

Project Fiche – IPA Annual Action Programme for Bosnia and Herzegovina
Support to implementation and enforcement of the BiH Food Legislation

1. Basic information

1.1 CRIS Number:

1.2 Title: Support to implementation and enforcement of the BiH Food Legislation

1.3 ELARG Statistical code: 03.11 – Food Safety, veterinary and phytosanitary policy

1.4 Location: Bosnia and Herzegovina

Implementing arrangements:

1.5 Contracting Authority: EC Commission in Bosnia and Herzegovina

1.6 Implementing Agency: EC Commission in Bosnia and Herzegovina

1.7 Beneficiary (including details of project manager): Agency for Food Safety BiH (FSA)

The main beneficiaries of this project are the BiH authorities in charge with establishment of the BiH food safety system, namely the Ministry of Foreign Trade and Economic Relations (MoFTER), the BiH Agency for Food Safety as the competent authority, administration of complementary State-level Agencies for phytosanitary and veterinary issues, entities and local level administration for implementation and enforcement, as well as business operators and consumers which interests in terms of protection of health and delivery of safe food and feed appear as an ultimate goal of the assistance.

Financing:

1.8 Overall cost: 1,000.000 EUR

1.9 EU contribution: 1,000.000 EUR

1.10 Final date for contracting: N+2

1.11 Final date for execution of contracts: N+4

1.12 Final date for disbursements: N+5

2. Overall Objective and Project Purpose

2.1 Overall Objective:

To guarantee the safety of food and feed to both BiH and EU consumers by implementing the EU principles on Food Safety.

2.2 Project purpose:

Secure implementation of the BiH Food safety legislation through the human resource strengthening and provision of equipment in order to provide a high level of food safety and increased competitiveness of the BiH agricultural products on domestic and international markets.

2.3 Link with AP/NPAA / EP/ SAA

The following are quotations from the European Partnership:

Short term:

Establish and make operational the State Food Safety Agency.

Enhance laboratories and inspection capacity in the veterinary and phytosanitary sectors, establish a reference laboratory and develop sampling procedures in conformity to EU requirements.

Medium term:

Prepare a programme for upgrading food processing establishments to meet EU requirements.

BiH Progress report for 2006 states that the food safety responsibility is shared between the State level and the Entity level authorities, including approvals prior to import, food certificates and food laws and regulations. The 2005 State Food Safety Law set up a system for transposition of Old Approach directives which apply to food products. It also determined the tasks of the recently established Food Safety Agency of Bosnia and Herzegovina (FSA), which is the designated competent institution for food legislation. The report also recognised that the Agency needs to be better equipped in human resources to perform its tasks more efficiently. Co-operation and co-ordination between the State and the Entities needs to be improved further to ensure proper implementation of legislation.

The aim and design of IPA 2007 project have fully taken into account these recommendations in view that the main expected result of the assistance is related to strengthened capacities of the FSA to coordinate and oversee an implementation of the BiH Food safety legislation.

2.4 Link with MIPD

In the area of European Standards, MIPD envisages that specialised agencies, including Food Safety and Phytosanitary Agency will be operational and implementation of acquis aligned legislation will be advanced to improve animal, plant and public health and consumers protection and increase competitiveness of BiH agricultural products.

2.5 Link with National Development Plan

Social and economic advantages will be created for farmers, food processors and traders as higher-quality agricultural products will increase sales possibilities on the internal market as well as for export purposes.

Spin-off effects for specific rural development activities may follow.

2.6 Link with national/ sectoral investment plans

Introduction of GHP- and HACCP systems will certainly reduce the number of farmers, food processors and traders remaining in business or joining the food sector because more severe hygiene rules will be applied. The BiH's food sector as a whole will become more competitive and more attractive for domestic and/or foreign investors. In addition, the envisaged World Banks' assistance from IDA loan will include a complementary support of some 0.5 MEUR to the Food Safety Agency of BiH in form of the capacity building, development of food safety information system and an upgrade of targeted laboratories and inspection services to achieve full synergy with the proposed EC assistance.

3. Description of project

3.1 Background and justification:

The quality and safety of food products is an issue of concern to consumers, the food industry and the government. The alignment of the BiH food legislation with the acquis is a major precondition for the implementation of market economy mechanisms and an important stage in pre-accession to the EU. Due to non compliance with basic requirements for import of animals and its products from third countries to the EU, BiH was imposed an export ban since

2000. The FVO inspection mission on fishery products was performed in 2005 and provided a number of recommendations for improvement concerning an overall food safety chain, which have been taken into consideration when preparing the activities of this project. Briefly, despite of substantial improvements in terms of modification of legislation to meet EU requirements, considerable efforts would be required to increase competitiveness of the BiH food products on EU market.

BiH requires a comprehensive Food Safety Strategy in order to (i) describe the current situation and intended steps in the medium term, (ii) improve coordination and ensure streamlining between all the competent authorities at State-level (State Agencies for Food, Veterinary, Phytosanitary, MoFTER, Ministry of Civil Affairs for health issues) and lower administration (entities Ministries of Agriculture, inspections, national laboratories, scientific institutes, etc) and (iii) rationalise number and functioning of laboratories by increasing their specialisation. Some laboratories in BiH are used for implementation of the residue monitoring and control of infectious diseases. Food Safety Agency is elaborating on a further rationalization of the laboratories currently active in the country. A national laboratory plan would be required as a condition for more substantial support to provision of equipment and training in this field. A further contribution to the elaborated model for the laboratories will be expected during the development of the BiH Food Safety strategy, as a component envisaged for implementation during the second phase of the project's implementation.

The food safety policy of BiH is based on the current legislation in this area. The basic legislation includes the Food Law adopted in 2004, which transposes the general principles of the EU food law (EC Regulation 178/2002) and provides the institutional framework for the application of a food-safety policy. According to this legislation, the main functions assigned to the Food Safety Agency, as the BiH competent body with national responsibility for co-ordinating the enforcement of food safety legislation in the country are:

- putting consumer interests first and foremost
- providing advice to Ministers, regulators, the food industry and consumers on food safety issues
- ensuring the co-ordinated and smooth delivery of food safety services to an agreed high standard by the various state agencies involved
- ensuring that food complies with legal requirements, or where appropriate, with recognised codes of good practice
- working with the food industry to gain their commitment in the production of safe food
- setting food standards based on sound science and risk assessment
- risk management in association with frontline agencies and the food sector, and
- communicating risks to consumers, public health professionals and the food industry.

In addition, BiH needs to establish and make operational and efficient a system for the implementation of regulation transposing the EC regulation on official food and feed control (882/2004), a number of recently prepared horizontal and vertical regulations in the field as well as to continue with transposition and implementation/enforcement of series of new regulations/directives in cooperation with other BiH competent authorities and to support establishment of related technical infrastructure. This includes:

- creation of scientific laboratories for risk analysis
- network of reference and food testing laboratories
- internationally recognised accreditation body

- the pool of competent food hygiene inspectors for approval of a correct implementation of HACCP systems in food establishments
- approval and registration system of food establishments including regulatory framework, human resources and IT equipment.

As such, the aim of this project would be to focus on further implementation of these aspects in line with the EU Food Safety requirements.

The importance of compliance with international food safety standards in order to enhance the country's export potential is also an emerging issue, in view of importance of food production for the BiH economy. However, the level of awareness amongst the food producers and business operators on the one hand, and the inspection services in the other, on application of self-control standards and requirements are limited. In view of legislative requirements, the introduction of HACCP standard has to some extent advanced in comparison to the voluntary food safety programmes, such as EUREPGAP. The capabilities of producers and business operators to establish and implement regular control of hygienic and health-technical conditions of production at all sites under their control are becoming one of key export requirements. In addition, their prospects for better position on internal market are likely to increase by enhanced application of food safety standards.

