

Standard Summary Project Fiche – IPA 2008 centralised National programme

Development of the Food Safety Services

1. Basic information

1.1 CRIS Number: 2008/020-316

1.2 Title: Development of the Food Safety Services

1.3 ELARG Statistical code: 03.12

1.4 Location: Montenegro

Implementing arrangements:

1.5 Contracting Authority

European Commission, EC Delegation, on behalf of the beneficiaries

1.6 Implementing Agency

European Commission, EC Delegation, on behalf of the beneficiary

1.7 Beneficiary (including details of the project manager)

The main Beneficiaries are:

- Ministry of Agriculture, Forestry and Water Management (MAFWM)
- Ministry of Health, Labour and Social Welfare (MOH)

Other institutions featuring in the action are:

- Veterinary Directorate (MAFWM)
- Veterinary Laboratory (MAFWM)
- Institute of Public Health (MOH)
- Sanitary Inspectorate (MOH)
- Ministry of Education and Science (MES)
- University of Montenegro
- Biotechnical Institute of Podgorica (BIP)
- Institute of Marine Biology (BIP)
- Centre of Ecotoxicological Research (Ministry of Tourism and Environmental Protection)

The Project Managers will be:

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Financing:

1.8 Overall cost (VAT excluded): € 2.166 million

1.9 EU contribution: € 2 million

1.10 Final date for contracting:

Two years from the date of the signature of the Financing Agreement.

1.11 Final date for execution of contracts

Two years after the final date for contracting.

1.12 Final date for disbursements

One year after the final date for execution of the contracts.

2. Overall Objective and Project Purpose

2.1 Overall Objective

Food safety ensured for the benefit of consumers and the raise in food stuff production and trade.

Project purpose

To improve the operational capacity for food safety control in Montenegro.

2.3 Link with AP/NPAA / EP/ SAA

The short-term priorities of the **European Partnership** include the adoption of the Food Safety Law; a law on animal welfare and a new veterinary law; and strengthening the veterinary and phytosanitary services, including control and laboratory capacity. It also emphasises the need to continue the alignment of legislation with the EU veterinary and

phytosanitary *acquis*, including setting up an integrated food safety system and the preparation of a programme for upgrading food processing establishments.

The latest **Progress Report** notes that some progress has been made on food safety, veterinary and phytosanitary policy, and that this should be maintained and extended. It also states that Montenegro needs to review the organisational set-up of its administration in the sector and assign clear responsibilities and powers to individual departments. Capacity needs to be significantly increased in drafting subsidiary legislation and in inspection and associated control systems, which include the laboratory network.

Article 78 of the **SAA** provides for the alignment of the standards of consumer protection in Montenegro with those of the EU. It also stipulates that there should be effective legal protection for consumers in order to improve the quality of consumer goods and maintain appropriate safety standards.

2.4 Link with MIPD

The 2008-2010 **MIPD** includes food safety as one of the main areas of cooperation. It gives priority to food safety, veterinary and phyto-sanitary standards in the field of animal and plant diseases control, promotion and protection of food products, animal disease control. It also highlights the importance of implementing international agreements in the field of public health (communicable and non communicable diseases); supporting to the fishery sector (covering both marine and inland fisheries); and industry standards. Furthermore, the MIPD refers to the need to harmonise food safety legislation and increase the capacity of the veterinary, sanitary and phyto-sanitary services in order to increase awareness about rights and obligations of producers and consumers.

2.5 Link with National Development Plan

The National Programme for Integration of Montenegro into the EU specifies the short-and medium-term priorities of the country with regard to the food safety system. Chapter 3.12. Food safety, veterinary and phytosanitary policies, subsection 3.12.1. Food safety, outlines the following priorities: (i). in-depth analysis of the current national legislation with regard to the *acquis*; (ii) alignment of the secondary legislation, (iii) strengthening the capacity for health protection control (including testing and monitoring). More details are provided in Annex 4.

2.6 Link with national/sectoral investment plans

The improvement of the food safety system, together with adequate food legislation, which conforms to European and international standards, is the basis of the Food Safety Strategy. This was drafted by the Ministry of Health, Labour and Social Welfare, along with the MAFWM and expert assistance from other relevant institutions in 2006.

The Montenegro Food Safety Strategy is drawn up taking due account of Regulation EC No 178/2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety. It is drawn up according to the Action Plan for the European Partnership.

3. Description of project

3.1 Background and justification

A substantial and progressive liberalisation of the Montenegro market for agricultural products has been agreed under the SAA, WTO accession, and the Central European Free Trade Agreement (CEFTA). In parallel, effective consumer protection is necessary in order to safeguard public health. The data provided by the Institute of Public Health demonstrate a relatively high number of cases of food borne diseases, particularly high incidence of enterocolitis accuta, bacteria toxinfectio alimentarius and salmonellas.

Numbers of Food Borne Cases Diagnosed

Disease / Agent	2003	2004	2005	2006
Salmonella	321	321	367	236
Toxiinfectio alimentaris	229	283	206	219
Enterocolitis accuta	1,184	1,074	1,014	1,768
Staphylococcus aureus		22		
Cl. botulinum	4		4	
Shigella	28			
Echinococcus	2	1	3	3
Trichinella	23	9	1	1

This significant incidence of outbreaks (6 times higher than in the EU) is mainly explained with the availability of perishable food (creams, mayonnaise, season salads) – a fact that points to unsatisfactory conditions of hygiene for food preparation and storage. Cases of botulism and trichinellosis imply the consumption of inadequately prepared food or food conserved in unhygienic conditions.

The problem analysis exercise held with during the preparation of this project identifies clearly the development of legislative basis and administrative infrastructure able to ensure market surveillance and law enforcement as two key priorities for enhancing the food safety system in the country.

The veterinary law is being revised. A system for identification of bovine animals and registration of their movements has been implemented with EU funding. Identification of sheep and goats, and registration of their movements, is at an early stage and will be supported with EU funding as well. Inspection services and laboratories have received some equipment under the CARDS programme. Montenegro joined the World Organisation for Animal Health (OIE) in December 2007.

Along with the measures focused on animal health, Montenegro has adopted several laws and amendments to laws in the phytosanitary sector, including laws on protection of plant variety rights, plant nutrition and forest reproductive materials which already conform to the *acquis*.

Although the new Food Law (December 2007) is based on EU Food Law, it is not a direct transposition. An English translation is now available and there are gaps in the legal powers and procedures necessary for a comprehensive food safety system. Secondary legislation has yet to be developed and will not come into full effect for approximately two years. A detailed

programme for producing secondary legislation is presented in the National Programme for Integration of Montenegro into the EU.

The procedures, the preparation of guidelines, instructions and quality management have not been developed. In addition, the separation between risk management and risk analysis is not fully in step with EU principles. Other shortcomings have been noted in cross-departmental liaison: absence of a single contact point; unequal development of the inspections (sanitary, phytosanitary and veterinary); and control plans for zoonoses, residues and contaminants. The classification into four categories of establishments has yet to be carried out, and they do not meet the requirements in respect of general operational hygiene. The quality of raw milk is inadequate, there are no rendering plants, and no animal by-products plans for safe disposal of risk materials.

In the meantime many existing programmes, for example laboratory test programmes, need to be increased, equipped and strengthened. They need to adopt new methods in order to comply with EU requirements. Furthermore, reference laboratories have yet to be nominated (whether in the country or externally); and there is a lack of expertise in sampling and traceability, as well as in microbiological capabilities for sub-typing pathogens such as salmonella, E. coli, campylobacter and zoonotic organisms.

The need for an integrated network of data systems for food safety is apparent, with no product labelling and tracing system to link with the animal identification system. There is no unified data information system linking border posts, the register of food processing establishments and sanitary inspection. There is no linkage between veterinary, phytosanitary and sanitary inspectorates for rapid dissemination of information. And for the time being there is no technical possibility of linking to EU systems such as RASFF and ADNS.

This all points to significant gaps in the capacity to ensure food safety which has to be addressed through a change in public administration in this sector, and provision of adequate equipment for laboratories concerned with food control. Training is required in order to enable compliance with EU food safety systems. There is also a need to address the current fragmentation and distribution of food safety services around different departments and physical locations (some in poor condition) and bottlenecks in coordination and communication. Equally, the generally disjointed approach and the inefficient use of limited physical and human resources have to be overcome.

3.2 Assessment of project impact, catalytic effect, sustainability and cross border impact (where applicable)

The project is designed as an instrument to ensure positive **impact** on the consumers' health in Montenegro. A significant decrease in number of outbreaks due to food borne diseases is expected by 2015 – by at least 50% compared to 2006 (last available data).

The project will have a **catalytic effect** on the development of the food-related industry in compliance with the EU standards. By adopting the EU acquis on food safety (primary and secondary) the project will improve the control thus inducing changes in the activities of the economic operators bringing to the improvement of the production and trading facilities in line with the newly adopted standards. On the other hand, the enhanced food safety systems will have also have a catalytic effect on other major government objectives, such as the development of the tourist industry and rural development.

Sustainability issue will be addressed through the improved capacity for monitoring and control of the respective bodies and the established legislation, which will allow further harmonisation of the food safety system with the EU standards in the sector.

This project will have **cross-border impact** as it will ensure the same standards and control on food safety for locally produced and imported (mainly from neighbouring countries) food stuff. In long-term perspective, it will encourage the development of some programmes (e.g. laboratory testing, zoonosis control programmes) jointly with neighbouring countries.

