

**Project Fiche – IPA National programmes / Component I**

**1 IDENTIFICATION**

<b>Project Title</b>	Strengthening Food Safety Laboratories
<b>CRIS Decision number</b>	2013 / 024-935
<b>Project no.</b>	07
<b>MIPD Sector Code</b>	Agriculture and rural development
<b>ELARG Statistical code</b>	03.12 - Food safety, veterinary and phytosanitary policy
<b>DAC Sector code</b>	31110 - Agricultural policy and administrative management
<b>Total cost</b> (VAT excluded) <sup>1</sup>	EUR 4 400 000
<b>EU contribution</b>	EUR 4 000 000
<b>Management mode</b>	Decentralised management
<b>Implementing Agency</b>	<p>The Central Finance and Contracting Unit (CFCU) within the Ministry of Finance will be the contracting authority and will be responsible for all administrative and procedural aspects of the tendering process, contracting matters and financial management, including payment of project activities. The Head of the CFCU will act as Programme Authorising Officer (PAO) of the project.</p> <p>Ms. Anila Boshnjaku (Tanku)            General Director of the CFCU/ Ministry of Finance            Email: <a href="mailto:atanku@minfin.gov.al">atanku@minfin.gov.al</a>            Tel: 00355 4 245 1180            Address: Blvd. "Deshmoret e Kombit", No. 3, Tirana</p>
<b>Implementation management</b>	<p>Ministry of Agriculture, Rural Development and Water Administration / Directorate for European Integration            Director Ariana Misha (SPO)            Tel.: +355 42 227920            Cel.: +355 672084014            Email: <a href="mailto:anamisha@yahoo.com">anamisha@yahoo.com</a>            Blvd."Deshmoret e Kombit" 1002-Tirana, Albania            web: <a href="http://www.mbumk.gov.al">www.mbumk.gov.al</a></p> <p>Florian Paspali            Director General of Food Safety and Veterinary Institute            Cel :0682071180            Email: <a href="mailto:flori_alb@yahoo.it">flori_alb@yahoo.it</a></p>
<b>Implementing modality</b>	Stand-alone project

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<sup>1</sup> The total project cost should be net of VAT and/or of other taxes. Should this not be the case, clearly indicate the amount of VAT and the reasons why it is considered eligible.

<b>Project implementation type</b>	One technical assistance service contract with IPA funds and one supply contract merging IPA and national funds under joint co-financing
<b>Zone benefiting from the action(s)</b>	Albania

## 2 RATIONALE

### 2.1 PROJECT CONTEXT: ISSUES TO BE TACKLED AND NEEDS ADDRESSED

The Albanian Government considers food safety and consumer protection as a priority in its policy agenda. The creation of the National Food Authority (NFA) in Albania was based on the strategic priorities set in the European Commission's "White Paper on Food Safety". The NFA was sanctioned in the new Food Law approved by the Albanian Parliament in January 2008 in line with EU standards and requirements. This institution has significantly increased its operational capacity and started to expand its activity across the 12 regions of the country. In the second phase, financed through IPA 2009, the completion and consolidation of the NFA structure and functions is taking place in line with a competences and functions transfer plan, including the veterinary and phytosanitary domain, prepared during the first phase. This however generates the need to establish full capacity to perform risk assessments, to manage emergency situations and to communicate on risks. This is to be achieved through additional technical assistance to be provided directly to the National Food Authority and cooperating structures.

Under IPA 2009 a draft report was prepared regarding the future strategy of the laboratories, suggesting the reinforcement of 11 NFA regional offices and the Reference Food Safety and Veterinary Institute (FSVI). This recommendation was subsequently discussed with the main stakeholders and is the starting point of this project.

The gradual takeover of responsibilities by NFA is hampered by the lack of appropriate physical infrastructure, such as office space and laboratories. To be able to perform its duties with regard to these functions, the NFA needs adequate physical infrastructure to accommodate the planned number of staff (part of which will move from the Ministry of Health and Municipalities) and IT Centre capacity, both at central and regional level. The NFA is going to be completed with necessary offices and laboratory spaces in 11 regions of the country, through the IPA 2010 project that has already started its implementation.

Further, there is a need to enhance the capacities of the Reference Food Safety and Veterinary Institute (FSVI) to carry out food safety, veterinary and phytosanitary tests. FSVI needs to strengthen its quality management in accordance with EU standards and accreditation rules. Also the relevant laboratories of FSVI need to be upgraded in order to meet the ISO 17025 accreditation requirements.

This project aims to strengthen the Ministry of Agriculture by supporting the development of capacities for carrying out food safety, veterinary and phytosanitary tests in the Food Safety and Veterinary Institute (FSVI) and the NFA regional laboratories.

## 2.2 LINK WITH MIPD AND NATIONAL SECTOR STRATEGIES

According to the **MIPD 2011-2013**, in the area of rural development, the main goals are (i) raise competitiveness of agriculture and the agro-processing sector supporting restructuring and development of value adding activities (aimed at increasing the financial value of products), (ii) protect and improve the environment through the sustainable management of natural resources in rural areas (iii) improve the quality of life in rural areas and diversify various economic activities through the creation of new jobs (iv) development of institutional capacities to plan, manage and effectively coordinate activities in support of rural development.