In response, the training on Good Hygiene Practice (GHP), Euro-Retailers Produce working group of Good Agricultural Practices (EUREPGAP) and Hazard Analysis and Critical Control Points (HACCP) systems will be required in order to assist food operators to meet the hygiene standards in terms of implementation of hazard analysis and control principles and observance of hygiene rules. The role of the FSA would be to support development and implementation of guidelines and, if required, for certifying food business operations applying HACCP. The support should be provided in definition of programme for upgrading food processing establishments to meet EU requirements. In addition, operators should be trained on principles of traceability to ensure that adequate procedures are in place to withdraw feed and food from the market in case that risk is posed for consumers' health.

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

The impact of the project is very important from a nutritional point of view as well as for a further economic development of BiH. Locally-produced food will be safer and as a consequence more competitive to imported foodstuffs. The safer food may offer opportunities for export purposes. In addition, the production of safer feed will also reduce import needs of animal feed and contributes to a higher level of animal health.

3.3 Results and measurable indicators:

1. Demonstrated capacity of the Food Safety Agency (FSA) to perform its basic tasks resulting from the food legislation, in particular related to the risk assessment, coordination of risk management and communication with all stakeholders involved in the food safety chain.

Indicators:

- FSA takes proactive role in gathering of currently available **information** and analysis on food safety issues.
- FSA supports developing and operating of the food safety **monitoring and surveillance** programmes.

- **Network** of contacts established with relevant Agencies, laboratories and consumer groups.
- Basic FSA capacities to identify and respond in a real time to potential and real hazards for consumers' health. Plan for **crisis management** and **emergencies** developed and agreed in cooperation with other competent bodies.
- FSA supports establishing standards and methodologies for enhanced **inspection** control of food safety, **hygiene**, and quality control and **laboratory** analysis.
- FSA providing basic scientific and technical support to definition of the BiH **policy** and further transposition of the EU **legislation** in the fields which impact on food and feed safety.
- **Consumers'** communication platform developed. Consumers are provided with easily accessible and understandable information on issues of health protection.
- FSA actively contributes to increased awareness of **business operators** on food hygiene requirements and traceability .National guides prepared to support implementation of GHP. Food business operators trained on implementation of HACCP and EUREPGAP standards.
- Medium term **BiH food safety strategy** developed defining the future legislative and administrative requirements for achieving the EU acquis compliance.

2. Existing food safety, hygiene and quality control improved through the enhanced capacities of the competent **inspection bodies**.

Indicators:

- Inspection **surveillance** introduced and inspectors take samples based on defined procedures and sampling techniques;
- Food inspectors performing an **audit role** in assessing industry compliance with GHP(General Hygiene Practices) and HACCP (Hazard Analysis and Critical Control Point) principles.
- Inspectors trained in use and proper maintenance of equipment to assure **compliance** with design parameters and FSA **operations procedures** and guidelines;
- Harmonised **enforcement measures** defined and applied BiH wide based on the relevant legislation. Food inspectors' audit reports fully in line with FSA procedures and guidelines.

3. Authorised **laboratories** perform more specific analysis based on internationally recognised methods and procedures.

Indicators

- Draft **national laboratory plan** prepared and endorsed by the key stakeholders.
- Number of laboratories performing **analyses** according to good laboratory practices fully harmonised with international methods and procedures;
- Selected laboratories progressing towards **accreditation**;
- Participation of the laboratories in **proficiency testing** schemes initiated.

4. Established BiH **register of food business operators**.

Indicators

- Developed **procedure** of registration and working instructions;
- **Feasibility study** for BiH register of business operators prepared indicating operational; and financial aspects of creating and maintaining data base.
- Design of software and hardware needs defined.
- **Communication** with remote units proposed.
- Number of **businesses registered**.

5. Enhanced trading position of **food producers and processors** through application of food safety programs and standards for self-control.

- a. Increased general awareness on **HACCP** and **EUREPGAP standards**.
- b. Number of primary producers and food business operators has capacity to apply GHP, HACCP and EUREPGAP standards.

3.4 Activities:

Activity 1: Support to capacity building of the Food Safety Agency (FSA) staff to assume responsibilities derived from the food safety legislation

- 1.1. Training for the further alignment and implementation of **legislation with the EU acquis**.
- 1.2. Training in basic elements of **risk assessment** selected FSA staff.
- 1.3. Training in basic elements of **risk management**.
- 1.4. Training in **drafting of the initial national control plan**.
- 1.5. Training in basic elements of **risk communication**, including the Rapid Alert System, to selected FSA staff.
- 1.6. Support preparation of the **national laboratory plan** based on assessment of current BiH situation and a need for prioritizations and rationalisation in order to comply with international standards.
- 1.7. Training to support to setting the standards and methodologies for enhanced **inspection control**, hygiene, quality control and **laboratory analysis**. (to be scheduled when the required laboratory equipment and other (accreditation) procedures are in place.)
- 1.8. Training to the primary producers and food operators on **GHP** (General Hygiene Practices), **EUREPGAP and HACCP standards**. This activity may include some study tours abroad.
- 1.9. Drafting of the **BiH food safety strategy** in a participatory manner and by involvement of key stakeholders.
- 1.10. Support to creation of FSA **communication platform** will be provided by focusing in particular on provision of user friendly information targeting consumers.

Activity 2. Support to inspections

Support to inspections will be provided in form of the training and transfer of know-how. The training will include the following main topics:

- Training on implementation of the official food/feed controls, audits of the activities of the food business operators and inspections on food businesses' own control systems;
- Training in the basic technique of sampling;
 - Training in statistically based sampling techniques;
 - Training on GHP en HACCP: basic principles and assessment of GHP and HACCP systems implemented at primary production and by the food processors.
- Food technology: training to cover basic principles of food processing.

It is recommended to maintain training records for all inspectors receiving these trainings as the records should form an integral part of the system of authorisation.

Activity 3. Support to laboratories

A draft of the **national laboratory plan** should be prepared in cooperation with the competent authorities to ensure their rationalisation and increased specialization in the field¹. The detailed laboratory training plan will be prepared in anticipation of the subsequent IPA 2008 assistance for provision of the laboratory equipment.

While the details of initial laboratory equipment needs are provided in Annex IV to this document, the final selection of the laboratories that will receive the EC equipment will be determined by the beneficiaries, based on the following minimum criteria:

- a. Laboratory(is) should actively work towards accreditation to ISO 17025 standards.
- b. Methods used in the laboratory(is) must, wherever possible be based on EN ISO/ISO methods or other internationally recognized methods.
- c. Methods used by the laboratory must, wherever possible, be validated by the use of certified reference materials.
- d. The laboratory receiving the equipment must participate in relevant proficiency testing schemes.
- e. Only laboratories which can demonstrate public ownership will be considered for equipment supply.

Activity 4. Support to registration of food and feed business operators

- Definition of the procedures for approval and registration of food establishments
- Feasibility study for the BiH register of business operators.
- Feasibility study for BiH register of business operators prepared indicating operational and financial aspects of creating and maintaining data base.
- Training provided to support registration of businesses.

Activity 5: Support to introduction of food safety standards

¹ The report on assessment of the BiH veterinary, food and feed laboratories is provided in Annex 3. This report will serve as basis for preparation of the BiH National Laboratory Plan.

- General training to farmers and business operators will be provided on GHP, EUREPGAP and HACCP.
- Training for different NGO's and advisory services to apply train-trainers techniques.

3.6 Conditionality and sequencing

The activities should be implemented in a way to first support capacity building, the transfer of know-how and creation of the national laboratory plan, to create basis for the delivery of sophisticated laboratory equipment from subsequent IPA intervention.

Existence of core staff (18 employees, until now) within the Food Agency and the adoption of food legislation provide intuitional and legal framework for the project implementation.

3.7 Linked activities

The food safety policy of BiH is based on the Food Law adopted in September 2004, which transposes the general principles of the EU food law (Regulation (EC) No 178/2002) and provides the institutional framework for the application of a food safety policy.