The project will also allow sharing of information through the EU information systems such as the Rapid Alert System for Food and Feed (RASFF), Advance Disease Notification System (ADNS) and the Trade Control and Expert System (TRACES). Given the relatively small size of Montenegro it is likely that

3.3 Results and measurable indicators

The project will achieve the following results:

(1). Legislation compliant with the EU food safety standards for food safety in place

This result will be measured by applying the following indicators:

- Completed secondary legislation (80% of the specified in the NPI of Montenegro implementation rules adopted);
- Decreased gap between the legislation of Montenegro and the EU acquis regarding food safety, certified by the EU progress report.

(2). Enhanced capacity of the bodies responsible for food safety control

This result will be measured by applying the following indicators:

- Increase in the number and frequency of the control checks (by at least 30%) along with decreased individual time for each inspection (by 30%);
- Increase in the number of samples analysed (by products) – by 20%
- Increase in the number of establishments visited (by 20%)
- Increase in the number of detected and reported irregularities concerning food safety (by 15%).

(3). Enhanced capacity of the reference laboratories to implement analysis related to food safety

This result will be measured by applying the following indicators:

- Increase in the number and variety of analysis related to food safety (by 20%);
- Decreased time and cost for specific analysis concerning food safety (by 10%);
- Clear designation of the role of the reference laboratories (legislatively regulated);

(4). Developed administrative capacity of the Council on Risk Assessment (National Council for the Assessment of Food Safety - NCAFS)

This result will be measured by applying the following indicators:

- Number of reports, opinions and advises issued;
- Number of claims evaluated;
- Established system for internal review of the operations.

(5). Improved information exchange on food safety matters between the responsible institutions

This result will be measured by applying the following indicator:

- Decreased time and cost for information exchange on food safety-related issues.

3.4 Activities

The project will be implemented through the following activities:

Activities related to Result 1: Approximation of the Legislation

This component is designed to address the needs of aligning the primary and the secondary legislation of Montenegro with the EU acquis. The following actions will be implemented:

- Analysis of the current state of play and preparation of a Table of correspondence to outline the need of future legislative efforts;
- Assessment of the priorities concerning the food safety-related implementation regulations;
- Preparation of a team of national experts, through specialised training, mentoring and consulting, able to draft and to manage a drafting process regarding food safety;
- Drafting of legislative proposals, implementation rules and provision of on-going support for their adoption and implementation;

- Raising the awareness of the key stakeholders on the latest developments in the legislative framework for food safety (at EU and national level) through a series of information/training sessions across the country and publications.

Activities related to Result 2: Building the capacity of the bodies responsible for food safety

These activities include:

- Assessment of the precise needs of the bodies involved in executing control on food safety in terms of man power, equipment, training, inter-institutional coordination and communication, etc.;
- Preparation of training programmes and plans and delivery of targeted training on (i) EU system for food safety control, (ii) effective methods for inspections, control and monitoring, (iii) quality sampling incl. ensuring traceability of sampling;
- Elaboration of appropriate guidelines, instructions and quality management procedures at both institutional and inter-institutional level in order to ensure clear division of the responsibilities between the different bodies concerned with food safety;
- Upgrading/preparation of the inspections and control programmes and plans and on-going support for their implementation (particular attention to be given to the single integrated residue plan, zoonosis control plan, trichinellosis control plan);
- Upgrading/developing of the contingency plans with relevance to food safety (incl. Avian Influenza, brucellosis, tuberculosis, salmonellosis, listeriosis) and organisation of simulation exercises for each contingency plan;

Activities related to Result 3: Building the capacity of the reference laboratories

These activities concern the improvement of the food safety testing through upgrading of the testing capacity through purchase of equipment needed by the laboratories to implement the required analysis. The activities include:

- Assessment of the required technical support, equipment and training of the reference laboratories;
- Preparation of technical specification for the equipment needed;
- Supply of the equipment and training of the end users on how to operate with the delivered equipment;
- Training to the laboratory staff on effective sampling and testing methods in line with the EU standards, incl. microbiological and chemical testing and testing for food borne pathogens;
- Evaluation of the impact of the purchased equipment on strengthening the food safety system in the country.

Activities related to Result 4: Building the administrative capacity of the National Council for the Assessment of Food Safety

These activities are designed to support the efforts of the Montenegro Government to establish a National Council for the Assessment of Food Safety as an advisory body and a first step to separating risk assessment from risk management. These activities include:

- Training, consultancy and on-going support to the Committee's members for establishing Committee's mode of operation;
- Drafting of the operational rules and procedures for convening meetings, taking and communicating decisions and other subjects as required by the Committee itself;
- Provision of support for initiating and managing public consultations and involvement of the other stakeholders in ensuring food safety;
- Drafting of a proposal (mechanisms and organisational arrangements), upon assessment of the situation, for further separation of the risk management and risk assessment.

Equally, the members of the Committee will be involved in all other trainings according to their needs and competences.

Activities related to Result 5: Creation of integrated automated data system

These activities concern setting up an integrated data system, which will eventually have to be linked with traceability and product labelling systems which will be used by industry as well as with the existing EU integrated data systems such as RASFF. These activities include:

- Assessment of the existing IT capacities in all reference institutions to be linked;
- Design of a comprehensive IT system to satisfy the needs of all bodies involved in food safety and allowing distribution of information to and between the operational control points and among the various in country inspection services and laboratories;
- Establishment of the system and linking it to the existing animal identification and registration system.

3.5 Conditionality and sequencing

The achievement of the overall objective of the project is dependent on the following conditions:

- Motivation and ability (access to funding, to qualified consultants, etc.) of the food-related business to introduce the necessary food safety systems compliant with the EU standards;
- Permanent solution found for treatment of animal by-products
- Support laboratories are accredited with an internationally accredited authority.
- Permanent solution is found to ensure any type of testing necessary
- Raised consumers' awareness on food safety issues and more demanding behaviour,
- Water and other pollution kept at the same level

Attainment of the project purpose requires the following conditions to be met:

- Continuous commitment of decision-makers for ensuring full operation of the food safety system indicated by the provision of required resources and adoption of the needed legislation;
- Strong inter-institutional coordination and commitment to exchange information related to food safety;
- Food operators are motivated and able to support the improvement of the food safety systems.

The implementation of the activities and the achievement of the results depend on the following conditions:

- Laboratories designated with specific roles for food safety (legislative regulation) in order to avoid duplication of efforts and efficient use of scarce resources;
- Public and private operators supply the necessary data into the data network.

Regarding sequencing, it is necessary to ensure effective sequencing of the three envisaged contracts. Contract 1 will be launched first in order to ensure technical assistance in assessing the precise needs of equipment and in preparing the technical specification for its purchase. The equipment itself will be purchased through contracts 2 and 3 (one funded by the EU and one funded by the Montenegrin Authorities). In its turn, the Contractor under Contract 1 has to ensure further training on new testing methods after the equipment is delivered and has to finally evaluate the impact of the new equipment on the variety and number of analysis made. This would require that Contracts 2 and 3 are completed early enough to allow for the implementation of the mentioned activities.

3.6 Linked activities

At an Agricultural Donor Meeting hosted by the Minister of Agriculture, Forestry and Water Management on 10 December 2007, it was agreed that the European Commission would be the leading donor in the area of food safety and must assume responsibility for the legal and regulatory aspects. Other donors, such as the **World Bank** (WB) and GTZ, have converging interests and will provide support in specific areas.

The **WB** is negotiating with the Government a project valued approximately € 15 million and called “Montenegro Institutional Development and Agriculture Strengthening (MIDAS)”. At the moment of drafting this fiche, discussions are revolving around the two large components:

- **Strengthening the MAFWM’s rural development programme** with particular emphasis on (i) facilitating a rural development grants programme; and (ii) developing the capacity of the advisory services consisting of the Plant Production Extension Service and the Livestock Selection Service.
- **Strengthening the MAFWM’s administrative and management capacity** in accordance with EU pre-accession requirements, in particular, (i) establishing a rural development unit as a proto-managing authority; (ii) supporting the Ministry’s systematization plan, including the design and construction of a proposed House of Agriculture (for which a feasibility study is likely to be funded by IPA 2007 ATA

funds); (iii) implementing an Agricultural Census; (iv) supporting the establishment of a farm register and other administrative registers; (v) furthering the first steps leading to the establishment of a proto-type Paying Agency; (vi) creating a modern food safety system (broad laboratory support, veterinary and phyto-sanitary border controls – Podgorica Airport and Port of Bar-, and disposal of animal by-products). The intensive upgrading planned by the WB in benefit of key laboratories such as the Veterinary Diagnostic Laboratory, the Marine Biology Institute and food industry will be subject to a close inter-donor coordination and Ministerial guidance in order to achieve synergy, timely sequencing and impact.

GTZ supports within its Economic and Employment Promotion Programme the quality improvement of specific food products for a value of approximately € 70,000 annually, which is again complementary to this proposed project. While the EC programme focuses on state services, GTZ is supporting business development services, including state services, producers' associations or private business development services.

So far, the **EU contribution** to ensuring food safety in Montenegro was provided mainly through the CARDS Programme, which has supported a number of initiatives in the field:

- **“Strengthening of the Veterinary and Phytosanitary Services of Montenegro”** Project funded at the amount of € 1.5 million (CARDS 2003). The project contributed to establishing business plans on appropriate investment strategies for private vets. A new Veterinary Laboratory building was completed and necessary equipment was purchased. The phyto-sanitary component improved (1) the phyto-sanitary diagnosis and inspections to prevent or reduce the spread of harmful organisms as required by the EU and other international standards and (2) the control, including the forecasting of common pests and diseases..
- **Development and Implementation of an Animal Identification and Registration System Initiative** is a package of projects, funded by CARDS (2003-2006) at the amount of € 1.7 million, and aimed at the introduction of a food safety control system in line with EU requirements enabling full traceability of all animal movements ("stable-to-table" approach). The **second phase of the "Animal Identification & Registration Initiative"**, which will be funded by IPA 2007 with the amount of € 1.4 million will ensure further actions to extend animal identification to small ruminants and develop a veterinary information system.
- **"Refurbishment of the Food Safety Laboratories in the Biotechnical Institute"** Project funded at the amount of €0.8 million(CARDS 2005).
- **"Modernisation of Equipment in the Dairy Sector in Montenegro" Project funded to the amount of €2.3 million (CARDS 2000).** 907 farmers and six dairy enterprises were selected to receive equipment. The programme has been based on the credit-in-kind principle, with repayments by beneficiaries into a revolving fund.