The main objectives in the sector are summarised by the targets of two national strategies:

A. The **Inter-Sectorial Rural Development Strategy and Agriculture and Food Sector Strategy**, which specifically mentions:

- Increased competitiveness in the agricultural and agro-food sector based on restructuring and development of value-added activities;
- Protecting and improving the environment through sustainable management of natural resources in rural areas;
- Improving the process of policy planning and rural development programs, and management of the support process (state aid scheme);
- Improving quality of life in rural areas and promotion of diversification; and
- Enhancing the involvement of the Local Government Unit-s, citizens and other stakeholders in the process of preparation and implementation of local development strategies in rural areas.

B. The **National Strategy for Development and Integration 2007-2013**, which mentions the need to update the legal framework and related physical infrastructure for the official inspection of food in line with EU standards.

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

The **Progress Report 2012** (4.12 Chapter 12: Food safety, veterinary and phytosanitary policy) of the European Commission stresses that an integrated animal database (including the animal health database) has been developed improving the registration of small ruminants and their vaccination against brucellosis. The lack of clear instructions and systematic recording, reporting and analysis of animal movements remains a serious concern in connection with disease transmission and traceability of animal products. Reporting of diseases by local veterinarians and submission of samples to check the health status of animals remains insufficient. Preparations in the veterinary field are not very advanced. Progress was made in the field of placing on the market food, feed and animal byproducts. Albania continued the approximation to the EU regulations on the import of food, monitoring of substances and residues in animal products, hygienic conditions and controls for bivalve mollusks and fish and the control of veterinary medicinal products. Food business operators' awareness of the new hygiene rules remains low, and alignment of food and feed establishments with hygiene standards a challenge. Preparations in this area are at an early stage. No progress can be reported in phytosanitary policy. Preparations in this area are not very advanced.

According to the Progress Report, in conclusion, progress has been limited in the areas of food safety and veterinary and phytosanitary policy. Efforts are needed to improve the definition of powers, responsibilities and lines of communication relating to risk management,

registration of movements of animals, control of animal diseases, and upgrading of food and feed establishments.

In addition, **Regulation EC 854/ 2004** clearly states the importance of the food control laboratories as the essential part of the entire national food safety and control network in the country. The proficiency of the national food safety activities depends significantly on the performance and effectiveness of the laboratory work.

## **2.4 PROBLEM ANALYSIS**

Recently, the protection of consumers from unsafe food was under the responsibility of different Institutions such as Ministry of Agriculture, Ministry of Health and local government bodies, resulting in a lack of clear responsibilities.

The National Food Authority (NFA) was created following the approval of the new Food Law by the Albanian Parliament in January 2008. The organization and functioning of NFA was approved by the Decision of Council of Ministers in October 2009 while the agency became operational by 1<sup>st</sup> September 2010.

The primary role of the NFA will be the enforcing of food safety related regulations while other tasks regarding policy development, preparation of legislation and crisis management will be shared with other responsible ministries.

In accordance with the Minister Order No. 262, dated 25.08.2010, the NFA immediately started to implement its tasks related to official control over all food establishments with the purpose to ensure a high level of protection on human health and consumers' interests.

To increase the efficiency of its functions, an IPA 2010 project is supporting the NFA with the restructuring of the necessary offices and laboratory space in 11 regions of the country.

Enforcing of legislation requires planning of official controls in line with risk assessment information. Such controls include also sampling of food products (animal or plant origin) and their analysis in regional laboratories.

A laboratory baseline study carried out through an IPA 2009 project provided a detailed assessment on the human resources, infrastructure, equipment and current activities in the regional laboratories.

FSVI is not part of the NFA but hold responsibilities as a national reference laboratory for animal health and some aspects of food testing. The institute has benefitted from considerable capital investment through various donor projects.

With about 60 staff, FSVI is housed in a well-equipped modern laboratory, with appropriate facilities for the tests carried out. The laboratory carries out all of the official control microbiological analysis for the Tirana region and some of the chemistry, where the NFA laboratory does not have the capacity. Beyond this, the institute is equipped to test for veterinary residues and metals in animal products, toxins in fish products, and an extensive range of microbiological organisms. The institute has a broad testing capability in animal health.

Since the merger of the previous food institute and the animal health institute into FSVI, almost the entire activity is focused on animals and products of animal origin.

The laboratory has modern equipment, although they sometimes lack suitable training for their use. A number of sections within the institute are working within an ISO 17025 quality system and a small number of tests have been accredited by Italian and Albanian accreditation bodies.

Albania imports annually around 380 tons of pesticides used mostly in fruits, vegetables, olives, grapes, grains in storage etc. However, there is no capacity to monitor their residues in these products. FSVI has not yet any capacity to carry out any pesticide residue analysis. Considering the size of producers, there is a potential risk that pesticide residues can be found especially in the retail markets being supplied directly by producers.