Over the past four years BiH has undergone a comprehensive process of creating the State-level agencies for veterinary, phytosanitary and food safety, in order to comply with more stringent food safety and hygiene standards to reach a higher level of protection of human and animal health.

Significant EC intervention in the food safety area is provided through the following projects:

- Phare-PRAQ III, Single Economic Space I and II
- CARDS - Transposition and Implementation of Technical Regulations, which created a solid base for establishing a more modern food and feed safety system in BiH.
- SIDA - Quality and Regulatory Infrastructure Development for Food safety and Quality in South East Europe, a four year regional programme with delayed commencement from the originally envisaged 2006-2010.
- The finalisation of an agreement for the World Bank's IDA loan is in its final stage. It includes component related to strengthening capacities of the FSA, upgrade of laboratories and equipment supply for inspection services. The envisaged assistance was fully coordinated with the planned EC support to ensure complementarities.

3.8. Lessons learned

Experience from previous EC assistance has shown that future support should be provided to support development of implementation mechanism for the acquis harmonised legislation and to reinforce the capacities of the FSA to coordinate this process. The focus of past assistance in the field was to support development of the national legislation and establishment of the FSA and transposition of a number of horizontal regulations/directives into the national legislation. As such, the future assistance to the sector should be implemented in phases over the period 2007-2009 with initial support provided to capacity building of the FSA staff and main support services for control and laboratory analysis. The next phases of this programme should aim at creation of scientific network as the basis for provision of scientific opinions of the FSA within the areas of its competence. More attention should also be paid in this advanced stage to scientific and technological development of BiH in the field of food safety in order to support country's strategic aims and policy needs.

4. Indicative Budget (amounts in €)

Activities	TOTAL COST	SOURCES OF FUNDING											
		EU CONTRIBUTION				NATIONAL CONTRIBUTION			PUBLIC CONTRIBUTION			PRIVATE	
		Total	% *	IB	INV	Total	% *	Central	Regional	IFIs	Total		
Contract 1.1: TA for support to implementation and enforcement of BiH Food Legislation	1.000.000	1.000.000	100	1.000.000									
TOTAL	1.000.000												

* expressed in % of the Total Cost

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

Contracts	Start of Tendering	Signature of contract	Project Completion
Contract 1.1: TA for support to implementation and enforcement of BiH Food Legislation	1 st quarter following the signature of the FA	Q2 2008	Q4 2009

All projects should in principle be ready for tendering in the 1ST Quarter following the signature of the FA

6. Cross cutting issues (where applicable)

- 6.1 Equal Opportunity
- 6.2 Environment
- 6.3 Minorities

ANNEX 1: Logical framework matrix in standard format

LOGFRAME PLANNING MATRIX FOR Project Fiche	Programme name and number: Support to implementation and enforcement of the BiH Food Legislation	
	Contracting period expires	Disbursement period expires
	Total budget : 1,000,000 EUR	IPA budget: 1,000,000 EUR

Overall objective	Objectively verifiable indicators	Sources of Verification	
To guarantee the safety of food and feed to both BiH and EU consumers by implementing the EU principles on Food Safety.	Decrease of food contamination cases at national level Exports of food/feed products are increasing, in 2010 compared to 2009	Annual report of FSA Communications released from Council of Ministers (law adoption) Annual reports of FSA and Inspectorates Annual EC reports on BiH progress Export statistics show data	
Project purpose	Objectively verifiable indicators	Sources of Verification	Assumptions
Secure implementation of the BiH Food safety legislation through the <u>human resource strengthening</u> and <u>provision of equipment</u> in order to provide a high level of food safety and increased competitiveness of the BiH agricultural products on domestic and international markets.	Appropriate legislation (by-laws) fully adopted by Council of Ministers, by end of project. Decreasing by 25% of food contamination cases at national level the first 5 years (2008/2013)	Communications released from Council of Ministers Annual report prepared by FSA Annual report prepared by PHA Equipment in designated laboratories is in operation FVO reports	Drafted legislation is adopted by relevant bodies Recruitment of FSA-staff is successful Food/feed products are offered for export purposes
Results	Objectively verifiable indicators	Sources of Verification	Assumptions
R1 Demonstrated capacity of the Food Safety Agency to perform its tasks resulting from the food legislation, in particular related to the risk assessment, risk management and its communication with all stakeholders involved in the food safety chain.	FSA takes proactive role in gathering of currently available information and analyses on food safety issues. FSA supports developing and operating of the food safety monitoring and surveillance programmes. Network of contacts established with relevant Agencies, laboratories and consumer groups.	Annual reports of different scientific committees are prepared through FSA Annual report prepared by FSA Consulting website and booklets issued	FSA/SVO/PHA cooperate properly in risk management

<p>R2 Existing food safety, hygiene and quality control improved through the</p>	<p>Basic FSA capacities to identify and respond in a real time to potential and real hazards for consumers' health.</p> <p>Plan for crisis management and emergencies developed and agreed in cooperation with other competent bodies.</p> <p>FSA supports establishing standards and methodologies for enhanced inspection control of food safety, hygiene and quality control and laboratory analysis.</p> <p>FSA providing basic scientific and technical support to definition of the BiH policy and further transposition of the EU legislation in the fields which impact on food and feed safety.</p> <p>Consumers' communication platform developed.</p> <p>Consumers are provided with easily accessible and understandable information on issues of health protection.</p> <p>FSA actively contributes to increased awareness of business operators on food hygiene requirements and traceability.</p> <p>National guides prepared to support implementation of GHP.</p> <p>Training organised for the food business operators on implementation of HACCP and EUREPAG standards.</p> <p>Medium term BiH food safety strategy developed.</p> <p>Inspection surveillance introduced and</p>	<p>Progress reports of project</p> <p>Monitoring reports</p> <p>Annual reports, prepared by EC, on the overall operation of official controls in (candidate) Members</p> <p>Reports by FVO</p> <p>Primary production (GHP) and food business operators (HACCP) make use of FSA-assistance</p> <p>Annual reports prepared by FSA and by associations of business operators.</p>	<p>Inspection services staff available and committed to the project.</p>
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<p>enhanced capacities of the competent inspection bodies.</p>	<p>inspectors take samples based on defined procedures and sampling techniques.</p> <p>Food inspectors performing an audit role in assessing industry compliance with GHP (General Hygiene Practices) and HACCP (Hazard Analysis and Critical Control Point) principles.</p> <p>Inspectors trained in use and proper maintenance of use and proper maintenance of equipment to assure compliance with design parameters and FSA operations procedures and guidelines;</p> <p>Harmonised enforcement measures defined and applied BiH wide based on the relevant legislation. Food inspectors' audit reports fully in line with FSA procedures and guidelines.</p>	<p>Procurement of basic equipment ensured through the donors funding.</p>
<p>R3 Authorised laboratories perform more specific analysis based on internationally recognised methods and procedures.</p>	<p>Draft national laboratory plan prepared and endorsed by the key stakeholders.</p> <p>Number of laboratories performing analyses according to good laboratory practices fully harmonised with international methods and procedures; Selected laboratories progressing towards accreditation;</p> <p>Participation of the laboratories in proficiency testing schemes initiated.</p>	<p>Commitment at political level to optimise the number of laboratories.</p> <p>Laboratories cooperate with FSA</p> <p>Laboratories willing to participate in networking.</p>
<p>R4 Established BiH register of food business operators</p>	<p>Developed procedure of registration and working instructions;</p> <p>Feasibility study for BiH register of business operators prepared indicating</p>	