Along with the national projects the EU has provided financial support for a number of regional projects aimed at enhancing food safety in the Adriatic area and Western Balkans:

- **Interregional Centre for food safety and risk analysis – SARA Project**, funded through Interreg III A Italy/Adriatic/CARDS 2005 with the amount of €15,000.

- **Adria Food Quality (AiA) Project**, funded by the Interreg III A Italy/Adriatic/CARDS2004 with €42,200.

3.7 Lessons learned

The preparatory phase for this project fiche has included extensive consultation to gain an insight into the needs perspectives of stakeholders and beneficiaries.

The experience gained previously in Montenegro, as well as elsewhere in the former Yugoslavia and in the accession countries, demonstrates that the establishment and operation of food safety systems is a complex and difficult task due to limited resources and manpower in place to build the necessary food safety capacity. These resources are even more scarce in the case of countries, small in size and population, like Montenegro. Therefore the need of adopting the efficiency perspective in establishing effective food safety system is of utmost importance. At project level the project strategy and methodology should integrate this perspective. Different measures are planned to maximise the use of the available resources (organisation and management study at an earlier stage, followed by the commitment of the necessary resources and manpower, combination of effective training and consulting methods, etc.)

Similarly, a great deal of knowledge has been accumulated throughout Europe on the delivery of IT systems in the food safety sector. IT programmes will be designed to take into account knowledge gained from relevant developments elsewhere and make best use of new and proven technology.

Although impact achieved through the previous assistance overall is satisfactory, a number of challenges remain:

- *Enforcement*: The capacity to enforce the law has to receive more attention.
- *Conditionality*: Often project implementation is hampered by the insufficient allocation of staff and resources on behalf of the main beneficiaries. This project will tackle this issue through an initial assessment of the capacity and needs of the bodies involved in establishing effective food safety system.
- *Institutionalisation of training activities*: Past assistance experience shows that a properly organised training effort as opposed to ad hoc organised training is crucial. Therefore the training must be based on the priorities agreed with the stakeholders. But the actual delivery of the training must be primarily locally-based and concentrated to ensure maximum impact and to avoid disruption to other functions of the stakeholder institutions. Training delivery is more efficient if it comprises a) structured seminars, b) strategic mentoring services for key officials and c) peer learning activities to ensure coherence and value from knowledge and skills acquired through the various capacity building activities.
- *Advocacy and Awareness*: it is important to note that the implications of the new food safety system are relatively unknown, not only to the wider public, but to some extent to professionals in the primary production and processing sectors. Therefore the project will pay special attention to awareness raising and consultations.

- *Right combination of expertise:* the combination of experts under the ongoing technical assistance project (old Member States and new Member States and Potential Candidate Countries) has proved to be effective in blending tradition, innovation and quick adaptability to meet the needs of an emerging market economy.

4. Indicative Budget (amounts in €)

			SOURCES OF FUNDING									
			TOTAL EXP.RE	IPA COMMUNITY CONTRIBUTION		NATIONAL CONTRIBUTION					PRIVATE CONTRIBUTION	
ACTIVITIES	IB	INV	EUR (a)=(b)+(c)+(d)	EUR (b)	%	Total EUR (c)=(x)+(y)+(z)	%	Central EUR (x)	Regional/ Local EUR (y)	IFIs EUR (z)	EUR (d)	%
contract 1	X	–	1,250,000	1,250,000	100							–
contract 2	–	X	750,000	750,000	100							–
contract 3	-	X	166,000			166,000	100	166,000				–
TOTAL IB			1,250,000	1,250,000	100							
TOTAL INV			916,000	750,000	82	166,000	18	166,000				
TOTAL PROJECT			2,166,000	2,000,000	92	166,000	8	166,000				

Amounts net of VAT

Contract 1 is a service contract, aimed at approximation of the legislation, ensuring training and consulting activities. Contract 2 is a supply contract aimed at purchasing the needed equipment for ensuring food safety testing and monitoring. Both contracts 1 and 2 will be funded by the EU and respectively the procurement and contracting be managed by the EC Delegation.

Contract 3 is also a supply contract, which will be funded, tendered and managed by the Montenegrin National Authorities. Its purpose is to supply additional equipment needed for ensuring the food safety testing.

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

Contracts	Start of Tendering	Signature of contract	Project Completion
Contract 1 (service)	Q1/2009	Q4/2009	Q3/2011
Contract 2 (supply)	Q1/2010	Q3/2010	Q4/2010
Contract 3 (supply)	Q1/2010	Q3/2010	Q4/2010

Contracts 1 and 2 will be managed by the EC Delegation to Montenegro.

Contract 3 is not under the competence of the Contracting Authority and represent the parallel national public contribution to the procurement of supplies. However, it is expected that the technical assistance hired under Contract 1 will contribute to the preparation of some technical aspects in the procurement of equipment for both supply contracts (Contract 2 and 3).

6. Cross cutting issues

6.1 Equal Opportunity

The programme will be equal opportunity sensitive and ensure access of women, disabled and elderly to its benefits, particularly with regards to access to training and increasing opportunities for employment and career advancement. The advertising of job vacancies and recruitment will support fair and open competition.

Equal opportunity needs will be considered as an integral part of the project with regular monitoring to ensure relevant issues are given due prominence. In particular the equal opportunity issues will be taken into account in relation to the establishment of all management procedures and training programmes.

In terms of consumers' awareness, the programme has to pay special attention to the gender dimension taking into account distinct gender habits in relation to food consumption, participation in shopping practices and cooking. The importance of food health conditions and healthy food for vulnerable people, such as disabled and elderly, is obvious.

6.2 Environment

Care of the environment is a major issue with regard food safety and – potentially – the development of food safety systems may have a significant negative environmental impact if production and processing systems are designed without considering the environmental aspects. This applies particularly to the disposal of animal, plant and food waste. Additionally food packing materials are a very significant source of environmentally unfriendly waste in developing and developed countries.

As measures to protect the environment may carry an additional financial cost, it is important that environmental impact is assessed and considered while drafting the food safety legislation. Overseeing this task will be the responsibility of the national authorities involved in the project and will be supervised by the Contracting Authority.

6.3 Minorities

The programme will be sensitive to minority issues and will ensure access of all ethnic groups to resources and services. One aspect to tackle this issue is to ensure information on food safety standards in the own language of the key minority groups. Another aspect concerns the respect to minority and human rights while drafting legislation, which should ensure equal protection of consumers independently of their culture, history, language and religion.

ANNEXES

- 1 - Logical framework matrix in standard format
- 2 - Amounts contracted and disbursed per quarter over the full duration of the programme
- 3 - Description of Institutional Framework
- 4 - Reference to laws, regulations and strategic documents
- 5 - Details per EU funded contract

ANNEX 1: Logical framework matrix in standard format

LOGFRAME PLANNING MATRIX for Project Fiche		Programme name and number:	Development of the Food Safety Services in Montenegro
Development of the Food Safety Services in Montenegro		Contracting period expires: 2 years from signing Financing Agreement	Disbursement period expires: 1 year after the final date for execution of the contracts
		Total budget : €2.166 million	IPA budget: €2 million
Overall objective	Objectively verifiable indicators	Sources of Verification	
Improved protection of consumers and ensured food safety according to the EU	<ul style="list-style-type: none"> • Reduced (by 50%) of the frequency of food safety incidents, particularly those caused by enterocolitis accuta, bacteria toxinfecio alimentarius and salmonellas, by 2015; • Acquis Chapter on food safety closed by 2015 	Government monitoring reports EU Progress Reports RASFF alerts Monstat Reports	
Project purpose	Objectively verifiable indicators	Sources of Verification	Assumptions
Strengthening of the food safety system in Montenegro in line with the EU standards	<ul style="list-style-type: none"> • Increasing number of complying samples, by food product and hazard; • Decreasing number of non-complying samples, by food product and hazard; • Decreasing number of establishments with infringements; • Decreasing in withdrawals (in volume) from the supply chain, by food product and by reason; • Decreasing number of penalties, by monitored hazard 	MHLWS and MAFWM reports	<ul style="list-style-type: none"> • Motivation and ability (access to funding, to qualified consultants, etc.) of the food-related business to introduce the necessary food safety systems compliant with the EU standards; • Permanent solution found for treatment of animal by-products • Support laboratories are accredited with an internationally accredited authority. • Permanent solution is found to ensure any type of testing necessary. • Raised consumers' awareness on food safety issues and more demanding behaviour. • Water and other pollution kept at the same level

Results	Objectively verifiable indicators	Sources of Verification	Assumptions
<ol style="list-style-type: none"> 1. Legislation compliant with the EU acquis on food safety is in place; 2. Enhanced capacity of the food safety-related authorities; 3. Capacity of the food safety laboratories enhanced; 4. Built up capacity of the NCAFS 5. An integrated automated system for food safety created. 	<ul style="list-style-type: none"> • Completed secondary legislation (80% of the specified in the NPI of Montenegro implementation rules adopted); • Decreased gap between the legislation of Montenegro and the EU acquis regarding food safety, certified by the EU progress report. • Increase in the number and frequency of the control checks (by at least 30%) along with decreased individual time for each inspection (by 30%); • Increase in the number of samples analysed by products (by 20%); • Increase in the number of establishments visited (by 20%) • Increased number of persons involved in official control and monitoring activities • Increase in the number of detected and reported irregularities concerning food safety (by 15%). • Increase in the number and variety of analysis related to food safety (by 20%); • Decreased time and cost for specific analysis concerning food safety (by 10%) • Number of reports, opinions and advises issued; • Number of claims evaluated; • Established system for internal review of the operations. • Decreased time and cost for information exchange on food safety-related issues; 	<p>MHLSW and MAFWM reports Project reports EU monitoring reports</p>	<ul style="list-style-type: none"> • Continuous commitment of decision-makers for ensuring full operation of the food safety system indicated by the provision of required resources and adoption of the needed legislation; • Strong inter-institutional coordination and commitment to exchange information related to food safety; • Food operators are motivated and able to support the improvement of the food safety systems.