Risk management is very much related with these laboratory analyses whose effectiveness suffers from various constraints:

1. There is a lack of standard and rapid methods of analysis such as biochemical tests, or immunological tests that serve for a wide range of applications including histamine, aflatoxins, pathogenic microorganisms, different residues in foods, etc.;
2. There is a lack of validation of the test method in the laboratories;
3. There is a lack of facilities for the transport and storage of samples;
4. A number of laboratories have simple and outdated equipment used for classical and some routine tests that cannot be used for a wider spectrum of basic analysis. The current inventory of equipment does not ensure full coverage of already existing analytic and diagnostic methods either from a clear lack of tasks division or from lack of maintenance and replacement of amortized equipment.
5. There is no maintenance and repair service for equipments that have not been used.
6. Occupational safety in many laboratories is unsatisfactory due to lack of specific equipment as fume hoods or biological cabinets. Almost all laboratories lack equipment used in microbiological analysis,
7. Methods for physical/chemical tests available in all laboratories refer to Albanian standards of 1987 that need to be brought up to date with faster modern techniques;
8. Many phyto-sanitary checks are made mainly on crops or planting material with regard to plant health and are based on visual observations and simple microscopic determination. There are no checks on stored or imported products regarding the presence of pathogens and consequently there are no analysis regarding the detection of mycotoxins associated with grain, silage and other animal feed.
9. Veterinary checks refer to very few diseases such as anthrax, brucellosis or enterotoxemia, with the diagnostic capacity remaining low. Although present in the country, parasitic diseases such as e.g.fluke are not recorded from the laboratory books. In addition, there is no equipment to carry out the necropsy of dead animals to take specimens for further analysis in the national laboratory.
10. Staffing can be considered appropriate although very much under loaded. However, their expertise seems limited due to lack of training with updated methods and techniques.
11. Limited internal quality control measures are applied in any of the laboratories and calibration of equipment almost missing.
12. A serious problem found was the absence of rules and procedures for laboratory waste management in general. There were no standard written procedures for disposal of the blood, sera, tissue samples, used microscopic slides, sharp instruments, syringes, needles and bacterial cultures etc. Most of laboratories did not have proper facilities for safety disposal and waste management.
13. Laboratories suffer from lack of necessary consumables and reagents that are supplied in insufficient quantity and some time late.
14. There is a range of laboratory analysis not carried in the laboratories including additives, allergens several contaminants and pathogens.

Besides these technical deficiencies, the biggest problem affecting the laboratory network is related to the missing of a clear policy about the structure, organization and tasks of the system. Consecutively, there is no planning on activities, resources and requirements from laboratory people regarding the improvement of the system are mostly on an ad hoc basis.

It exists a general believe that laboratory system should carry out most of the analysis required on food safety or quality without considering the heavy financial implications such opinion bears. As part of the revision of the system, the new project shall consider the outsourcing of services as a cost saving and reliable practice until the carrying of such services in the country are fully justified

However, following the information provided by the baseline study funded under the IPA 2009 project, there is the awareness and willingness to conduct a significant reform in the laboratory system to increase its efficiency and effectiveness in order to ensure reliable and timely information about the potential food-borne risks. Such policy will require that most of the regional laboratories conduct simple basic measurements made of screening and fast diagnostic tests while confirmation be carried out at the FVSI with regard to safety and likely at another laboratory if not FVSI on quality standards and food adulteration.

Such system will require the setting up of a sound sampling and transporting system to allow the confirmation of cases in about real time and allow for taking measures for the minimizing of risks.

## **2.5 LINKED ACTIVITIES AND DONOR COORDINATION**

**EU-IPA 2008** “Improving consumer protection against zoonotic diseases”

**EU-IPA 2009** “Consolidation of the food safety system in Albania” aims at strengthening and consolidating the administrative structures responsible for ensuring the enforcement of EU compliant food safety measures. One of the important outcomes of the project will be a strategic document on the situation and solutions for a Food safety System of Laboratories in compliance with EU Standards.

**EU-IPA 2010** project aims to support the food safety and veterinary infrastructure in Albania through construction and rehabilitation of the National Food Authority (NFA), Regional offices and laboratories and the central veterinary laboratory at FSVI.

A main objective of the project “**Strengthening of the Food Control Institutions**” funded by Italian Government and implemented by the WHO is to modernise and upgrade the scientific and managerial capacity of food laboratories and inspection services in Albania to meet international standards and accreditation requirements, and to provide a sound basis for the work of the new National Food Authority. A specific objective is to establish suitable food laboratory structures. The aim is to achieve at the central level accreditation of certain analyses that are needed to monitor important microbiological and chemical hazards in the food chain, in particular shellfish/seafood. It also supports communication on and coordination of food safety issues and support the development of real-time reporting system between the public health, food and veterinary sectors, including the relevant laboratories.

## **2.6 LESSONS LEARNED**

The Albanian laboratory system has suffered many serious problems such as understaffing, lack of training programmes to update the staff with new standards and techniques and especially shortage of financial resources to cover the minimal needs regarding the operational and maintenance costs.

Keeping a good laboratory system working in line with the required standards is expensive due to relatively high depreciation costs of equipment and buildings, costs of human capital and running costs.

Therefore, the preliminary step toward a sustainable and cost-efficient laboratory system is strongly tied to a sound restructuring of the whole system. Restructuring will in return free the government from unnecessary contribution to the IPA project itself (less consumables and operational costs will be required to run the system).