<p>R5 Enhanced trading position of food procedures and processors through application of food safety programs and standards for self-control.</p>	<p>operational; and financial aspects of creating and maintaining data base. Design of software and hardware needs defined. Communication with remote units proposed. Number of businesses registered</p> <p>Increased general awareness on HACCP and EUREPGAP standards. Number of primary producers and food business operators has capacity to apply GHP, HACCP and EUREPGAP standards.</p>		
Activities	Means	Costs	Assumptions
<p>A1 Support to capacity building of the Food Safety Agency (FSA) staff to assume responsibilities derived from the food safety legislation</p> <p>A2 Support to inspectors by means of training and provision of equipment</p> <p>A3 Support to laboratories</p> <p>A4 Support to registration of food and feed business operators</p> <p>A5 Support to introduction of food safety standards</p>	<p>Technical Assistance: Food safety expert/team Leader Legal expert in the field of food safety Laboratory expert Pool of short-term experts</p>	<p>Technical Assistance: 1.000.000 euro</p>	<p>Requested budget is provided</p>

Pre-conditions: none

ANNEX II: amounts (in €) Contracted and disbursed by quarter for the project

Contracted	1st Quarter 2008	2nd Quarter 2008	3rd Quarter 2008	4th Quarter 2008	1st Quarter 2009	2nd Quarter 2009	3rd Quarter 2009	4th Quarter 2009	1st Quarter 2010
Contract 1.1		1.0 M							
Total		1.0 M							
Cumulated		1.0 M							
Disbursed	1st Quarter 2008	2nd Quarter 2008	3rd Quarter 2008	4th Quarter 2008	1st Quarter 2009	2nd Quarter 2009	3rd Quarter 2009	4th Quarter 2009	1st Quarter 2010
Contract 1.1		0.125M	0.125M	0.125M	0.125M	0.125M	0.125M	0.125M	0.125M
Total		0.125M	0.125M	0.125M	0.125M	0.125M	0.125M	0.125M	0.125M
Cumulated		0.125M	0.25M	0.375M	0.5M	0.625M	0.75M	0.875M	1.0M

ANNEX 3: BiH Laboratory assessment report - Food safety

The assessment was performed by the expert team engaged on EC project "Assistance in preparation of IPA programme BiH in the field of Food Safety". The assessment was performed in the period January-February 2007 with following objective:

- to prepare investment proposal for supply of equipment for IPA 2007 programme;
- to provide basis for preparation of the BiH National Laboratory Plant that will be defined during the project component related to provision of technical assistance;
- to identify follow up investment needs for proposal for EC finance from IPA 2008-2009 assistance.

Prior to visiting the laboratories we had an introductory meeting with staff from the BiH Sarajevo University – Faculty of Veterinary Medicine ‘Department of Food Hygiene & Technology’. During the course of this meeting we were provided with some information regarding the system of food inspection together with a list of laboratories that are involved in the ‘Official Control’ of food.

Food inspection

Under the current system, a number of inspectorates, are involved in the ‘Official Control’ of food. Their responsibilities are divided as follows.

Veterinary inspection:

- animal health, production and welfare
- food of animal origin: production plants, warehouses, transport

Sanitary inspection:

- Foodstuffs of non animal origin, such as those derived from plants and cereals, fruit, vegetables, beverages etc.
- Foods such as ready prepared meals that include ingredients of animal origin may well be subject to sanitary inspection.
- Water

Trade inspection:

- Foodstuffs: declaration and quality

Phytosanitary inspection:

- Plant production

Laboratories

Veterinary laboratories

- Provide diagnostic services for food of animal origin.
- Current veterinary laboratories are organized as a two tier system.
- Authorized laboratories are designated by the Entity Ministry of Agriculture
- Reference laboratories are designated by the State Council of Ministers

List of authorized labs

1. Veterinary Institute of the Veterinary faculty Sarajevo – 5 Departments – 39 employees (23 experts).
2. Veterinary Institute Banja Luka - consists of 3 Departments plus one small branch office in Bijeljina and employs a total 49 persons (37 experts).

3. Veterinary laboratory Mostar – 5 employees (1 expert)
4. Veterinary laboratory Tuzla – 5 employees (1 expert)
5. Veterinary laboratory Zenica
6. Veterinary laboratory Bijeljina
7. Veterinary laboratory Bihac
8. Veterinary laboratory of Cantonal Veterinary Station – Sarajevo – 8 employees

Agricultural Institutes – have some responsibilities for the quality control of cereals and other plants (including fruits and vegetables)

1. Agricultural Institute Sarajevo – 5 Departments plus laboratories – employing 20 people (7 experts).
2. Agronomic Institute of the University of Mostar – 6 Departments, two field stations plus laboratories – employing 15 people (10 experts)
3. Agricultural institute Banja Luka - registered as an Institute for Science and Research, 9 Departments plus laboratories employing a total of 72 people (33 experts)

Institutes for Public Health – are responsible for the control of sanitary conditions in food production.

1. Cantonal Institute for Public Health Sarajevo
2. Cantonal Institute for Public Health Zenica
3. Cantonal Institute for Public Health Bihac
4. Cantonal Institute for Public Health Tuzla
5. Cantonal Institute for Public Health Mostar
6. Federal Institute for Public Health Sarajevo
7. Federal Institute for Public Health Mostar
8. Institute for Public Health of RS Banja Luka - control of sanitary conditions of production in RS

Although there are 20 or more laboratories, many of these are barely operational.

Bosnia & Herzegovina – Sarajevo University – Faculty of Veterinary Medicine

The Department of Food Hygiene & Technology includes a suite of laboratories that are used for both teaching and research activities and for chemical analysis and microbiological examination of food for the purpose of ‘Official Control’. Another laboratory undertakes some analysis of animal feeds.

Laboratory of the Veterinary Institute of the Veterinary Faculty Sarajevo

Equipment in the laboratory includes:

- An **HPLC system** comprising –
- Perkin Elmer 758A UV – Visible detector
- Perkin Elmer series 200 Isochratic pump
- Column oven

This equipment was originally used for the analysis of meat for hormone residues but since none were detected, it is now used for analysis of food for the presence of certain antibiotic residues, including tetracyclines and sulphonamides. The methods used for the detection of antibiotics are apparently

based on those published by the Association of Official Analytical Chemists (AOAC). Screening for hormones is now undertaken using ELISA based test kits.

PCR

- A separate laboratory has been adapted for carrying out analyses based on the use of the polymerase chain reaction (PCR).
- The equipment currently in use is a conventional 'thermocycler' to carry out the PCR process. The amplified DNA or protein fragments are then further identified by the use of gel electrophoresis.
- Currently this technique is used for the identification of bacterial strains including those of E.coli, Staphylococcus aureus, Listeria monocytogenes etc.
- This technique is also used for meat speciation.
- No analysis is currently undertaken to detect the presence of ingredients of genetically modified origin.

Gas Chromatographs

- The department is equipped with 2 gas chromatographs both of which are based on Perkin Elmer Autosystem XL instruments.
- The first is equipped with a flame ionization detector only and is used predominately for the determination of the fatty acid composition of oils and fats.
- The second instrument is equipped with an electron capture detector (ECD) and can be used for the detection of organochlorine pesticide residues and polychlorinated biphenyls (PCBs).

Atomic Absorption Spectrometry

- The laboratory is equipped with a –
- Perkin Elmer Analyst 300 Flame AA,
together with
- HGA 850 – Graphite Furnace
- MHS10 – Hydride generation system

As far as the expert could tell, background correction is achieved by the use of a deuterium arc rather than by the Zeeman system. The laboratory did not appear to be equipped with facilities for the preparation of samples by microwave digestion. The atomic absorption spectrometer is used for the analysis of both food and animal feeds.

Mycotoxins

The laboratory is using ELISA based techniques for the determination of aflatoxin M₁ in milk.

Antibiotic residues

Transia plate test systems are used for the detection of chloramphenicol residues and TetraSensor kits are used for the detection of Beta-agonists.

Beta-agonists include substances such as clenbuterol and salbutamol. They may be used to affect the growth of beef animals and produce a leaner carcass. Clenbuterol is the only beta-agonist licensed for veterinary use, for the treatment of respiration disorders, but all beta-agonists including clenbuterol are prohibited within the EU for use as growth enhancing agents.

Microbiology

The microbiology laboratory was relatively well equipped with incubators etc. and work surfaces appeared to be constructed of impervious material that could be easily disinfected.