Activities	Means	Costs	Assumptions
<p><i>1. Approximation of the Legislation</i></p> <ul style="list-style-type: none"> • Analysis of the current state of play (Table of correspondence); • Assessment of the priorities regarding implementation regulations; • Preparation of a team of national legislation drafting experts; • Drafting of legislative proposals and implementation rules; • Raising the awareness of the key stakeholders on food safety. <p><i>2. Building the capacity of the bodies responsible for food safety</i></p> <ul style="list-style-type: none"> • Assessment of the precise needs; • Preparation of training programmes and training; • Elaboration of appropriate guidelines, instructions and QM procedures; • Upgrading of the inspections and control programmes and plans • Upgrading of the contingency plans and simulation exercise for their testing. <p><i>3. Building the capacity of the reference laboratories:</i></p> <ul style="list-style-type: none"> • assessment of the needs; • Preparation of technical specification for the equipment needed; • Supply of the equipment and training of the end users; • Training on effective sampling and testing methods; • Evaluation of the impact of the equipment on the food safety system. <p><i>4. Building the administrative capacity of the National Council for the Assessment of Food Safety (NCAFS)</i></p> <ul style="list-style-type: none"> • Training, consultancy and on-going support • Drafting of the operational rules and procedures; • Provision of support for initiating and managing public consultations.; • Proposal for further separation of the risk management and risk assessment <p><i>5. Creation of integrated automated data system</i></p> <ul style="list-style-type: none"> • Assessment of the existing IT capacities; • Design and establishment of a comprehensive IT system 	<p>Contract 1 – service contract (1.25 M€) - to cover approximation of legislation, training, consulting, assessment of the needs, preparation of technical specification and evaluation of the capacity after equipping. This contract is implemented with EU funds and managed by the EC Delegation.</p> <p>Contract 2 - supply (0.75 M€) - for purchasing of equipment for ensuring food safety control and monitoring. This contract is implemented with EU funds and managed by the EC Delegation.</p> <p>Contract 3 - supply (0.166 M€) - will cover the purchase of the equipment for food safety-related testing. It will be tendered and managed by the Montenegrin authorities.</p>	<p>Total: 2.166.000 EUR EU Funds: 2 M EUR National Funding: 0.166 MEUR</p>	<ul style="list-style-type: none"> • Laboratories designated with specific roles for food safety (legislative regulation) in order to avoid duplication of efforts and efficient use of scarce resources; • Public and private operators supply the necessary data into the data network.

ANNEX 2: Indicative amounts (in €) contracted and disbursed by quarter over the full duration of the programme

Contracted	Q4 2009	Q1 2010	Q2 2010	Q3 2010	Q4 2010	Q1 2011	Q2 2011	Q3 2011
Contract 1	1,250,000							
Contract 2				750,000				
Cumulated	1,250,000	0	0	2,000,000	0	0	0	0
Disbursed	Q4 2009	Q1 2010	Q2 2010	Q3 2010	Q4 2010	Q1 2011	Q2 2011	Q3 2011
Contract 1	375,000		375,000			375,000		125,000
Contract 2				450,000	300,000			
Cumulated	375,000	0	750,000	1,200,000	1,500,000	1,875,000	0	2,000,000

Contracts 1 (service) and 2 (supply) will be funded by the EU budget and will be tendered and managed by the EC Delegation to Montenegro.

Contract 3 (supply) will be tendered, managed and funded by the national authorities of Montenegro.

ANNEX 3: DESCRIPTION OF INSTITUTIONAL FRAMEWORK

The law on Food Safety confers the responsibility for the food safety in Montenegro to the following institutions:

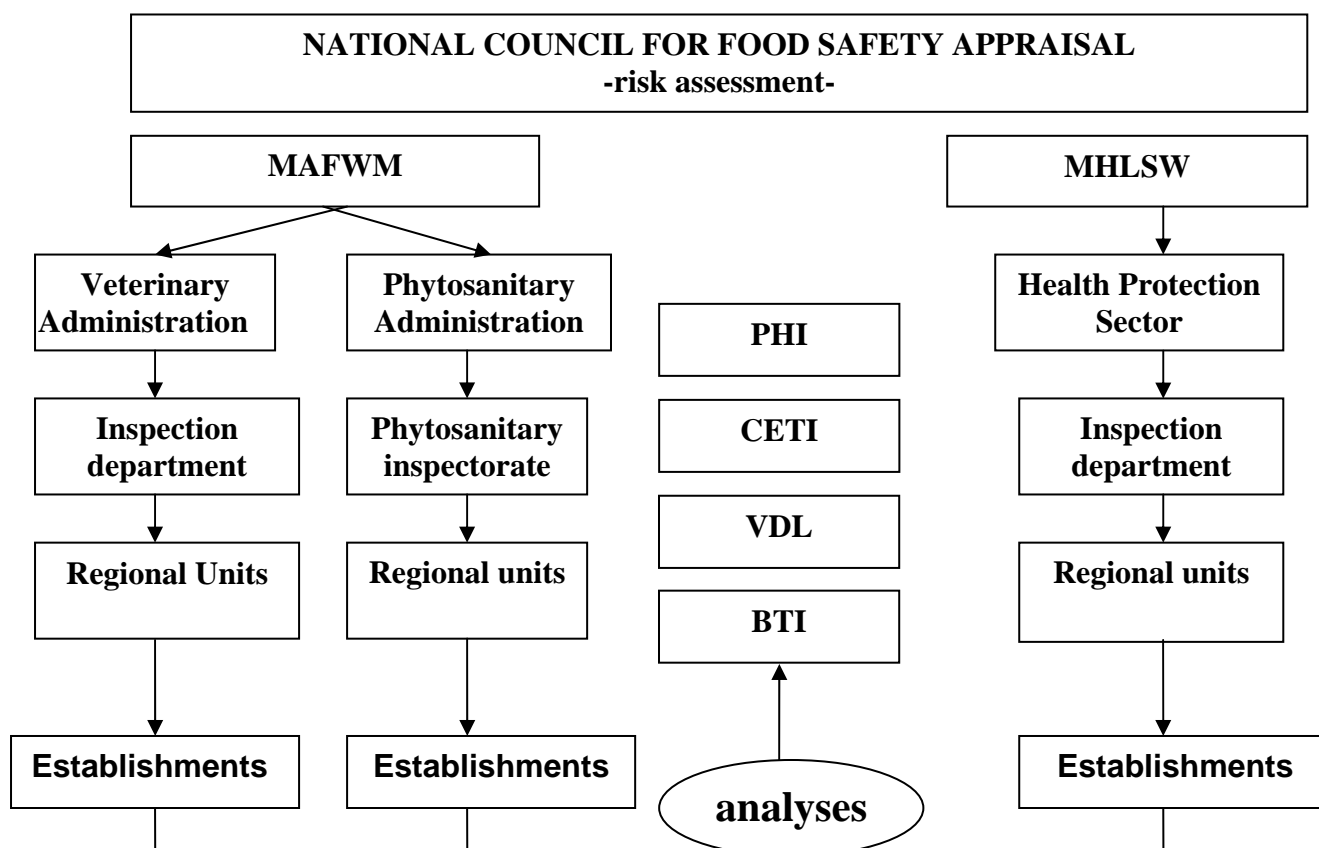
- **The Ministry of Agriculture** approves the regulations governing the safety of vegetable food at the level of primary production, as well as of the food of animal origin, composite food and animal feed. It cooperates with international organizations and competent authorities dealing with the food safety in other countries.

The jobs involving safety of vegetable food at the level of primary production are carried out by the **public authority responsible for phyto-sanitary matters**.

Veterinary Administration performs the duties required for the safety of food of animal origin, composite food and animal feed in the production process, international trade activities, wholesale and retail sale of meat, fish and other aquatic animal and plant products.

- **The Ministry of Health, Labour and Social Welfare** approves the regulations and carry out the tasks relevant for the area of vegetable food safety after the primary production stage, as well as of composite food and other food in the production process, international trade, wholesale and retail sale and of the separately declared packed food of animal origin and composite food in retail trade.

The holders of administrative tasks and inspection controls are the Sector of Health Protection, the composition of which includes the Department of Health and Sanitary Inspection and its Territorial Units of Health and Sanitary Inspection.