To avoid likely delays in the implementation of the project, it is necessary that all the laboratories (whose construction is planned to be completed during 2013) are provided with the planned furniture. Such measure will require that government plans the procurement of these goods during 2013.

Timely provision of consumables and other operating capital to laboratories remains a prerequisite before these labs start and work with updated procedures and techniques.

### **3 DESCRIPTION**

#### **3.1 OVERALL OBJECTIVE OF THE PROJECT**

Support the national administrative capacities to ensure improved levels of food safety over the whole food chain.

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

Strengthen the capacity of the laboratory network to carry out monitoring and analysis of food and feed products in accordance with the required standards.

#### **3.3 RESULTS**

**Result 1:** A restructured cost-efficient laboratory network has become an important player in providing reliable and timely information on the safety of marketed food and animal health.

**Result 2:** Laboratory staff trained and motivated to adopt new techniques and methods,

**Result 3:** The analytic and diagnostic capacity of the laboratory system is enhanced due to upgrading of the equipment and application of improved methods and techniques

#### **3.4 MAIN ACTIVITIES**

##### **Related to result area 1 (technical assistance service contract – IPA contribution):**

- 1.1. Recommend the design and assist the adoption of a national plan for the restructuring and reorganization of the laboratory network
- 1.2. Advise re-defined roles and tasks of each food safety, veterinary and phytosanitary laboratories in accordance with the relevant policy indications,
- 1.3. Design a medium-term human resources training plan to ensure increased proficiency of the managerial and analytic staff to comply with assigned workload and tasks in the areas of pesticide residues monitoring, microbiological diagnostics in food and feed, food quality standards, zoonotic diseases, laboratory management etc,

- 1.4. Establish a detailed inventory of equipment along with a replacement, maintenance and repair plan. Repair and complete unused equipment and put those in function,
- 1.5. Identify the needs on consumables and reagents and prepare the relevant procedures for the supply and quality checks.
- 1.6 Introduce and adopt the necessary standards to ensure good laboratory management practices including Standards of Operating Procedures based on the Bio-Safety Level of the facility, quality assurance and control, safety of personnel, validation of tests, calibration of equipment, sampling and information, etc.

**Related to results area 2 (technical assistance service contract – IPA contribution):**

- 2.1 The capacity for the monitoring and analysis of pesticide residues in food and animal feed in line with Regulation 396/2005/EC,
- 2.2. Introduce and implement rapid detection methods in food microbiology with regard animal origin products (including E.Coli, staphylococcus ssp, listeria, salmonella ssp, clostridium, campylobacter etc) and plant origin (mycotoxins)
- 2.3. Replace old food quality standards (STASH) with new international ones. Establish capacity for rapid analysis of the constituents of finished product and discovery of food adulteration,
- 2.4. Carry out on-job and special training with regard to the diagnosis and measurement techniques in the above mentioned areas of expertise.
- 2.5. Prepare FSVI laboratory of pesticide residues analysis for accreditation

**Related to result area 3 (supply contract – IPA contribution and national contribution):**

- 3.1. Supply equipment and consumables for the analysis of pesticide residues (including GC, GC-MS, HPLC, LC-MS, GPC)
- 3.2. Supply general use equipment and consumables for the new Central Veterinary Laboratory to be built under IPA 2010 programme for the departments of bacteriology, parasitology, virology, histopathology and rabies
- 3.3. Complete of regional animal health laboratories with simple equipment and kits to increase the diagnostic capacity,
- 3.4 Supply regional laboratories with equipment to ensure occupational safety for personnel (e.g. fume hoods and biological cabinets)
- 3.5 Provide necessary equipment and kits for the regional laboratories to ensure basic microbiology analysis on food of animal and plant origin
- 3.6 Provide minimum equipment needed for measuring food quality in selected laboratories
- 3.7 Provision of reagents
- 3.8 Provision of furniture for the new Central Veterinary Laboratory
- 3.9 Provision of IT equipment and any air-conditions system as necessary



### **3.5 ASSESSMENT OF PROJECT IMPACT, CATALYTIC EFFECT AND CROSS BORDER IMPACT (WHERE APPLICABLE)**

#### **Project impact**

The main impact of the project will be on producers and traders to improve the quality and safety of the food produced in accordance with the standards and on consumers to benefit from a higher level of protection.

#### **Catalytic effect**

By reducing the costs due to negative impact of low quality and unsafe food, the consumer will be able use any savings to buy other services or goods,

Likely increasing of exports due to improved quality and safety of food may change the structure of production and processing toward profitable activities.

#### **Cross border impact**

A higher quality and safer food will encourage also border trade.

### **3.6 SUSTAINABILITY**

Sustainability of the project will depend on:

- Appropriate staffing of the laboratories in line with the required qualifications,
- Avoid turnovers of the analytical staff,
- Ensure a continuous and satisfactory supply with necessary utilities (power, water, waste disposal) and consumables (kits, glassware and reagents)
- Allocate the necessary operational funds for maintenance and repair of equipment.