Methods used for the microbiological examination of foods are those that are included in the current food laws, published by the Federal Republic of Yugoslavia.

Although it was claimed that checks are carried out on batches of prepared media, including checking the ability of particular types to support the growth of specific bacteria, the reference cultures used, are obtained locally, from other institutes. Whilst the laboratory can be commended for at least conducting some quality checks, it is normally recommended that bacterial cultures used for such checks, are obtained from recognized reference culture collections such as ATCC or NCTC.

Cantonal Veterinary Laboratory – Sarajevo

This is the only laboratory in Bosnia & Herzegovina that is accredited to ISO 17025 by the Bosnia & Herzegovina Institute for Accreditation. The laboratory's scope of accreditation includes 39 methods for the analysis or examination of food and water.

The laboratory has been accredited since June 2004 and has been re-assessed in 2005 and 2006. All assessments have been satisfactory. The Laboratory Director is Nedim Brdarić who holds a Doctorate in Veterinary Medicine. The Technical Manager is Lejla Zahirović who also holds a Doctorate in Veterinary Medicine. The Head of Microbiology holds a Master's degree and specializes in the identification of E.coli. The Head of Chemistry has a PhD and specialises in the study of heavy metals in foods. The laboratory occupies 3 or 4 floors of a building and whilst it is in a good state of repair it is not an ideal location for a laboratory.

Sample reception

This is placed immediately inside the main entrance to the laboratory and there is an inner door that provides access to the laboratory itself. Clients, including Veterinary and Sanitary Inspectors are not permitted to enter the laboratory and are required to deliver their samples via a hatch, to the sample receptionists.

ELISA Techniques

The laboratory is equipped with an Idexx Plate Reader and has kits suitable for the detection of the following:

- Brucella abortis – in milk
- Salmonella spp.
- Q Fever – in milk
- Stilbene
- Nortestosterone
- Staphylococcal toxins
- Alachlor – in water used for meat processing
- Chloramphenicol
- Sulphamethazine
- Aflatoxin B₁

Results of the ELISA assays are assessed by an Idexx Plate Reader and the laboratory has stored a number of programmes for the above listed assays in a computer linked to the plate reader. The laboratory also undertakes the analysis of water. Most of the tests undertaken are based on the use Hach test kits with results being assessed by the use of a Hach DR/4000 U spectrophotometer. The Hach test method for nitrate has been adapted for use in determining nitrates in meat.

Proximate Analysis

A second laboratory is used for the analysis of moisture, ash, fat etc. of food. In particular, it was noted that when it is necessary to determine the total nitrogen content of food, in order to calculate protein content, the apparatus required has to be assembled on every single occasion. The lack of dedicated equipment such as that provided via block digestion and semi automated distillation units, inevitably leads to a lack of reproducibility. As far as the expert could tell little or no recovery checks for nitrogen, or for ammonia at the distillation stage, are carried out.

Metallic contaminants

This laboratory is also used for dry ashing samples, prior to the determination of metallic contaminants, including lead, cadmium etc. The prepared samples are then analysed using an atomic absorption spectrophotometer, located in another institute. It is difficult to understand why the Institute for Accreditation are prepared to accredit the laboratory for the determination of metallic contaminants in food, particularly as the atomic absorption spectrophotometer used, is not under the direct control of the accredited laboratory. Similarly, the expert does not believe that dry ashing of samples prior to the determination of metallic contaminants at low levels, is an appropriate technique.

Mycotoxins

Currently the laboratory carries out analysis for ochratoxin and aflatoxins B1 using ELISA test kits. Using such kits the laboratory frequently detects mycotoxins at levels that would exceed those set in EU regulations governing the levels of these substances in a range of foodstuffs. However the laboratory is still required to work to the Former Yugoslav laws. Since the limits set in the older Yugoslav law are significantly higher than those that apply in EU Regulations, no action can be taken since, although levels exceed EU limits, they are still in compliance with the former Yugoslav limits.

Microbiology

Media for microbiological examination of foods are prepared from complete dehydrated media and are tested for sterility and pH. Some checks are carried to ensure that the prepared media is able to support the growth of target organisms. Again, the reference cultures used, are obtained locally, from other institutes rather than from recognized culture collections such as those of ATCC and NCTC. The laboratory is equipped with modern incubators for which temperature records are maintained. Incubator temperatures are monitored using digital minimum and maximum thermometers. This is good practice since it enables the detection of incidents such as overnight power failures. Currently, microbiological examination of food is restricted to testing for those organisms that are listed in the existing State laws. It is generally the case that the State law specifies the parameters for each food type. For example, under the existing law, there is no requirement to test for *Listeria* species or for *Listeria monocytogenes*. Furthermore, all methods are laid down in the State law and as a consequence, ISO methods are not widely used. As Bosnia & Herzegovina implement EU Regulations such as Regulation 2073/2005 on microbiological criteria for foodstuffs, specify the reference methods as EN-ISO or ISO methods. As EU Regulations are adopted into National law, official laboratories will be obliged to use EN – ISO or ISO methods.

Agricultural Research Institute – Sarajevo

The Institute is currently expanding its laboratory facilities. This expansion includes increasing the floor space of the laboratories, purchasing additional equipment and recruiting suitable staff. Once completed there will be 3 sections covering:

- Seeds, seedlings etc.
- Food – excluding milk and milk products
- Milk and milk products.

Originally the laboratory had 3 experts, one of whom was a microbiologist, the 2nd expert was a chemist and the 3rd expert, also a chemist with an MSc degree, was responsible for the section of the laboratory undertaking analysis for pesticide residues, metallic contaminants etc. Recently, an additional 9 specialist have been recruited, as follows: 3 Chemists, 3 Microbiologists, 2 Agronomists, 1 Veterinarian. All of the newly recruited staff are graduates and whilst they have all received basic training they still require further, more specialised training.

The laboratory undertakes microbiological examination of food together with general compositional analyses. 1 million KM is being provided from the Federal budget for the provision of milk testing equipment. The reconstruction of the previously destroyed buildings is also being funded from the Federal budget. It is hoped that in the future, the Agricultural Research Institute laboratory will be recognized as a 'National' food testing laboratory.

According to the Director, the testing capacity of the laboratory is under utilized. This mostly as a result of the fact that inspectors are not taking an adequate number of samples under the existing laws and so are not able to submit samples to the laboratory.

For example, the Director estimates that the laboratory currently has the capacity to undertake 10,000 analyses per year. In the past year, the laboratory undertook approximately 400 analyses, the majority of which were the microbiological examination of food. As a further example, in the past 3 years, only 3 samples have been submitted for pesticide residue analysis.

Seed Testing Laboratory

This laboratory undertakes basic tests on seeds, such as determination of content, germination tests etc. Some tests for viruses are undertaken using ELISA test kits. The plate reader used for assessment of the microtitre plates used for the ELISA tests, appeared to be rather old.

Microbiology Laboratory

The incubators used in the laboratory seemed to be in reasonable condition. Other equipment includes a laminar flow cabinet. Only 1 autoclave was available so presumably this is used both for media preparation and for the sterilization of waste, prior to its disposal. Other equipment is sterilized by means of dry sterilisation.

As far as could be ascertained, there was no ‘Stomacher’ available for the homogenisation of samples, prior to microbiological examination. Instead, it would seem that samples are homogenized manually which inevitably increases the risk of contamination, from one sample to another.

Water for use for reconstitution of media etc. was prepared by distillation. Again, as far as the expert could see, no checks on the quality of the water produced, such as measurement of its conductivity, were undertaken, prior to it being used.

Chemistry laboratory

Equipment included a digital polarimeter, used for the determination of sugars in a range of foods. At the time of the expert’s visit, the laboratory was undertaking compositional analysis of jams from a local manufacturer. This work was being undertaken on a commercial basis and as such, care needs to be taken to ensure that there are no conflicts of interest. Determination of fat content is undertaken using conventional Soxhlet apparatus. Similarly, the determination of the total nitrogen content of foods was undertaken using the traditional Kjeldahl method and equipment.