MAFWM – Ministry of Agriculture, Forestry and Water Management

MHLSW – Ministry of Health, Labour and Social Welfare

VU - Veterinary Administration

PA- Phytosanitary Administration

NC – National Council for Food Safety Appraisal

BTI – Biotechnical Institute

VDL – Veterinary Diagnostic Laboratory

CETI – Centre for Ecotoxicological Researches

IPH – Institute for Public Health

ANNEX 4: Reference to laws, regulations and strategic documents

4.1 EU legislation

Main legislation in the field of food safety and veterinary medicinal products

Foodstuffs

Dir.89/108/EEC	Quick frozen Food
Dir. 89/396/EEC	Marking of Food- lots
Dir. 86/363/EEC	Residues (pesticides) in Food of animal origin
Dir. 86/363/EEC	Residues (pesticides) in Food of animal origin
Dir. 90/642/EEC	Residues of pesticides in Food of plant origin
Dir. 92/59/EEC	General product safety
Dir. 94/36/EEC	Colours in Food
Reg. 3954/87 944/89	Max. level of radioactive contamination
Reg. 737/90	TC Agricultural-product imports following Chernobyl
Reg. 2081/92	FS with protected geographical indications & designations of origin
Reg. 2082/92	FS with specific character
Reg. 2232/96	Flavouring substances
Reg. 466/2001	Contaminates in food
Reg. 258/97	Novel foods
Dir. 2000/13/EC	Labelling Food
Dir. 2002/63/EC	Methods of sampling for the official control pesticide residues in and on products of plant and animal origin
Dir. 2002/99/EC	Health rules governing the production, processing, distribution and introduction of products of animal origin for human consumption
Reg.178/2002	Establishing the European Food Safety Authority and laying down procedures in matters of food safety
Reg. 1829/2003	Labelling GMO derived food
Reg. 852/2004	Hygiene of Foodstuffs-general rules

Health protection & disease control

Dec. 93/140/EEC	Parasites in fishery products -PH
Dir. 95/70/EC	Molluscs diseases - AH-PH
Dir. 98/83/EC	Water directive - I/C-PH
Dec. 1999/879/EC	B.S.T. - PH
Dir. 88/409/EEC	Meat hygiene and Inspection fees -PH
Dir. 91/271/EEC	Urban waste water - AH-PH
Dir. 96/22/EC	Prohibition of Thyreostatics, cert. hormones and β -Agonists - PH
Dir. 96/23/EC	Control of Residues in live animals and products - PH
Reg. 999/2001	TSE – prevention, control & eradication

Reg. 2160/2003 Salmonella & food borne zoonoses control

Dir. 2003/99/EC Monitoring zoonoses

Trade in products

Reg. 1907/90 Marketing standards for eggs

Dir. 91/67/EEC Aquaculture products - P/M-T/C-AH-PH

Reg. 2991/94 Spreadable fats

Reg. 2406/96 Marketing standards for fishery products

Reg. 2772/1999 Beef labelling system

Dir 2001/110/EC Honey

Reg 1774/2002 Animal by-products - PM -AH-PH

Dir. 2002/99/EC Health rules governing the production, processing, distribution and introduction of products of animal origin for human consumption

Dir. 2004/41/EC Repealing rules on products of animal origin

Dir. 2004/68/EC Import & transit of certain ungulates

Reg. 852/2004 Hygiene of Foodstuffs-general rules

Reg. 853/2004 Hygiene of Foodstuffs- specific rules

Reg. 854/2004 Specific rules on official controls on products of animal origin

Measures on veterinary pharmaceuticals and related areas

65/65/EEC Council Directive of 26 January 1965 on the approximation of provisions laid down by law, Regulation or administrative action relating to medicinal products, as amended

75/320/EEC Council Decision of 20 May 1975 setting up a pharmaceutical committee

78/25/EEC Council Directive of 12 December 1977 on the approximation of the laws of the Member States relating to the colouring matters which may be added to medicinal products

81/851/EEC Council Directive of 28 September 1981 on the approximation of the laws of the Member States relating to veterinary medicinal products

81/852/EEC Council Directive of 28 September 1981 on the approximation of the laws of the Member States relating to analytical, pharmacotoxicological and clinical standards and Protocols in respect of the testing of veterinary medicinal products

88/320/EEC Council Directive of 7 June 1988 on the inspection and verification of Good Laboratory Practice (GLP)

90/167/EEC Council Directive of 26 March 1990 laying down the conditions governing the preparation, placing on the market and use of medicated feeding stuffs in the Community

90/219/EEC Council Directive of 23 April 1990 on the contained use of genetically modified micro-organisms

90/220/EEC Council Directive of 23 April 1990 on the deliberate release into the environment of genetically modified organisms

90/2377/EEC	Council Regulation (EEC) No 2377/90 of 26 June 1990 laying down a Community procedure for the establishment of maximum residue limits of veterinary medicinal products in foodstuffs of animal origin
90/676/EEC	Council Directive of 13 December 1990 amending Directive 81/851/EEC on the approximation of the laws of the Member States relating to veterinary medicinal products
90/677/EEC	Council Directive Of 13 December 1990 Extending the scope of Directive 81/851/EEC on the approximation of the laws of the Member States relating to veterinary medicinal products and laying down additional provisions for immunological veterinary medicinal products
91/412/EEC	Commission Directive of 23 July 1991 laying down the principles and guidelines of good manufacturing practice for veterinary medicinal products
92/74/EEC	Council Directive of 22 September 1992 widening the scope of Directive 81/851/EEC on the approximation of provisions laid down by law, regulation or administrative action relating to veterinary medicinal products and laying down additional provisions on homeopathic veterinary medicinal products
93/41/EEC	Council Directive of 14 June 1993 repealing Directive 87/22/EEC on the approximation of national measures relating to the placing on the market of high-technology medicinal products, particularly those derived from biotechnology
93/2309/EEC	Council Regulation (EC) of 22 July 1993 laying down Community procedures for the authorization and supervision of medicinal products for human and veterinary use and establishing a European Agency for the Evaluation of medicinal Products
95/297/EC	Council Regulation (EC) of 10 February 1995 on fees payable to the European Agency for the Evaluation of Medicinal Products
95/540/EC	Commission Regulation (EC) of 10 March 1995 laying down the arrangements for reporting suspected unexpected adverse reactions which are not serious, whether arising in the Community or in a third country, to medicinal products for human or veterinary use authorized in accordance with the provisions of Council Regulation (EEC) No 2309/93
95/541/EC	Commission Regulation of 10 March 1995 concerning the examination of variations to the terms of a marketing authorization granted by a competent authority of a Member State
95/542/EC	Commission Regulation (EC) of 10 March 1995 concerning the examination of variations to the terms of a marketing authorization falling within the scope of Council Regulation (EEC) No 2309/93
95/1662/EC	Commission Regulation (EC) of 7 July 1995 laying down certain detailed arrangements for implementing the Community decision-making procedures in respect of marketing authorizations for products for human or veterinary use
96/2141/EC	Commission Regulation (EC) of 7 November 1996 concerning the examination of an application for the transfer of a marketing

authorization for a medicinal product falling within the scope of Council Regulation (EC) No 2309/93

1999/879/EC Council Decision of 17 December 1999 concerning the placing on the market and administration of bovine somatotrophin (BST) and repealing Decision 90/218/EEC

Feeding stuffs

Dir. 70/524/EEC, 2002/C/329/01	Additives in FS
Dir. 2002/32/EC	Undesirable subst. in animal nutrition
Dir. 79/373/EEC	Compound FS
Dir. 82/471/CEE	Certain products in FS
Dir. 93/113/EEC	Enzymes, micro-organisms in FS
Dir. 95/69/EC	Approval of FS plants
Dir. 96/25/EC	Straight FS
Reg. 1829/2003	GMO Food & Feed
Reg. 1831/2003	Sampling and Analysis of FS
Dir. 70/373/EEC (repealed on 1.1.2006)	Additives in FS
Dir. 70/524/EEC, 2002/C/329/01	Undesirable subst. in animal nutrition
Dir. 2002/32/EC	Compound FS

4.2 Montenegrin Legislation transposed to match the Equivalent EU Legislation

- Law on plant protection (Sl. List RCG br. 28/2006). in accordance with celex No. 32000L0029)
- Law on wine (Sl. List RCG br. 36/07) (Celex No. 31999R1493) and (Celex No. 32002R753).
- Law on organic agriculture (Sl. List RCG br. 49/04) in accordance with (Celex No. 31991R2092 i Celex No. 32007R0834)
- Law on geographical origin (Sl. List SCG br. 20/06)
- Law on Animal Identification (Sl. List RCG br. 48/07), in accordance with (Celex No. 32000R1760, 32004R0021, 32004R0911, 32003R1082),(Celex No. 31992L0102, 31996L0093) (Celex No. 32001D0672).
- Food safety law (Sl. List CG br.14/07) (Celex No. 32002R0178) (Celex No. 32005R0183, 32004R0852, 32004R0853, 32004R0854, 32004R0882, 31998L0083).
- Law on veterinary (Sl. List RCG br. 11/ 04 and 27/07).
- Animal welfare law (Sl. List CG br.14/08)

4.3 Key extracts from the Government of Montenegro Food Safety Strategy, March 2006

Assuring the safety and quality of food and proper nutrition represents one important issue which is related to the protection and improvement of the public health.

Supply of safe and pure food which protects and improves health represents the basic right of every individual.

Safe food represents not only the food of certain texture, but food which does not consist microbiological, physical, chemical, radiological or any other contaminants.

Contamination is possible at all stages of the food chain from primary producer through consumer: animal diseases, environment pollution, inadequate primary production practices, improper agricultural practices, improper hygienic handling of food, inadequate storage conditions, transport, improper technological procedures and etc.

Any of the above stated hazards may occur at a variety of points in the food chain and cause long term or short term illness. Due to many potential food hazards, an integrated holistic approach, which includes control of all risks involved at all stages of the food chain from raw material to food consumption, is generally accepted.

The food safety must be introduced at national and international level, taking into consideration the international food trade and liberalization of food trade.