### **3.7 ASSUMPTIONS AND PRE-CONDITIONS<sup>2</sup>**

#### Assumptions

- It is assumed that the construction and/or upgrade physical infrastructure (buildings and basic furniture) of regional food safety and veterinary laboratories and central veterinary laboratory supported by IPA 2010 funds and national contribution are finalised before the delivery of new equipment.
- Government endorses a human resource development policy, strategy and action plan of staffing in the laboratories by avoiding high turnovers and keeping or nominating qualified, experienced and proficient people

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<sup>2</sup> Assumptions are external factors that have the potential to influence (or even determine) the success of a project but lie outside the control of the implementation managers. Such factors are sometimes referred to as risks or assumptions but the Commission requires that all risks shall be expressed as assumptions. Pre-conditions are requirements that must be met before the sector support can start.

## Pre-conditions

- A clear strategy on the laboratory network and need assessment for priority supplies is prepared and endorsed by the Ministry of Agriculture, before any supplies are delivered under this project;
- Government allocates the necessary human and financial resources to support an optimal laboratory activity carried out in line with its duties and planned workload. This means that for each laboratory which will receive assistance, a convincing report about available human resources will be provided through the Ministry of Agriculture.

## **4 IMPLEMENTATION ISSUES**

The project is going to be implemented under decentralised mode with one service contract for technical assistance, financed with IPA contribution, to cover activities 1 and 2 and one supply contract, financed with IPA contribution and national contribution (joint co-financing), to cover activity 3.

### **4.1 INDICATIVE BUDGET**

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

PROJECT TITLE			SOURCES OF FUNDING									
			TOTAL EXPENDITURE	IPA CONTRIBUTION		NATIONAL CONTRIBUTION					PRIVATE CONTRIBUTION	
	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)
Result 1 and 2												
Contract 1 Technical assistance	X		2 000 000	2 000 000	100	0	0					-
Result 3												
contract 2 Supply		X	2 400 000	2 000 000	84	400 000	16					-
.....												
TOTAL IB			2 000 000	2 000 000	100							
TOTAL INV			2 400 000	2 000 000	83.3	400 000	16.7					
<b>TOTAL PROJECT</b>			<b>4 400 000</b>	<b>4 000 000</b>	<b>90.9</b>	<b>400 000</b>	<b>9.1</b>					

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))

## 4.2 INDICATIVE IMPLEMENTATION SCHEDULE (PERIODS BROKEN DOWN BY QUARTER)

Contracts	Start of Tendering/ Call for proposals	Signature of contract	Project Completion
Contract 1 – service contract (IPA contribution)	Q1 2014	Q2 2014	Q2 2017
Contract 2 – supply contract (IPA contribution and national contribution under joint co-financing)	Q3 2014	Q4 2014	Q4 2015

## 4.3 CROSS CUTTING ISSUES

### 4.3.1 *Equal Opportunities and non discrimination*

Based on the fundamental principles of promoting equality and combating discrimination, participation in the project will be guaranteed on the basis of equal access regardless of sex, racial or ethnic origin, religion or belief, disability and age.

### 4.3.2 *Environment and climate change*

N/A

### 4.3.3 *Minorities and vulnerable groups*

Minorities will equally benefit from the project.

### 4.3.4 *Civil Society/Stakeholders involvement*

Relevant stakeholders consulted during the formulation of the project fiche are:

- Directorate of Food Safety within the Ministry of Agriculture.
- National Food Authority (NFA)
- Food Safety and Veterinary Institute (FSVI)
- Civil society, farmers and agribusinesses.

Stakeholders were consulted during various meetings organized by Ministry of Agriculture. Further, under IPA 2009 a draft report was prepared regarding the future strategy of the laboratories, suggesting the reinforcement of 11 regional offices and the Reference Food Safety and Veterinary Institute (FSVI). These recommendations were subsequently discussed with the main stakeholders, and are the starting point of this project.

## ANNEX 1: Logical framework matrix in standard format

LOGFRAME PLANNING MATRIX FOR Project Fiche		Project title and number		
		Contracting period expires no later three years from the date of conclusion of the Agreement		Execution period expires within a maximum of two years from the end date of contracting
		Total budget	4 400 000 Euro	
		IPA budget:	4 000 000 Euro	
Overall objective	Objectively verifiable indicators (OVI)	Sources of Verification		
Support the national administrative capacities to ensure improved levels of food safety over the whole food chain.	Degree of compliance with EU requirements and practices in the food safety standards	EC Progress Report  Consumer claims over food safety		
Specific objective	Objectively verifiable indicators (OVI)	Sources of Verification	Assumptions	
Strengthen the capacity of the laboratory network to carry out monitoring and analysis of food and feed products in accordance with the required standards.	List of analysis carried out by laboratories in line with international standards at the end of the project  Analytical capacity of equipment for the completion of the assigned analysis or tests  Number of ISFV and NFA staff capable to carry out lab tests in compliance with the EU requirements and standards at the end of the project.	Manuals and methods of analysis and diagnostic  Inventory and working status of equipment  Records of data from laboratory tests carried out on food and feed products  Results from proficiency tests	A clear strategy on the laboratory network is prepared and endorsed by the Government,  Government allocates the necessary human and financial resources to support an optimal laboratory activity carried out in line with its duties and planned workload	
Results	Objectively verifiable indicators (OVI)	Sources of Verification	Assumptions	