Instrumentation

The laboratory is equipped with a Perkin Elmer AAnalyst 100 atomic absorption spectrophotometer with flame atomization. Samples for analysis for metals are prepared by dry ashing or by the use of a manual wet oxidation procedure. Other equipment includes a Perkin Elmer Lambda 25 spectrophotometer which is used for a range of tests. The laboratory is also equipped with a Perkin Elmer Autosystem XL gas chromatograph, fitted with a flame ionization detector (FID) and an electron capture detector (ECD). Given that the gas chromatograph is only equipped with an ECD detector, the laboratory is limited to analyzing foods for the presence of organochlorine pesticide residues.

Public Health Institute Laboratory – Sarajevo

The laboratory undertakes analyses of samples submitted by the inspectors to ensure that it complies with laws governing food safety. The laboratory also requires that local food processors and manufacturers take out a contract to submit samples on a regular basis, for the purpose of quality control. The laboratory also undertakes analysis of food to provide data for use on export certificates.

The Federal Ministry of Health requires that certain products such as vitamin and mineral supplements, dietetic products etc. are registered, prior to be placed on the market. Manufacturers and importers of such products are required to submit samples of such products to the Public Health Institute for analysis, prior to them being placed on the market.

The laboratory is also responsible for analyzing products which are classed as for general use, such as, cosmetics, toys, materials and articles in contact with food. Materials and articles in contact with food include plastic packaging materials, cooking utensils and ceramic ware. Whilst these may be tested for metals that can be leached out during cooking, no migration tests are conducted on plastic materials for additives such as plasticisers and no tests are conducted on PVC for the presence of vinyl chloride monomer. The main reason for this lack of testing is that such requirements are not included in the current laws.

There is a requirement that new products marketed by local food manufacturers be tested by the Public Health Institute laboratory to ensure that it complies with food safety requirements etc. This is also required when changes are made to the product formulation or packaging. Samples for analysis to show compliance with food safety requirements are received from:

Health Inspectors

Border Inspectors

Market Inspectors

The majority of samples received by the laboratory are of non animal origin although there are some exceptions such as honey, where it is classed as a dietetic product.

Equipment

The laboratory is equipped with a Shimadzu AA 6650 atomic absorption spectrophotometer with a graphite furnace and facilities for determination of elements by hydride generation.

Mercury is determined by the use of a Leco AMA 254 mercury analyzer. This instrument utilises a direct atomic absorption cold vapour method with gold amalgamation. The analysis can be performed using solid samples without any further sample preparation.

An Ethos D microwave digestion system is available for the preparation of samples, prior to analysis for metallic contaminants by atomic absorption spectrometry.

A Shimadzu Ion Chromatograph was available for water analysis but this type of instrument can also be used for food analysis. The laboratory is also equipped with a Shimadzu 1700 UV – Visible spectrophotometer. Many of the tests carried out on water were based on the use of Hach test kits.

Some 18 months previously, the laboratory had been supplied with a Shimadzu gas chromatograph with a quadrapole – MS detector (QP 2010S). Although the laboratory personnel received some initial training, more specific training had not been provided. As a result, the equipment has remained unused. This, despite the fact that this equipment could be utilized for pesticide residue analysis.

Microbiology

The expert briefly visited the microbiology laboratory. Basic equipment such as a colony counter and stomacher were available. There 3 relatively modern incubators available, although in one case, it was apparent that the temperature regulator was not working correctly. The microbiologist claimed that the incubator was capable of maintaining a correct and consistent temperature and that this was monitored on a daily basis.

Media preparation and sterilization of media, equipment and waste are carried out in another laboratory. It was not possible to visit this part of the laboratory at the time of the expert's visit.

During the course of the visit, the expert noted that a gold fish bowl, complete with fish, was being kept in the microbiology. Such a practice would not be acceptable, particularly where that laboratory is accredited.

Public Health Institute Laboratory – Mostar

Currently the laboratory is located across 2 sites. The laboratory in which water is analysed is located in a modern building whereas the food laboratory is located in an older building, on the site of the local hospital.

At the time of the expert's visit, new laboratories were being constructed in the same building as the current water testing laboratories. It was envisaged that these new laboratories would be available for occupation within 2 or 3 months, at which point, the food laboratory would be transferred. The laboratory's responsibilities include analysis of food, water, materials and articles in contact with food, cosmetics etc.

The laboratory receives samples of domestic food products from the Sanitary Inspectors and imported foods from the Border Inspectors. It faces competition from some private laboratories and from the Veterinary laboratories.

Whilst some surveillance of pesticide residues is undertaken, this is restricted to residues of organochlorine pesticides since the current laws only include limits for a small number of organochlorine residues and PCBs.

Equipment

The **water laboratory** was well equipped and included:

- A Shimadzu 8400S FTIR spectrometer
- A Shimadzu 1700 UV – Visible spectrophotometer
- Equipment for the determination of Total Organic Carbon (TOC) in water
- A Shimadzu high performance liquid chromatograph (HPLC) equipped with a –
- Tertiary gradient solvent delivery system
- Diode array detector
- Fluorimetric detector

The laboratory was also equipped with 2 atomic absorption spectrometers, 1 of which was a Shimadzu AA 6300 equipped with a graphite furnace. The 2nd spectrometer was set up for flame atomization.

Pesticide residues

Preparation of samples for determination of pesticide residues was carried out in a separate laboratory which was well equipped with fume cupboards. Equipment for sample preparation included:

- Vacuum manifold for use with solid phase extraction (SPE) cartridges
- An automated system for clean up of sample extracts by gel permeation chromatography.
- Rotary evaporator

A 2nd laboratory was equipped with gas chromatographs, the use of which included the analysis of sample extracts for pesticide residues. One gas chromatograph was fitted with a flame ionization detector (FID) and an ECD detector. This instrument was suitable for analysis for the presence of organochlorine pesticide residues. The second gas chromatograph was equipped with a Quadrapole – MS detector (Shimadzu QP2010S). Again, this laboratory is not suitably equipped to undertake the analysis of food for organophosphorus pesticide residues.

Water Microbiology

This laboratory was used for the microbiological examination of water samples. The majority of methods used are based on membrane filtration of the water samples. The laboratory was clean and bright and appeared to be most suitable for such work.

Food Analysis

Equipment available in the food testing laboratories included a high performance liquid chromatograph (HPLC) equipped with:

- Tertiary gradient solvent delivery system
- Diode array detector
- Fluorimetric detector
- Autosampler
- Temperature controlled column oven

This equipment was mainly used for the determination of preservatives, including sorbates and benzoates, caffeine, theobromine and intense sweeteners such as aspartame, saccharin etc. This laboratory also undertakes the analysis of food for metallic contaminants. Equipment available for this purpose included:

- Leco AM254 Mercury Analyser
- Ethos D Microwave digestion system
- Varian Spectra AA 110 atomic absorption spectrometer with facilities for:
 - Graphite furnace atomization
 - Flame atomization
 - Cold vapour generation

As far as the expert could tell, back ground correction was achieved by means of a deuterium arc. Other equipment included a Varian Cary UV – Visible spectrophotometer.

In the opinion of the expert, once the food testing laboratory has been relocated, the laboratories of the Public Health Institute in Mostar, will be housed in a modern well fitted out building. The level of equipment is considered to be very good. Without exception, each of the staff appeared to be well qualified and committed to their work.

Public Health Institute Laboratory – Banja Luka

The laboratories are housed in a rather old building to which members of the public, seeking medical advice, also have access.

Food Microbiology

Much of the equipment in this laboratory was rather old. This was particularly true of the incubators and one would seriously question the ability of these incubators to properly maintain the set temperatures. Media is prepared in a separate laboratory.

Water Analysis

This section of the laboratory is certificated by the Ministry of Health for the analysis of drinking waters, mineral waters etc. The majority of the analysis undertaken is by traditional methods. Samples that require analysis for metallic contaminants are passed through to the section of the laboratory that is equipped with an AA spectrometer.