Beside many economic benefits for consumers – wider variety of accessible and affordable food, distribution over far distances, sale of authentic products, global food trade has placed considerable obligations on all countries, considering occurrence of any potential hazards in food which may cause harm to public health. The occasional incidents in the last decade, such as (“mad cow disease”, dioxine contaminated fodder) when contamination from a single source has found its way onto every continent causing the diseases, have raised anxiety among consumers. The serious threat at global level is new zoonoses called Avian Influenza which can be also transmitted by unsafe food.

The introduction of new technologies, including genetic engineering and the development of modern technological procedures, increases a demand for monitoring and caution measures related to a still unknown health effects.

Changed nutrition habits and urban lifestyle, more complex requirements for raw and final foodstuffs considering their production, storage, transport and distribution, development of collective nutrition, vulnerable groups of population, increased number of elderly and persons with weak immunity, request new approach toward food and nutrition.

On the other hand, health problems related to foodborne diseases and improper nutrition are growing and represent serious problem in our country and in the world. The consumption of sanitary unsafe food leads to outbreaks of food contamination with short or long term impact on health. Foodborne diseases are related indirectly or directly with the disease groups which are identified as a major causes of death – diseases of cardiovascular system, diabetes and other.

Improper nutrition, insufficient or excessive calorie intake and lack of vitamins represent growing concern in our country. Foodborne diseases outbreaks appear also more or less in our country. Recognising timely the growing incidence of foodborne diseases, as a very important issue, WHO has set activities to be carried out for improvement of the food safety system as a priority, in order to minimize the foodborne diseases. WHO has established the global strategy in the year 2001, which provides support to the activities of the State Members.

Ministry of Health has established according to WHO objectives, National Committee for Food Safety acting as an expert advisory body with the representatives of all competent bodies and institutions, as well as dominant experts in this area. In addition to this document, above stated Committee has drafted in the year 2005, document called "Country Profile" which presents detailed current situation in the area of the food safety in Montenegro.

Basic Strategy objective for the food safety and nutrition is protection and improvement of public health by minimizing health and social difficulties which have appeared as a consequence of the foodborne diseases.

Protection of health and improvement of the life quality is a major goal of the Government of Montenegro.

In accordance with it, the task of the Ministry of Health, Ministry of Agriculture and Water Management and other relevant institutions is to determine all activities and measures that improve food safety system and reduce the risk of foodborne diseases.

The improvement of the food safety system and proper nutrition with adequate food legislation which conforms to European and international standards, is the basic and essential part of this Strategy, drafted by the Ministry of Health and Ministry of Agriculture and Water Management together with the expert assistance from the other relevant institutions according to the Program of the Government of Montenegro for the year 2006.

The incidence of the foodborne diseases should be minimized according to the following activities:

- defining and development of integrated, holistic and sustainable food safety system and building capacities
- implementation of GHP, GMP i HACCP-a measures along the entire »food chain«, from primary producer to consumption in order to prevent consumer exposure to unacceptable risk levels
- scientific based assessment, management and risk communication
- mutual cooperation with all subjects involved in the food chain,
- raising the awareness about the importance of the food safety and sanitary measures,
- epidemiological surveys related to the foodborne diseases

Building capacities of the effective food safety national system is an important goal because this system plays an important role in preparation and training of the countries which have to enter international trade trends. Countries are obliged to produce and provide safe and wholesome food and to ensure in the same time that the imported food conforms to their national requirements.

In accordance with the Directive 178/2002/EC of the European Council and Parliament of the date 28.01.2002, institutional solutions have been envisaged, that is, the establishment of National body, which integrates and coordinates all parts of the food safety system. This body should officially communicate with the European Commission and with other international bodies, organisations and agencies and would carry out important activities related to the public health protection, animal and plant protection and environmental protection.

According to Action Plan for European partnership, and Working Program of the Government of Montenegro, the draft of Law on Food Safety is envisaged. This Law has to set general rules and requirements related to hygiene, sanitary food safety, animal's fodder and the

obligations of subjects dealing with food in the view of hygiene and sanitary food safety. The draft of this Law has to conform to the legal EU achievements and to represent a framework for further harmonization with other EU legislation.

Analysis of the current condition

In the food safety area, regulations which are enacted at the Republic level are applied as well as previous Federal regulations. When the authority had changed from the Federal to the Republic level, during the period of 1998 -2000, Montenegro took over the complete control of foodstuffs in regard to the export / import foreign trade – food control.

Since Constitutional Chart has been set, all legal regulations as well as application of all regulations in the food safety area are in charge of the Government of Montenegro. The Standardization Law, the Law on Technical requirements for products and assessment of product compliance with the prescribed requirements, The Law on Accreditation and Quality Regulations are exceptions which according to Constitutional Chart of the State Community S&M are passed by the Ministry for Internal Economic Relation.

A great number of laws are applied in the food safety area, Codes of practice, Regulations, Directives, Guidelines and other regulations and general acts, which are set at republic and federal level and are as follows:

- The Law on inspection surveillance «Official Gazette of Montenegro, no. 39/03 – General Law for all inspections
- Law on Sanitary correctness of foodstuffs and Goods of General Use, Official Gazette of FRY, no. 53/91;
- Veterinary Law «Official Gazette of Montenegro, no. 11/04 (which was harmonised with the EU standards when passed)
- Law on Sanitary Surveillance of Foodstuffs and Goods of General Use, Official Gazette, no. 26/73, 4/88;
- Law on Sanitary Inspection « Official Gazette of Montenegro», no. 56/92;
- Law on Health Protection «Official Gazette of Montenegro», no. 39/04;
- Law on Health Protection of the population from the communicable diseases, Official Gazette of Montenegro, no. 32/05, harmonized with recommendations and WHO programs;
- Law on medical means, «Official Gazette of Montenegro» No.79/04;
- Law on drugs «Official Gazette of Montenegro» No.80/04;
- Law on market inspection «Official Gazette of Montenegro», No. 56/92;
- Law on quality control of agricultural products and foodstuffs in the foreign trade «Official Gazette of FRY» 12/95, 28/96;
- Law on Standardization«Official Gazette of Montenegro», No.44/05;
- Law on technical requirements for products and Conformity Assessment of these products with these requirements, «Official Gazette of Montenegro» No. 44/05;
- Law on Accreditation «Official Gazette of Montenegro» No. 44/05;
- Law on Waters «Official Gazette of Montenegro» No. 16/95;
- Law on Plant Protection «Official Gazette of FRY» No. 24/98, 26/98;
- Law on Plant Protection from diseases and pests «Official Gazette of Montenegro» No. 4/92, 59/92, 27/94;
- Law on Agricultural land «Official Gazette of Montenegro» 15/92, 59/92, 4/93;
- Law on Measures to promote Cattle-raising «Official Gazette of Montenegro» No. 4/92;
- Law on Protection of Agricultural and Forest Plants species «Official Gazette of FRY». 28/00;
- Law on seed and reproductive material, «Official Gazette of Montenegro» No. 39/92, 59/92;

- Law on Sea Fishing «Official Gazette of Montenegro» No. 55/03;
- Law on Fresh Water Fishery «Official Gazette of Montenegro» 39/76, 51/76, 34/88, 4/92;
- Law on Olive grove «Official Gazette of Montenegro» No. 55/03;
- Law on Wine and grapes and wine products «Official Gazette of Montenegro» No. 9/83, 15/83, 27/94;
- Law on Organic Agriculture, «Official Gazette of FRY» No. 28/00;
- Law on Genetically modified organisms «Official Gazette of FRY», No. 21/01;
- Law on Protection from the Ionizing Radiation, «Official Gazette of FRY» No. 46/96

Strategic activities

Existing legislative framework of the food safety system represents a legal inheritance from the previous period, when regulations were based on traditional approach which lacked preventive measures and responsibilities of producer. The surveillance and responsibilities were directed towards inspection services and to final product.

In accordance with the objectives of the Government of Montenegro to make all necessary efforts in order to realize free trade in the South Eastern Europe and to enter WTO membership, establishment of legislative infrastructure is one of the most important elements of the system which have to be harmonised with the EU system and international standards.

Strategic priority is establishment of the new legislative framework which will regulate all the aspects of the food safety system. Providing the conditions for holistic and integrated approach in order to set obligations, responsibilities, and the rights of all participants involved in the food and nutrition chain, should be the characteristic of this legislative framework. The draft of new regulations should include aspects related to the high level of health protection, clear definitions to strengthen the consistency and legal security, harmonisation with the EU standards and international standards as well as its updating, activities based on the scientific and transparent facts necessary for the risk assessment, and risk management, traceability of the food products, clear provisions which determine the responsibility of participants in the food chain, provisions which determine obligatory offer of the safe food products in the market place.

Apart from addressing all aspects of the food safety sector, it is necessary that new legal framework clearly define obligations, authorisations and responsibilities of official bodies involved in the food safety system.

