 Minority and vulnerable groups

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

6.5 Good-governance and fight against corruption

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

ANNEXES

- 1- Log frame in Standard Format
- 2- Amounts contracted and Disbursed 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 / sector 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 *grants schemes*: account of components of the schemes
 - 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 constructing works):

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

ANNEX 1: Logical framework matrix in standard format

LOGFRAME PLANNING MATRIX FOR THE PROJECT FICHE: Capacity building of the competent authorities for food safety, veterinary and phytosanitary policy	Programme name and number: National Programme for the former Yugoslav Republic of Macedonia under the IPA Transition Assistance and Institution Building Component for 2009 CRIS number: 2009/021-665	
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 : EUR 1 938 250	IPA budget EUR: 1 744 425

Overall objective	Objectively verifiable indicators	Sources of Verification
The overall objective of the project is to improve the protection of human animal and plant health by strengthening institutional capacity of food safety system	- SAA progress requirements - Progress Report follow up	Documents from the Government and the EC

Project purpose	Objectively verifiable indicators	Sources of Verification	Assumptions
Improve the institutional framework for food safety, in the country by strengthening the existing system of competent bodies and institutions in order to ensure integrated multidisciplinary approach, covering all food chain stages	- 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: Administrative and institutional strengthening of the competent authorities for food safety and veterinary policy <ul style="list-style-type: none"> - The food, 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 - Risk analysis system in line with EC Regulation 178/2002 is established and 	<ul style="list-style-type: none"> - Implemented EU requirements in all food chain stages; - Official cooperation between the responsible authorities in the area of risk assessment; risk communication and management is functional; - Operational Manual of procedures for communication between competent authorities developed - Developed methodology procedures for Risk Assessment - Plan for food crisis management – revised and upgraded - Developed working procedures for Crisis 	<ul style="list-style-type: none"> - National Gazette - Project Reports - Monthly progress reports - Official Gazette - Publications from the competent authorities 	<ul style="list-style-type: none"> - Political commitment remains - 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>operational</p> <ul style="list-style-type: none"> - 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 - Crisis management system is established - Traceability enforcement is established - RASFF (notification and information) is established and operational - Information systems and platforms for food control authorities is upgraded and linked with food and feed business operators self control data collection, as well as interested consumers complains notification 	<p>Units</p> <ul style="list-style-type: none"> - Developed procedures for, management based on the results of risk assessment - Methodology of informing consumers of product recall and the minimum scope of data included in recall notices, developed; - Trained staff in performing Risk Assessment, Risk Communication, Risk management and Crisis Management within the competent authorities. 		
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Results	Objectively verifiable indicators	Sources of Verification	Assumptions
<p>Component 2: Implementation of ABP strategy</p> <ul style="list-style-type: none"> - designed work plan for transport, storage and disposal of animal-by products - Layouts for construction of rendering plant developed 	<ul style="list-style-type: none"> - Work plan for transport, storage and disposal of animal-by products is prepared - Layouts for rendering plan for disposal of animal-by products are developed 	<p>Project documents reports</p>	<p>Appropriate and fruitful cooperation with all stakeholders is established.</p> <p>Funds are or will be made available to finance likely investments.</p>
<p>Component 3. Phytosanitary Monitoring Programmes for plan health)</p> <p><i>The expected results are:</i></p> <p>Strengthening of surveillance of harmful organisms and monitoring of harmful organisms.</p>	<p><i>Measurable indicators:</i></p> <ul style="list-style-type: none"> - Monitoring programmes for harmful organisms, and plant protection products developed and operational 	<p>Project reports</p>	
<p>Component 4: Preparation for Accreditation of inspection services in accordance with adequate EU standard - EN 45004 or another standard if</p>	<p>The measurable indicators are: Inspection services within competent authorities for veterinary and food are ISO 17020 accredited</p>	<p>Project documents Official Gazette Accreditation dossier</p>	

<p>more relevant for the tasks in question)</p> <ul style="list-style-type: none"> - Competent inspection services performing reliable official controls according to international standards - Documented quality system for inspection performance is established 			
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Activities	Means	Costs	Assumptions
<p>Component 1: institutional strengthening of the competent authorities for food and veterinary policy</p> <ul style="list-style-type: none"> ▪ Building up a sustainable business plan, functional analysis and division of responsibilities; ▪ Preparation of official procedures for communication between the responsible bodies for food safety; ▪ Assistance in capacity building of the staff in the competent authorities for food safety, veterinary and phytosanitary policy; ○ 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. ▪ Risk assessment, risk communication and risk management assistance ○ Development of communication tools to facilitate effective communication with the public and the authorities; ○ Development of detailed Operational Manual of procedures for risk assessment, risk management and risk communication; ○ Delivery of training for procedures for risk communication (informing consumers about product recall) ○ Revising and upgrading the Plan, trainings of Procedures for food crisis management 	<p>Technical Assistance project and contract</p>	<p>Service contract</p> <p>Total : EUR 1 938 250 IPA : EUR 1 744 425 Nat. co-fin. : EUR 193 825</p>	<ul style="list-style-type: none"> - ToR prepared in time. - Cooperation arrangements with other stakeholders are appropriately established.