Food Analysis

Equipment for the proximate analysis of food included a Gerhardt Soxtherm apparatus for the determination of fat content. The laboratory was also equipped with a block digestion system and semi automated distillation unit for the determination of the nitrogen content of foods. The conditions in this laboratory were very cramped, to the point that there is a need to question the safety of the staff working there. The laboratory is equipped with 2 spectrophotometers, one of which is a Varian Cary spectrophotometer and the other, a Spectronic Gensys 2. These instruments are used for a variety of analyses including:

- The determination of theobromine in chocolate to estimate the quantity of cocoa solids.
- The determination of caffeine in products such as energy drinks.
- The determination of colours in foods. Bosnian law is not yet aligned with that of the EU and so in a number of cases, products that can be legally marketed in the EU are prohibited from sale in Bosnia.

Atomic Absorption Spectrometry

The laboratory is equipped with a Unicam 969 AA spectrometer with graphite furnace atomization. Facilities are also available for the determination of mercury by the cold vapour generation technique.

Gas Chromatography

The laboratory is equipped with 2 gas chromatographs.

- 1) A Xemo A5 instrument with a flame ionization and a 'Hot Wire' detector
- 2) A Unicam 610 series gas chromatograph with an electron capture detector and a nitrogen selective detector.

Both instruments are rather old and it is likely that the laboratory will find it increasingly difficult to obtain the necessary spares to maintain these instruments in an operational condition.

Liquid Chromatography

The laboratory is equipped with a Pharmacia HPLC system with a UV detector and a fluorimetric detector. We were told that this equipment was used for the analysis of foods for additives such as preservatives and that it was also used as a confirmatory technique for certain mycotoxins, including aflatoxins, patulin, ochratoxins and zearalenone.

Thin layer chromatography and Elisa techniques are also used for ochratoxin, aflatoxin B₁ and zearalenone. The microtitre plates are evaluated using a Tecan Sunrise plate reader.

The laboratory was also equipped with a rather old but serviceable Perkin Elmer 762 Infra-red spectrometer which was apparently used to identify materials such as plastic packaging and for the detection of mineral oil in water.

Proficiency Testing

The laboratory has participated in a number of inter-laboratory studies which whilst not of the same standard as an International proficiency test, have at least enabled the laboratory to gain some independent assessment of their performance.

Radioactivity Monitoring

The laboratory is equipped with a Canberra gamma spectrometer located in a separate area. The equipment is used to monitor food and environmental samples for the presence of gamma emitters such as Caesium 137.

It is expected that by the end of 2007, they will acquire a spectrometer that is capable of being used to detect alpha and beta emitters.

Veterinary Institute Laboratory – Banja Luka

Again, the laboratories are housed in a rather old building which is far from ideal for use as a laboratory.

Microbiology

The first of the laboratories visited only undertakes basic microbiological examination of food. The methods used in the laboratory are as laid down in the law of the former Yugoslav Republic. Activities such as sample preparation, homogenisation, plating out, etc. are carried in one of the two laboratories. Incubators used in the laboratory are rather old and one would question the ability of these incubators to maintain a set temperature, within acceptable limits. The laboratory does however monitor the temperature of these incubators on a regular basis.

The second laboratory is used for the preparation of media. Whilst the laboratory carries out some tests on the prepared media, the reference organisms used for this purpose are from a local source rather than from a recognized culture collection. As far as the expert could see, the laboratory had access to only 1 autoclave, which was presumably used to sterilize media and to sterilize waste, prior to disposal. The laboratory carried out some monitoring for antibiotics etc., using Elisa based tests and tests that rely on the inhibition of bacterial growth. This residue monitoring includes, chloramphenicol, sulphonamides, beta-lactams and beta-agonists.

Analysis of Animal Feeds and Food

A second laboratory of the Veterinary Institute, undertakes the microbiological examination of animal feeds. This examination includes total viable count (TVC), Clostridia, Salmonella, Moulds and E.coli.

This laboratory also undertakes basic chemical analysis of animal feeds and food. The analyses undertaken include those for fat, moisture, protein, calcium etc. At the time of our visit, the laboratory was unable to undertake a number of these analyses, simply because the person responsible for this work was away on maternity leave. Nobody else in the laboratory has been sufficiently trained to undertake this work.

The determination of fat is by the Soxhlet method and protein is determined by the traditional Kjeldahl method. Certainly the equipment available can only be described as basic.

Milk Testing

A separate area of the laboratory has been equipped with automated systems for analysis of milk for payment purposes. Such equipment includes a Fossmatic FT 6000 and a Bactoscan.

Using this equipment, milk can be analysed for fat and protein content, somatic cell count and for a 'total bacterial count'.

Methods of Analysis for Contaminants

Mycotoxins

The majority of laboratories visited, are using ELISA techniques and/or thin layer chromatography as a screening technique for the detection of aflatoxins in food and feeds. Little or no analysis is undertaken for ochratoxins, patulin etc.

Pesticide Residues

In the area of pesticide residue analysis, there appears to be no equipment to enable the determination of organophosphorus pesticide residues. For fruits, vegetables and products of cereal origin, there must be a significant risk that consumers are exposed to such residues and that the EC MRLs for such compounds are exceeded.

In the future, the FSA will have to have access to the equipment necessary to check compliance with the majority of the MRLs set in EU Regulations and Directives, for pesticide residues in food and in animal feeds. The corresponding EU Regulations and Directives are as follows.

- I. Regulation (EC) No 396/2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin.
- II. Regulation (EC) No 178/2006 amending Regulation (EC) No 396/2005 to establish Annex I listing the food and feed products to which maximum levels for pesticide residues apply.
- III. Directive 76/895/EEC, as amended, relating to the fixing of maximum levels for pesticide residues in and on fruit and vegetables.
- IV. Directive 86/363/EEC, as amended, on the fixing of maximum levels for pesticide residues in and on foodstuffs of animal origin.
- V. Directive 86/362/EEC, as amended, on the fixing of maximum levels for pesticide residues in and on cereals.
- VI. Directive 2002/63/EC establishing Community methods of sampling for the official control of pesticide residues in and on products of plant and animal origin.

Recommendations for the Operation of Official Food Control Laboratories in Bosnia & Herzegovina.

1. Regardless of the origin of food, laboratories involved in the Official Control of Food should be required to provide an impartial and confidential service to the Food Safety Agency.
2. There should be adequate funding of the laboratories by Central or Local government to enable them to undertake the necessary chemical analysis and microbiological examination of food and animal feeds.

3. The food manufacturers should not be required to pay for the analysis and/or examination of samples, taken by inspectors, as part of their activities in the Official control of Food or of Animal Feeds. Neither should they be compelled to take out a contract to submit a certain number of samples to an official laboratory, in addition to those that are taken by inspectors as a part of their inspections.
4. Instead, food producers and processors should be encouraged to take responsibility themselves for ensuring the food sold by them is both wholesome and safe. Given that many of the food manufacturers are relatively small, it is not reasonable to expect that they can each sustain their own laboratory facilities. For this reason, the establishment of independent laboratories to undertake analysis on a commercial basis, should be encouraged.
5. The Official laboratories must be managed in such a way that –
 - There are no conflicts of interest that could affect, or be thought to affect, their conclusions.
 - Staff are not under undue pressure that could affect the quality of analysis or its interpretation.
6. The Official Laboratories must –
 - Have policies and procedures to ensure the protection of its clients' confidential information and proprietary rights, including procedures for protecting the electronic storage and transmission of results.
 - Have policies and procedures to avoid involvement in any activities that would diminish confidence in its competence, impartiality, judgement or operational integrity.
7. The staff employed in the Official Laboratories should be suitably qualified and experienced.
8. The management team should include at least one person who has –
 - A detailed knowledge and understanding of food, its chemical analysis and microbiological examination.
 - A detailed knowledge and understanding of relevant law
 - Investigational skills to identify faults with food and to deal with problems with analysis
 - The ability to interpret analytical results in the light of the law.
 - If required and in support of the competent authority, the ability to act as an expert witness and present legal evidence in writing or in person.
9. Laboratory staff should not be directly involved in sampling food or feed. This must be the sole responsibility of the Inspectors, appointed by the competent authority. However, their expertise should not be ignored as they may well be able to offer advice to the inspectors, particularly in respect of sampling for microbiological examination and sampling for certain chemical contaminants.
10. An adequate number of properly equipped and adequately funded laboratories are required to carry out the routine analysis and microbiological examination of food and feeding stuffs.
 - These laboratories could be expected to cover –
 - Proximate analysis
 - Labelling verification
 - Preservatives
 - Colours
 - Sweeteners
 - Total Viable counts