In order to become rapidly integrated into global trends of the food production and trade, it is necessary that new law regulation is harmonised with the EU regulations and with the other international contracts as follows:

- Regulation 178/2002/ of the European Parliament which defines the general terms and conditions of the food, establishes National Body for the food safety and sets procedures related to the food safety;
- Regulation 851/2004 which regulates foundation of the European Centre for disease prevention and control, including also foodborne diseases;
- Regulation 852/2004 which relates to food hygiene;
- Regulation 853/2004 which determines specific hygienic rules and food hygiene;
- Regulation 854/2004 which determines specific control of the products of animal origin intended for nutrition;
- Regulation 882/2004, which refers to official controls carried out to ensure the compliance with the Law on Food, fodder, and rules for animal welfare;
- Regulation 258/97 which determines introduction of new food and new food ingredients;

- Decision 2119/98/ES of the European Parliament and Council of epidemiological surveillance of communicable diseases, with the accompanying Decisions of the European Commission 2000/57/ES, 2000/96/ES, 2002/253/ES, 2003/534/ES which regulate the surveillance of communicable diseases including also foodborne disease;
- Decision of the Commission 613/2004/EU, which refers to establishment of Advisory body for the food chain and animal and plant health;
- Directive 89/397/EES which refers to the inspection of food;
- Directive 93/99/ESS which refers to the additional measurements for food inspection;
- Directive 80/778/EEC (5) and 98/83/EC (6), which refers to the quality of drinking water;
- Directive 96/23/EC and Commission Decision 97/747, 2002/657, which refers to the monitoring of residues;
- Directive 79/700/EEC which refers to the sample testing methods of fruits and vegetables on pesticides residues;
- Directive 86/362/EEC which refers to the level of pesticide residues in cereals;
- Directive 86/363/EEC which refers to the level of pesticides in the foodstuffs of animal origin;
- Guideline 99/2002/EU which determines requirements for health protection of animals intended for production, processing, distribution and trade of products of animal origin used for nutrition;
- International Health Practice;
- Contract on foundation of the European Union;
- Codex Alimentarius Standards;
- Agreement on Sanitary and Phytosanitary measures WTO, OIE, and also WHO and FAO standards.
- Directive 89/398/EC on diet food;
- Directive 91/321/EEC which refers to infant's formula;
- Directive 96/5/EEC which refers to the production of baby's food.

4.4. Reference to the National Programme of Montenegro for Integration to EU

Chapter 3.12. Food Safety, Veterinary And Phytosanitary Policies

Section 3.12.1. Food safety

3.12.1.2. Short-term priorities

The transposition of a series of the EU regulations relevant to the food safety has been planned to be completed during 2008 – 2009, from so called “Hygiene Package”. It is important to assess the current situation as regards the production establishments and methods of production, as well as the technical and hygiene requirements for the production of food, with special focus on the food production establishments that apply the traditional methods of producing, as well as on the establishments of smaller capacities and the ones in specific geographical regions, in order to find out the weaknesses and to define the measures for meeting the EU requirements.

Direct sales of products of animal origin produced on the farms - such as soft and semi-hard cheese, cream (kajmak), honey, eggs and alike - prevail in Montenegro (in green markets, smaller retail sale shops or tourist establishments), whereas there is not any complete listing of those farms; therefore, it is necessary to undertake steps in order to develop the register of the farms. The already existing electronic database of the registered cattle/ farms, that is stored in the Veterinary Administration, is a good basis for gathering and systematizing the necessary information.

It is required to make a comparative analysis of the national legislation to the Regulation (EC) (Celex 32004R0882) for the purpose of the full adjustment of official veterinary controls, as well to create the conditions for approving and implementing the Rule Book on the By-Product of Animal Origin Management to the Regulation (EC) (Celex 32002R1774).

Legislative Framework

It is required also to make an in-depth analysis of the current national legislation (correspondent tables) for the purpose of adjusting to the *Acquis*. The Regulation passed by the Government of Montenegro shall govern the separation of competencies among the public authorities and the classification of the composite food. In order to meet the requirements prescribed under the Law on Food Safety and the Rule Book on Hygiene and Technical Requirements to be Met by Establishments for Producing Food of Animal Origin (expected in 2008), it should make the assessment of the current situation for the purposes of developing both the Programme of Monitoring the Food Production Establishments and the Schedule of Monitoring the Activities of the Entities Engaged in Food and Feed Related Activities (as per their activities). Within the framework of the implementation of the said Programme, it is required to make the entities engaged in food and feed related activities informed of the new requirements and encouraged to meet the EU requirements, so as to enable them to pursue the necessary preparatory activities on timely basis and to adjust their businesses until the accession date. This implies monitoring of the progress reached by the relevant authorities in the areas of: introduction of HACCP, DHP, DPP; introduction of documents on, i.e. information of the animal for slaughtering; food chain; traceability; labelling of product by new labels; as well as of the categorizing the establishments as per the assessment of the requirements fulfilment, and developing the programme of registering the establishments engaged in food related businesses.

Rule Book on Hygiene and Technical Requirements to be Met by Small Establishments for Food Producing via Applying Traditional Methods prescribes the direct communication with the EC as regards the anticipated discrepancies and to define, thereon, the opportunities for the permitted derogations from the *Acquis* in the area.

The Law on Food Safety confers the responsibility for the food related businesses on the entities that are engaged in food and feed businesses, which conditions the new method of doing controls. Special attention should be paid to the requirement for conformity of the control system intended for mussels growing (in harmony with the Strategy of Fishery Sector Development), as well as to the financial needs as regards monitoring the plankton, biotoxin and hard metal and alike.

It has been planned to introduce the following:

- Rule Book on Measures that are Applied to the Import of Goods for Personal Consumption
- Rule Book on Hygiene and Technical Requirements to be Met by Establishments for Producing Food of Animal Origin
- Rule Book on Hygiene and Technical Requirements to be Met by Small Establishments for Food Producing via Applying Traditional Methods
- Rule Book on the Requirements for Primary Production
- Rule Book on the Veterinary Control of Food of Animal Origin
- Rule Book on the Control and Monitoring of Salmonella
- Rule Book on the Monitoring of Zoonosis

- Rule Book on Fish Parasites, Bitoxine, Ca in MOM
- Rule Book on the Method of Border Controls of Imported Live Animal Consignments
- Rule Book on the Method of Border Controls of Imported Consignments of Products of Animal Origin
- Rule Book on the method of Border Controls of Imported Animal Feed Consignments
- Rule Book on Decreasing the Frequency in Controls of the Imported Consignments
- Rule Book on the Method of Veterinary Checks in Free Zones
- Rule Book on the Veterinary Requirements that Must be Met by Consignments in Free Zones
- Rule Book on BIPs
- Rule Book on the Requirements to be Met by Establishments for Breeding and Raising Animals for Food Production, and the requirements for the Protection of Animals on Farms
- Rule Book on the Model and Method of Issuing Veterinary Certificates for Animals and Products of Animal Origin
- Rule Book on the Health Status of Animals that are Raised for the Production of Food of Animal Origin for Human Consumption
- Rule Book on MRLs of Veterinary Medicines in the Food of Animal Origin
- Rule Book on the Health Status and Other Requirements for Other Food of Animal Origin – guts, rendered fat, blood...
- Rule Book on Microbiological Criteria for the Food of Animal Origin
- Drafting the Programme of Control of and Monitoring the Pesticide, Hard Metals, Microbiological Pollutants and Similar Residues in the Food of Animal Origin
- Programme of Recording the Entities Engaged in Food of Animal Origin Related Businesses.

The Ministry of Health, Labour and Social Welfare is planning to draft and approve the following secondary legislation:

- Regulation on the Hygiene and Technical Requirements for the Vegetable Food After Primary Production, as well as for Composite and Other Food
- Regulation on the Method of Controlling the Vegetable Food After Primary Production, as well as the Composite and Other Food
- Drafting the Programme of Controlling and Monitoring the Pesticide, Hard Metal, Microbiological Pollutant, Additive and Similar Residues in the Vegetable Food After Primary Production, as well as in Composite and Other Food
- Drafting the Programme of Recording the Entities Engaged in Vegetable Food Related Businesses after Primary Production, as well as in Composite and Other Food
- Regulation on the Microbiological Criteria for Food.

It has been planned to draft the Law on Health and Sanitary Inspection. The said Law will be the basis for approving a portion of regulations to be adjusted to the EU legislation.

In addition to other things, the Law shall regulate the organization of the work of health and sanitary inspections, in relation to the Law on Food Safety.

Institutional Framework

The Department of Food Safety should be established in the Sector of Health Protection within the Ministry of Health, Labour and Social Welfare, and the human resources should be recruited therefore, in harmony with the obligations arising from the Law on Food Safety.

It is required to anticipate necessary equipment and information support to the work of sanitary inspectors, as well as further specialization and training of inspectors and other professional staff in the area of transposing and implementing the EU legislation, via trainings, workshops and study visits.

Drafting the manuals or instructions and the continuation of trainings for sanitary inspectors in the control of the HACCP procedure, good production and hygiene practices and application of the SSOP procedure have been planned.

Strengthening the capacity of the Public Health Institute, including laboratories, accreditation, equipping and specialization of laborants.

As for the Veterinary Administration, it is required to establish organizational units within the Veterinary Sector in harmony with the short-term priorities stated under Chapter 3.12.2 Veterinary Policy.

As for the education and specialization, professional qualification and specialization of civil servants employed with the Veterinary Administration should be continued, as well as the training of veterinary inspectors in the control of HACCP and carrying out the internal and border controls.

Equipping of and adjusting the laboratory to the activities of the control of TSE; decision making and approval of the number and equipping of veterinary inspection border points (BIPs) and drafting instructions for the persons in charge of the control.

3.12.1.3. Mid-term priorities

It has been planned to make a preliminary evaluation of the effectiveness of the organizational structure of the food safety system with the aim to identify possible weaknesses of the system and to propose the measures for their elimination.

Legislative Framework

It is required to make comparative analyses of the Decision on the Amount of Remuneration for the Veterinary and Sanitary Checks in the Trade Across the Republic of Montenegro Border (Official Gazette of RM, No. 50/05) and of the Decision on the Amount of Remuneration for the Veterinary and Sanitary Checks in the Internal Trade (Official Gazette of RM, No. 55/07) to the Regulation (EC)

(Celex 32004R0882), while with the aim of complete the adjusting to the requirements under the Regulation as regards the amount of remuneration for the official checks.

Approving the Plan of Crisis Situation Management in the area of food safety.