<ul style="list-style-type: none"> ○ Design and for Crises Units in the area of food and feed safety ○ Training of staff on procedures for risk assessment methodology, statistical data collection for risk assessment; ○ Training of staff on risk assessment procedures for food contaminants; ○ Training of staff on procedures for risk communication; ○ Training of staff on procedures for risk management ○ Training of staff for identification of emerging risks; <p>Assistance in development operating procedures on food control based on risk assessment and used for the inspectors' daily work</p>			
<p>Component 2: _Implementation of ABP strategy</p> <ul style="list-style-type: none"> • Analysis of the current situation with regards to location, transportation and disposal of ABP • Design the work plan and layouts for rendering plant 			
<p>Component 3: Phytosanitary Monitoring Programmes for plant health</p> <ul style="list-style-type: none"> ▪ Monitoring programs for harmful organisms, and plant protection products developed ▪ Phytosanitary controls Strengthening and relevant staff trained 			
<p>Component 4: Preparation for Accreditation of inspection services in accordance with adequate EU standard - EN 45004 or another standard if more relevant for the tasks in question)Prepare the inspection services for ISO 17020 accreditation</p> <ul style="list-style-type: none"> • Set up a general accreditation guidelines and procedures for accreditation • Design and define writing procedures, methods and protocols • Establish a system for internal quality audit and a system for control of documentation and keeping records 			

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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.

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

ANNEX 2 - Amounts (in €) contracted and disbursed by quarter over the full duration of the project (IPA funds only)

	2011				2012				2013			
Contracted	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
Service contract				1 744 425								
Cumulated				1 744 425								
Disbursed												
Service contract				523 328		348 885		348 885		348 885		174 442
Cumulated				523 328		872 213		1 221 098		1 569 983		1 744 425

ANNEX 3: Description of Institutional Framework

1. Introduction

The Veterinary Directorate under the Ministry of Agriculture, Forestry and Water Economy of the former Yugoslav Republic of Macedonia is 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 in the country.
- providing expert opinions to the Government related to issues of veterinary area;
- providing services to appropriate/relevant subjects and citizens.

2. Sectors and their tasks and duties

2.a. Sector 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 former Yugoslav Republic of Macedonia;
- 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. 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 authorized drugs, approved wholesale distributors for veterinary medicinal products;
- Control of import and production of feeding-stuff;

- Establishment of a centre for pharmaco-vigilance.

2.c. Sector 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. Sector for border veterinary inspection

- Supervision and control import/transit of animals and products, raw materials and by products of animal origin. Therefore, the Veterinary Directorate has complete insight into 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 – the National Strategy on Integrated Border Management of the former Yugoslav Republic of Macedonia, 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:

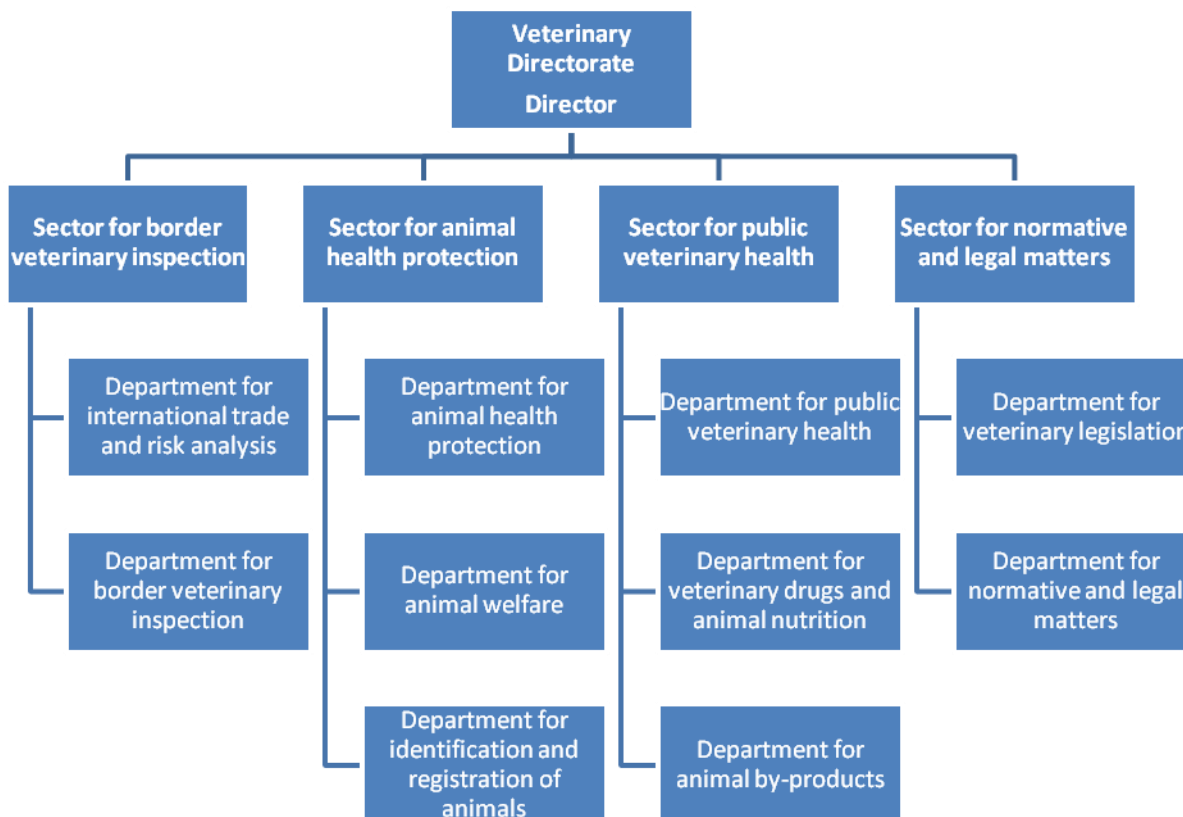
- Signature and ratification of the Stabilisation and Association Agreement;
- Participation to EU instruments/mechanisms, such as CARDS, the Schengen Agreement and the Stability Pact;
- Access to European and regional agreements and mechanisms on promotion of border management; and
- Signature and ratification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

Future border management is based on an integrated system for border management, closely related with the 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. An 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 focused to annul the risks originating from internal and international crime and terrorism. At the same time, the future system will be focused to permanent improvement of the 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.

The Veterinary Directorate for 2008, has a national budget of *381.413.300,00 MKD*.

Organigramme of the Veterinary Directorate



3. Food Directorate

Food Directorate within the Ministry of Health is the competent authority for control on foodstuffs of plant origin in all phases of production and distribution including import, export and control of catering.

3.1. Departments and their tasks and duties

- Department for food standards
 - Unit for normative, legal affairs
 - Unit for administrative work and informatics analytical system
 - Unit for consumer protection
 - Unit for food for special nutritional use, food supplements, GMO food and novel food
 - Unit for quality assurance
- Department for control of production and trade of food