<p>Result 1</p> <p>A restructured cost-efficient laboratory network has become an important player in providing reliable and timely information on the safety of marketed food and animal health</p>	<p>Structure and organization of the laboratories</p> <p>Type, number and quality of of analysis and diagnostic tests carried out by laboratory staff annually</p>	<p>Reports</p> <p>Laboratory records</p> <p>Validation reports</p> <p>Inspection reports</p>	<p>Number of appropriate staff is nominated in line with the planned workload</p> <p>Good laboratory practices have been introduced and implemented</p> <p>Laboratories are not suffering lack of utilities, consumables or other operational capital.</p>
<p>Result 2</p> <p>Laboratory staff trained and motivated to adopt new techniques and methods</p>	<p>Workload of the staff and compliance with methods used in laboratory analysis</p>	<p>Reports and audits</p> <p>Laboratory records</p> <p>Validation reports</p>	<p>No unjustified turnover of staff</p> <p>Introduction of incentives for the staff that encourage the willing to improve proficiency</p> <p>Appropriate management of the laboratories</p>
<p>Result 3</p> <p>The analytic and diagnostic capacity of the laboratory system is enhanced due to upgrading of the equipment and application of improved methods and techniques</p>	<p>Accuracy of analysis as confirmed by national reference laboratory</p> <p>Number of analysis and compliance of methods</p>	<p>Validation reports</p> <p>Inventory of equipment provided to laboratories</p> <p>Laboratory records</p>	<p>Provision of continuous supply of utilities (power, water etc)</p> <p>Replacing of old methods and techniques with the new ones</p> <p>Adequate training of staff with new methods and techniques is provided</p>
<b>Activities to achieve results</b>	<b>Means / contracts</b>	<b>Costs</b>	<b>Assumptions</b>
<p><b>Result 1:</b></p> <p>1.1.Recommend the design and assist the adoption of a national plan for the restructuring and reorganization of the laboratory network</p> <p>1.2.Advise re-defined roles and tasks of each food safety, veterinary and phytosanitary laboratories in accordance with the relevant policy indications,</p> <p>1.3.Design a medium-term human resources</p>	<p><b>Means / contracts</b></p> <p>Service contract for the technical assistance</p> <p>Supply contract for the equipment and other laboratory supplies</p>	<p><b>Costs</b></p> <p>2.0 Million Euro Technical assistance for Capacity Building</p> <p>2.4 Million for Laboratory supplies</p>	<p>Government endorses the strategy for laboratories and committed to its implementation</p> <p>Government provides in time the supplies foreseen as part of its contribution</p> <p>Laboratory infrastructure upgraded and supply of utilities have been ensured before the supply of new equipment</p>

<p>training plan to ensure increased proficiency of the managerial and analytic staff to comply with assigned workload and tasks in the areas of pesticide residues monitoring, microbiological diagnostics in food and feed, food quality standards, zoonotic diseases, laboratory management etc,</p> <p>1.4. Establish a detailed inventory of equipment along with a replacement, maintenance and repair plan. Repair and complete unused equipment and put those in function,</p> <p>1.5. Identify the needs on consumables and reagents and prepare the relevant procedures for the supply and quality checks.</p> <p>1.6 Introduce and adopt the necessary standards to ensure good laboratory management practices including Standards of Operating Procedures based on the Bio-Safety Level of the facility, quality assurance and control, safety of personnel, validation of tests, calibration of equipment, sampling and information, etc.</p> <p><b>Result 2:</b></p> <p>2.1 The capacity for the monitoring and analysis of pesticide residues in food and animal feed in line with Regulation 396/2005/EC,</p> <p>2.2. Introduce and implement rapid detection methods in food microbiology with regard animal origin products (including E.Coli, staphylococcus ssp, listeria, salmonella ssp, clostridium, campylobacter etc) and plant origin (mycotoxins)</p>			
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- 2.3. Replace old food quality standards (STASH) with new international ones. Establish capacity for rapid analysis of the constituents of finished product and discovery of food adulteration,
- 2.4. Carry out on-job and special training with regard to the diagnosis and measurement techniques in the above mentioned areas of expertise.
- 2.5. Prepare FSVI laboratory of pesticide residues analysis for accreditation