The enforcement of the approved regulations should be continued, as well as drafting new ones, with the aim to adjust fully to the EU legislation:

- Rule Book on the Control Inside the EU
- Rule Book on Enzymes and Microorganisms in Animal Feed
- Rule Book on the Standards for Putting Eggs on the Market

- Rule Book on Health and Other Requirements for Other Food of Animal Origin – Guts, Rendered Fat, Blood ...
- Rule Book on Prohibited Substances in Animal Feed
- Rule Book on the Hygiene of Animal Feed
- Rule Book on the Permitted Additives in Live Stock Feed
- Rule Book on the Products that are Used for Animal Feeding
- Rule Book on the Requirements for Putting the Mixed Animal Feed on the Market
- Regulation on the Ban on the Use of Thyreostatic Drugs, Hormones ...
- Rule Book on the Requirements for Putting the Mixed Animal Feed on the Market.

The Ministry of Health, Labour and Social Welfare is planning to continue the adjustment of the following pieces of legislation:

- Regulation on the Permitted Quantities of the Metal, Metalloids, Residues of Pesticides, Veterinary Medicines and Other Substances that are Harmful to Human Health and Food
- Regulation on the More Detailed Requirements for Drinking Water, Table Water and Natural Mineral Water
- Regulation on the Method of the Water Sampling and Analyzing
- Regulation on the Fast Frozen Food
- Regulation on the New Food
- Regulation on the Food Subjected to Ionizing Radiation
- Regulation on the More Detailed Requirements for Declarations, Labelling, Presentation and Advertising
- Regulation on the Requirements for Packaging Products, Materials and Objects that are in Contact with Food
- Regulation on Dietetic Food
- Regulation on the Requirements for Additives as Regards the Safety, Use and Maximum Permitted Quantities
- Regulation on the Permitted Concentrations of Radionuclides in the Food
- Regulation on the Requirements for the Food Supplement Safety.

It is planned to complete the records of all existing entities engaged in food related businesses.

Institutional Framework

Strengthening administrative structures and improving mutual coordination for the purpose of advancing the food safety will be continued inside the whole food chain, as well as strengthening administrative capacities for performing the adjustment of legislation. It is necessary to provide additional equipping of inspections and laboratories, as well as further specialization and training of

inspectors, professional staff and laborants in the implementation of regulations - via trainings, workshops and study visits.

For the purpose of faster exchange of data and information, it is required to introduce the informative software application in order to network all services inside the system of food safety, as well as the training of inspectors in the use of the application with the aim of a comprehensive monitoring of the food safety chain.

ANNEX 5: Details per EU funded contract

The project will be implemented through 3 contracts, presented in the table below

	Focus	Type of contract	Source of funding	Indicative Amount (EUR)	Indicative duration (months)
Contract 1	Approximation of legislation, capacity building measures, creation of a data system	Service	EU	1.250.000	20
Contract 2	Purchase of equipment for food safety testing and analysis	Supply	EU	750.000	12
Contract 3	Purchase of equipment for food safety testing and analysis	Supply	National funds	166.000	12

The implementation of contracts 1 and 2 is linked. Contract 1 will be launched first in order to ensure support for preparation of the technical specification for Contract 2. Correspondingly, Contract 2 will be completed before Contract 1, under which an evaluation of the impact of purchased equipment on the food safety control has to be done.

A. Contract 1 is a fee-based service contract.

The objective of this activity is to enable the various tiers of the Government apparatus which supports food safety to become competent in managing and operating the legal, inspection and control systems, as defined by the European Community, and to ensure that the food consumed is safe and free from chemical, microbiological and other substances which could compromise human health and safety.

The key contractor's tasks include:

(1). Legislation approximation activities – focus to be put on:

- Analysis of the current state of play of legislation in comparison with the EU acquis and preparation of a Table of correspondence;
- Preparation of legislative proposals according to the identified priorities;
- Preparation of a national team of experts able to draft national legislation on food safety;

(2). Capacity building activities – focus to be put on:

- Analysis of the needs of all food safety related state bodies in terms of equipment, IT, training, HR development, operational and procedural systems, etc. Preparation of the technical specification for the purchase of equipment for testing and analysis;
- Provision of consultancy, advise and on-going support on food safety to all state bodies in the chain;
- Organisation of training on at least 3 key subjects: (i) EU system for food safety control, (ii) effective methods for inspections, control and monitoring, (iii) quality sampling incl. ensuring traceability of sampling; (iv). effective testing methods in line with the EU standards, incl. microbiological and chemical testing and testing for food borne pathogens. More particularly, the training has to cover:
 - General principles of food safety and related issues in the EU including TRACES, RASFF and ADNS.
 - Risk analysis.
 - Approval and registration of establishments.
 - Reference laboratory system of the EU including requirements for accreditation.
 - Border controls and the EU Third Country regime.
 - Sampling, transport, labelling.
 - Data and information systems.

- Meat inspection and health marking.
 - Auditing of food premises including pre-requisite programs and HACCP.
 - Microbiological testing especially relating to zoonotic pathogens associated with food not currently tested for in Montenegro i.e. norovirus.
 - Designation of shellfish waters and validation and testing for marine biotoxins.
 - Traceability of food products throughout the food chain, for example meat.
 - Sampling and testing for Bovine Spongiform Encephalopathy (BSE).
 - Sampling and testing for Genetically Modified Organisms (only to be undertaken after designation of an appropriate in-country system).
 - Control of the animal by-products industry.
 - Animal health issues relevant to veterinary public health (Directive 2002/99)
- Upgrading and preparation (where needed) of the inspection and control plans;
 - Upgrading and preparation (where needed) of the contingency plans;

(3). Information and awareness raising activities – focus to be put on:

- Organisation of an information and awareness raising campaign on food safety;
- Establishing of an integrated automated IT system to link with traceability and product labelling system and animal identification and registration system.

(4). Project management activities – focus to be put on:

- Coordination of the activities of all long- and short-term experts involved in project implementation;
- Evaluation of the impact of purchased equipment on the food safety control;
- Reporting, communication with the beneficiaries and the CA.

In order to implement this major objective the Contractor has to provide at least:

Key expert 1: Project Manager

The Project Manager will drive the implementation of the service contract, provide overall guidance on project orientation and focus and ensure that contract objectives are met. He/she will ensure timely identification of short term and other expert requirements, determine their profiles and inputs, supervise and coordinate their actions and ensure quality control of all TA-team outputs. Besides the management aspects, he/she will particularly responsible for:

- Upgrading and preparation (where needed) of the inspection and control plans;
- Upgrading and preparation (where needed) of the contingency plans;
- Implementation of the awareness campaigns.

The required qualifications, skills and experience include:

- university degree in a relevant discipline, along with strong communication and leadership skills;
- at least 10 years of professional experience in the food safety sector preferably gathered in the EU and in CEEC / transition economies;
- excellent practical experience in food chain inspection, food safety policy and strategy formulation;
- previous experience as team leader or project director in a long term assistance project in a third country (new EU Member States and/or EU candidate or acceding countries is an advantage) in a relevant thematic area.

Key expert 2: Legislation Expert

The legislation expert will be responsible for implementing all activities related to the approximation of the legislation of Montenegro to the acquis: analysis of the current state of play in comparison with the acquis, drafting of legislative proposals and recommendations, providing consultation and training of a group of national experts on legislative drafting in relation to food safety. S/he has to demonstrate:

- up to date and in depth knowledge of the EU Food and Feed legislation and institutional structures required to implement the “farm to fork” food control policy;
- previous experience in assessing third country legislation and institutional arrangements (including food & feed inspection, laboratory control etc.) for compliance with EU food safety requirements is desirable, as experience in having assisted in defining food policy strategy and worked in legal alignment and institutional reform projects including laboratory control and accreditation in new Member States or Candidate Countries. Comparable experience in other third countries (EU trading partners).

Key expert 3: Capacity building Expert

S/he will be responsible for the developing and implementing all capacity building measures – consultancy, on-going support and training activities, assessment of the needs related to human resource management and development, as well as for drafting of operational rules and procedures. The CB Expert will also be responsible for evaluation of the project impact on the capacity of the relevant state bodies and for drafting of future precise measures for further extending of the capacity building programmes beyond the scope of the project. S/he has to:

- be experienced in provision of training and consultancy in relation to food standards, public health, consumer protection or similar;
- demonstrate excellent knowledge on the food safety issues in transition economies and to have previous experience in a candidate country;
- have previous experience in needs analysis related to training and capacity building; and to building effective training programmes based on participatory training approaches.

Key expert 4: Senior IT Expert

This expert will be fully responsible for the assessment of the IT needs of the relevant institutions and the establishment of an IT system. S/he will have previous experience in evaluation of the IT needs and developing IT systems, preferably for the needs of the food safety systems in the EU or candidate countries.

A number of short-term (senior and junior) experts will also be involved in this project.

B. Contract 2 is a supply contract.

A list of items of laboratory equipment will be identified and recommended to increase the capacity and capability of the laboratories involved in food testing activities. Items will be selected according to the World Bank MIDAS project which also intends to purchase lab equipment. The equipment will enable the laboratories to perform surveillance, monitoring, diagnostic and analytic activities on food and food-related samples to a higher standard thereby enhancing the safety of food products in Montenegro. The equipment will fill the gaps which have been identified in present test capability and raise the standard of test sensitivity and specificity for on-going activities.

The equipment to be purchased has been extensively discussed with the laboratories mentioned above and prioritised. The equipment will support both chemical and microbiological investigations. Account has also been taken of the potential of instruments being supplied by other donors such as the International Atomic Energy Agency thus avoiding overlap and duplication.

C. Contract 3 (National Contribution)

This contract will ensure the purchase of additional equipment for monitoring and testing related to food safety.