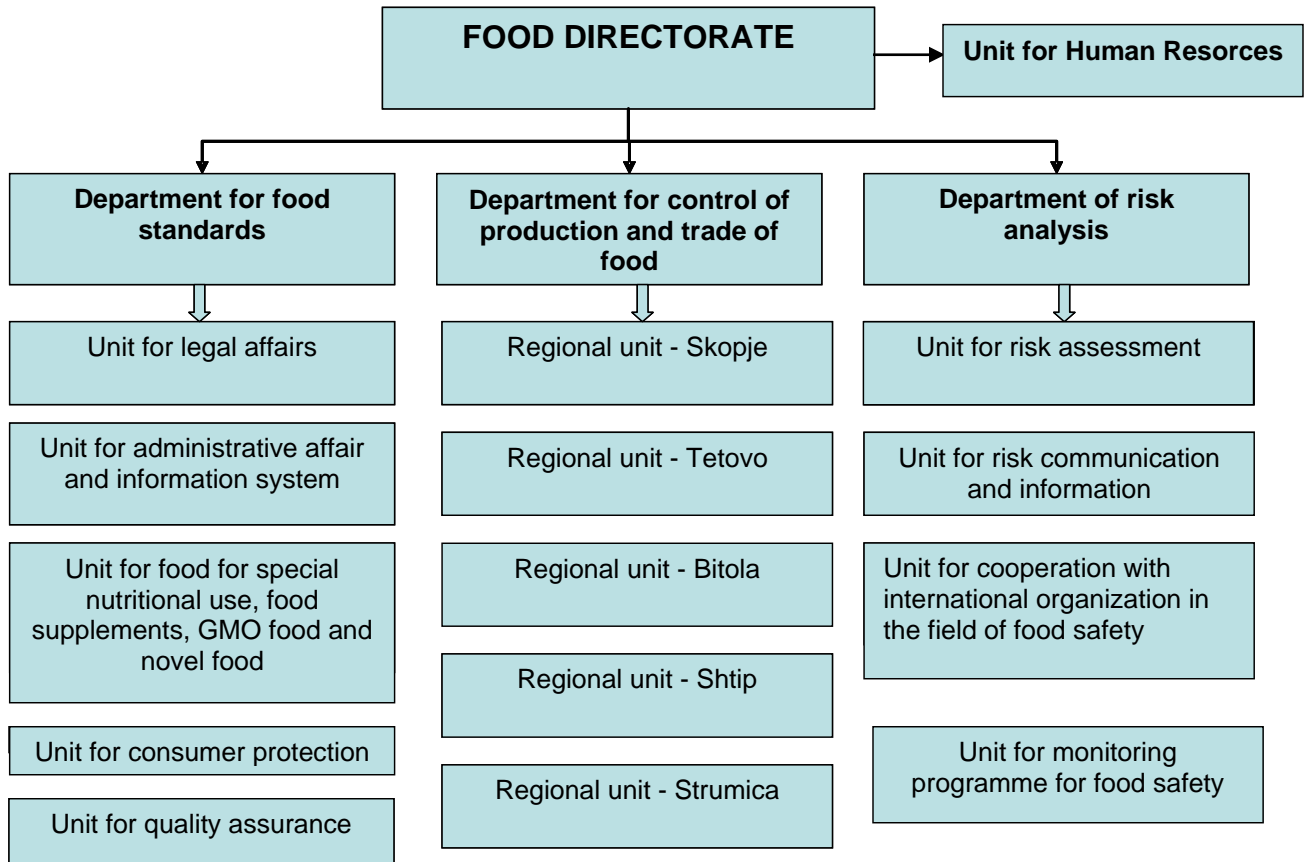
- Regional unit for control of production and trade of food, located in Skopje
- Regional unit for control of production and trade of food, located in Terovo
- Regional unit for control of production and trade of food, located in Bitola
- Regional unit for control of production and trade of food, located in Shtip
- Regional unit for control of production and trade of food, located in Strumica
- Department for risk analysis
 - Unit for risk assessment
 - Unit for risk communication and information
 - Unit for collaboration with other organizations
 - Unit for monitoring programme for food safety
- Unit for human resources

The Department for food standards comprises 5 units. Its main activity is the legislation drafting and harmonization of the national legislation with the EU acquis. The Unit for food for special nutritional use, food supplements, GMO food and novel food covers the registration and control of production and trade of these specific types of food. The Unit for consumer protection takes care of the consumer protection in the field of food safety and provides rapid information on all hazards from food products. The Unit for quality assurance is responsible for implementation of the ISO 17020 standard for accreditation of the inspection body.

The implementation of controls is carried out by the inspectors of the Department for control of production and trade of food deployed in five regional units (Skopje, Tetovo, Bitola, Shtip and Strumica). The export and import control is carried out on 12 border inspection posts.

The Department for risk analysis comprises 4 units and is responsible for assessing and communicating the food risks. The Unit for risk communication and information deals with the RASFF system and represents the national contact point for the system.

Organigramme of the Food Directorate



ANNEX 4: Reference to laws, regulations and strategic documents

Reference list of relevant laws and regulations

Key laws and regulations on the sector:

- Law on Veterinary Health, 2007;
- Law on Food Safety and Products and Materials in Contact with Food, 2002;
- Law amending the Law on Food Safety and Products and Materials in Contact with Food, 2007;
- Law on Livestock Breeding, 2007;
- Law on Public Veterinary Health, 2007;
- Law on Animal Welfare, 2007;
- Law on Animal By-products, 2007;
- Law on Animal Feeding;
- Law on Veterinary Medicinal Products.

Reference to AP/NPAA/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 encephalopathy (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 encephalopathy (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 EUR 4m in 2006 to just over EUR 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- authorised 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)”.

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”.

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 in RM (the programme aims at improving the regulatory, legislative and institutional structure in RM 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 RM in relation to production, trade and use of animal feed”.

Reference to national / sectoral investment plans

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

- National strategy on food safety;
- Annual work plan 2009 of the Food Directorate;
- Strategic Plan 2007-2011 of the Food Directorate;
- 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 arrangement

A steering committee will be established chaired by the directors of the competent authorities. The EC Delegation and the Secretariat for European Affairs shall be invited to participate with observer status. The 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, phytosanitary issues, animal waste management, 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 competent authority(ies). 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 Senior Programming Officer and the Steering Committee in which each co-operating national institution will be represented to ensure appropriate inclusion.

The expected contracting arrangements are:

- 1 Service contract will be concluded following an international tender procedure to support the project with a contract that has an expected duration of 18 – 24 months. It is expected to start at Q4 2011, and have a budget of approximately EUR 1 938 250 (IPA funds will be EUR 1 744 425 and the national co-financing EUR 193 825).