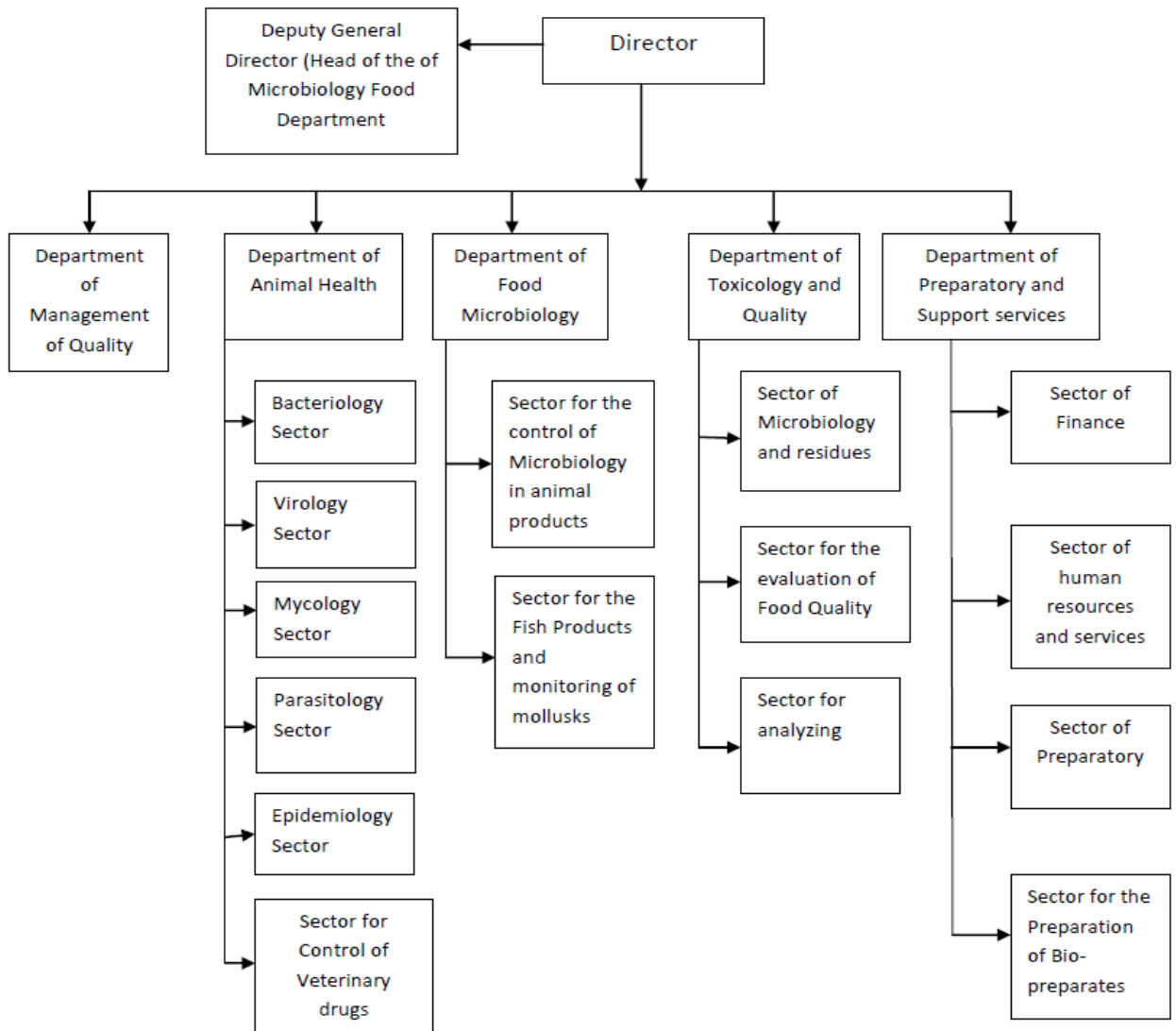
**Result 3:**

- 3.1. Supply equipment and consumables for the analysis of pesticide residues (including GC, GC-MS, HPLC, LC-MS, GPC)
- 3.2. Supply general use equipment and consumables for the new Central Veterinary Laboratory to be built under IPA 2010 programme for the departments of bacteriology, parasitology, virology, histopathology and rabies
- 3.3. Complete of regional animal health laboratories with simple equipment and kits to increase the diagnostic capacity,
- 3.4 Supply regional laboratories with equipment to ensure occupational safety for personnel (e.g. fume hoods and biological cabinets)
- 3.5 Provide necessary equipment and kits for the regional laboratories to ensure basic microbiology analysis on food of animal and plant origin
- 3.6 Provide minimum equipment needed for measuring food quality in selected laboratories



## ANNEX 2. Description of Institutional Framework

### The Structure of the Institute of Food Safety and Veterinary



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

1. Law no. 10.465, dated 29.09.2011 "On the veterinary service in the republic of Albania";
2. Regulation No. 2759/1, dated 12.8.1999, "On the control of TB in livestock";
3. Directives no. 77/391/EEC, dated May 17, 1977; 78/52/EEC;
4. Regulation "On the control of TB in livestock". This regulation aims at the protection of livestock health from Brucellosis, as well at taking permanent measures for the control of this infection in animals;
5. Regulation "On the control Brucellosis in small livestock". This regulation aims at the protection of livestock health from Brucellosis, as well at taking permanent measures for the control of this infection in animals;
6. Regulation "On the specific measures of controlling the blue tongue disease". This regulation aims at the protection of livestock health from the

blue tongue disease, as well as taking permanent measures for the control of this infection in animals;

7. Directive no. 93/119/EEC, dated December 22, 1993. Regulation “On the protection of animals while slaughtered, as well as the applied requirements for butchery shops”. This regulation aims at the implementation of the veterinary and sanitary measures in the process of animal slaughtering;
8. Regulation no. 466/2001/EEC, dated March 8, 2001. Regulation “On the establishment of maximal levels of pollution food substances”. This regulation aims at taking measures in order to increase the level of food safety for the animal originating products;
9. Regulation no. 854/2004/EC, dated April 29, 2004. Instruction “On the organization of official inspections to alive bivalve mollusks and fishing products”. This regulation aims at taking proper sanitary and veterinary measures in order to comply with the requirements for their export to the EU countries;
10. Directive Nr. 80/217/EEC January 22, 1980. Regulation “On the control of classic plague in pigs”; This regulation aims at protecting pigs’ health from the disease of pseudo pest and at taking proper permanent measures in order to control;
11. Instruction no. 3, dated 28.12.2002, “On cases of banning imported food products and information exchange with the exporting countries”;
12. The basic law that determines the institutional structure regarding the animal farming in Albania is Law No. 9426, dated 6.10.2005, “On the Animal Husbandry/Livestock Farming”, dated 06.10.2005, which adopts partially Directives 91/174/EEC, 88/661/EEC, 98/58/EC, 90/427 EEC, 94/28/EC, 77/504/EEC;
13. Law No. 8702, dated 1.12.2000, “On the identification and registration of animals and animal farms”, which adopts partially Directive 92/102, and Regulation 820/97 EC. It has completed the necessary normative framework, at the function of races programs and development of husbandry. For the implementation of this law, the DCM no. 143, dated 11.3.2004, “On the membership of the Ministry of Agriculture in the International Commission for animal registration (ICAR)”;
14. Law no. 9863, dated 28.01.2008 “On Food”.
15. Order nr. 168 date 24.5.2012 “On approval on BIP-s, where the veterinary and phytosanitary inspections on food and feed are carried out, in Republic of Albania”.
16. Order nr.178 date 04.06. 2012 “On approval of regulation “On lists of animals and products to be subject to controls at Border Inspection Posts”, based on Commission Decision 2007/275/EC.
17. Order nr.209 date 15.06.2012 “On approval of regulation “On laying down the methods of sampling and analysis for the official control of the levels of lead, cadmium, mercury, inorganic tin, 3-MCPD and benzo(a)pyrene in foodstuffs”, based on regulation 333/2007/EC.
18. Regulation on “The procedure for the establishment of maximum residue limits of veterinary medicinal products in foodstuffs of animal origin, such as flubendazole and lasalocid” (CELEX 32006R1055, 32006R1231, 32006R1451)

Regulation on “The procedures for the establishment of residue limits of pharmacologically active substances in foodstuffs of animal origin” (No 470/2009/EC of 6 May 2009)

Regulation “On the protection of animals kept for farming purposes” (CELEX 31998L0058, of 20 July 1998)

#### **ANNEX 4. Details per EU funded contract (\*) where applicable:**

Activity 1: Set up a monitoring, tests and diagnostics system for the use of the food safety laboratory network.

##### **Contract 1.1: Service Contract**

The precise type and number of tasks will be developed during the design period of the project, and confirmed during the inception phase of the TA contract. However from a primary analysis the Ministry has addressed that the total value of 2 million Euro to cover technical assistance to set up new analytical capacities (pesticide residues, food microbiology, rabies diagnostics etc), introduce and adopt of the necessary standards to ensure laboratory quality management practices including quality control, staff qualification, participation in proficiency tests, validation of tests, and calibration of equipment, sampling and information. There is also a need for replacing old analytical methods with more modern techniques. Another component is establishing procedures in line with EU standards and other international standards with regard to the setting up or consolidation of monitoring capacity.

With the new equipment in place there will be a need for training and qualification of laboratory staff with this new equipment and from other side there is a need for training regarding new methods and procedures that will be in place. Since FSVI it is a Reference institute in food safety and quality control which performs a broad spectrum analysis covering the area of food safety and quality control, there is also a need for some specific training of FSVI staff in international accredited institutions on pesticide residues analysis, rapid measurement methods, calibration of equipment, biotaxines, microbiology of food, animal health diagnostics with reference to zoonotic diseases etc. . :

Activity 2: Provision of the Laboratory equipment for the food safety labs both in ISFV and NFA Regional labs.

##### **Contract 2.1: Supply Contract**

The contract will cover the supply of equipment to:

Reference laboratory of FSVI Pesticide residues analysis (including Gas Chromatograph (GC), Gas Chromatograph – Mass Spectrometer (GC-MS), High Performance Liquid Chromatography (HPLC), liquid Chromatography – Mass Spectroscopy (LC-MS), Gel Permeation Chromatography (GPC) - (estimated amount €900,000)

- Equipment for the central veterinary laboratory (biological cabinets, water baths, incubators, microscopes, centrifuges, refrigerators, freezers, balances, stomachers, ELISA reader etc) and necessary glassware and consumables (estimated amount € 200,000)
- Furniture in the new central veterinary laboratory, reagents and IT equipment

#### Regional laboratories

- Basic equipment for the regional animal health laboratories (kits and simple measuring instruments for necropsy, basic equipment for culturing in microbiology, equipment for somatic cells count etc (estimated amount €300,000)
- Basic equipment for food microbiology (biological cabinets, incubators, microscopes, centrifuges, refrigerators, detection kits) and glassware, (estimated amount €300,000)
- Equipment for the measuring of food quality and standards in milk, dairy meat, flour and bread, oil and drinking water (estimated amount €300,000)

#### **ANNEX 5. Project visibility activities**

The project's visibility activities will include conferences, meetings, and promotional materials according EU visibility requirements