- Coliforms
 - Escherichia coli
 - Staphylococcus aureus
 - Salmonella spp.
 - Listeria spp.
 - Yeasts and Moulds
- 11.** One or possibly two laboratories are required to cover the more specialised chemical analysis of food and feed stuffs. Such analysis includes
- Metallic contaminants – Lead, Cadmium, Mercury, Arsenic etc.
 - Pesticide residues – Organochlorine, Organophosphorus, Fungicides (thiocarbamates) etc.
 - DNA techniques including GM analysis by the use of real time PCR
 - Mycotoxins – aflatoxins, ochratoxins etc.
 - PCBs, dioxins
 - Nitrates – vegetables etc.
 - 3 Monochloro – propane – diol (3-MCPD)
 - Veterinary residues
 - Vitamins
 - Food contact materials
 - Detection of Irradiated food
 - Monitoring of food for radio isotopes
- 12.** To perform these specialised analyses the following equipment is required.
- GC including GCMS. In addition to GCMS, gas chromatographs fitted with ECD, NPD and FID detectors are required.
 - For certain applications, high resolution GCMS may be required. This is particularly true if it is envisaged that Bosnia & Herzegovina will carry its own surveillance for dioxins.
 - An automated system for gel permeation chromatography is beneficial when applying multi-residue techniques for the determination of pesticide residues.
 - HPLC. The majority of applications require isocratic separations but in some cases gradient elution is more effective and is particularly useful when methods are being developed. For this reason, at least one system should be available that includes a quaternary gradient, solvent delivery system. Other requirements include a diode array detector and for the reliable detection of low levels of aflatoxins, a fluorescence detector together with a reactor for post column derivatisation.
 - LCMSMS may be required for confirmation of certain veterinary medicine residues.
 - Atomic Absorption fitted with a graphite furnace atomiser and Zeeman background correction. A second system should be available for use with flame atomisation and in conjunction with a hydride generation system for the detection of elements such as arsenic, selenium etc.
 - For multi-element analysis e.g. mineral waters an ICP – OES system may be required.
 - Mercury analyser. This may be a stand alone system of sufficient sensitivity or a cold vapour generation system for use in conjunction with an atomic absorption spectrometer.
 - Electrophoresis techniques
 - Immunoassay techniques
 - DNA techniques e.g. real time PCR for the detection of GM food, ingredients and feedstuffs.
 - Microscopy
 - Infra Red Spectroscopy
 - Extraction techniques (Super Critical Fluid etc.)
 - Radioisotope monitoring – since γ emitters are of most significance, a gamma spectrometer is most appropriate.
 - UV/visible spectroscopy

- Unified Laboratory Information Management Systems (LIMS) systems including database links
 - Effective information systems including access to relevant journals
13. A number of the existing laboratory facilities need to be upgraded to allow for proper provision of ancillary facilities e.g. piped gas supplies for gas chromatography, atomic absorption spectrometry, ICP etc.

Adequate provision of fume cupboards.

- Clearly separated areas for –
- General wet chemistry
- Extraction of pesticide residues, veterinary residues, mycotoxins etc.
- Preparation of samples for trace metal analysis
- Gas chromatography and liquid chromatography
- AAS and ICP – OES

Facilities for microbiological examination of food require significant upgrading e.g. flooring with coving to walls, walls that are easily cleaned, benches that provide a continuous surface that can be readily cleaned and disinfected.

- experienced in the inspection of food premises,
- have received additional training
- and have demonstrated their competence to undertake inspections of high risk activities.

ANNEX 4: Indicative equipment supply needs for reinforced implementation of the food safety legislation in BiH

1. Procurement of smaller equipment for the sampling and inspection

The envisaged equipment would be provided by the complementary World Bank's IDA facility and IPA 2007 project "Support for implementation of the IPPC Directive". It will include the following:

- Provision of equipment for routine sampling of foods and feeds for chemical analysis and microbiological examination.
- Provision of specialized equipment for sampling of consignments of cereals, groundnuts etc., for enforcement of regulations on contaminants in food and for undesirable substances in animal feeds.
- Provision of vehicles for food and feed control inspectors. Note: an inventory should be made of the real need of the number of vehicles in this regards as some existing cars can still be used.

Sampling and inspection

The quality of the data obtained from the chemical analysis or microbiological examination of food or animal feed samples is highly dependent upon the quality of the samples submitted to the laboratory. It is essential that sampling officers take samples in such a way as to not compromise their integrity by either contaminating such samples by use of inappropriate techniques, implements, sample containers etc.

There is need to strengthen the capacity of the food and feed inspection services by providing suitable equipment for taking samples, maintaining them in a fit state during transport from the field to the laboratory and ensuring that sampling officers have access to adequate vehicles in which to transport samples.

There are a number of EC Regulations regarding sampling of food for analysis of contaminants and for pesticides. These are as follows.

I. Regulation (EC) No 401/2006 laying down the methods of sampling and analysis for the official control of the levels of mycotoxins in foodstuffs.

II. Directive 2003/78/EC laying down the sampling methods and the methods of analysis for the official control of the levels of patulin in foodstuffs.

III. Directive 2001/22/EC laying down the sampling methods and the methods of analysis for the official control of the levels of lead, cadmium, mercury and 3-MCPD in foodstuffs.

IV. Directive 2002/63/EC establishing Community methods of sampling for the official control of pesticide residues in and on products of plant and animal origin.

2. Procurement of the laboratory equipment

As said before, appropriate laboratories (adequately equipped and accredited) for showing clear evidences of hazards should be in place. It certainly will take time to put this assistance fully in place. A short mentioning of the required important four analyses – each with its specific lot of equipment - will complete this proposal for projects to be carried out on food safety aspects:

The equipment envisaged to be procured from subsequent IPA assistance includes:

Lot 1: Analysis of food and animal feeds for the presence of organochlorine and organophosphorus pesticide residues.

The principle equipment requirements are:

a. Gas chromatograph fitted with capillary injectors, auto sampler and ECD detector for the determination of organochlorine pesticide residues.

B. Gas chromatograph fitted with capillary injectors, auto sampler and NPD (flame photometric) detector for the determination of organophosphorus pesticide residues.

C. Gas chromatograph fitted with capillary injectors, auto sampler and supplied with a mass spectrometric detector for use as a confirmatory technique in the determination of organochlorine and organophosphorus pesticide residues.

Ancillary equipment to enable efficient clean up of sample extracts and to minimise the risk of contamination leading to false results.

To allow for a high throughput of samples it is recommended that an automated system for clean up of sample extracts by gel permeation chromatography be provided.

By providing this equipment it will be possible to extend the range of analyses undertaken to include the determination of organophosphorus pesticide residues in cereals, fruits and vegetables etc. Currently it would appear to be the case that little or no surveillance of such residues is undertaken.

At the same time the FSA will have the equipment necessary to check compliance with the majority of the MRLs set in EU Regulations and Directives, for pesticide residues in food and in animal feeds. The corresponding EU Regulations and Directives are as follows.

I. Regulation (EC) No 396/2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin.

II. Regulation (EC) No 178/2006 amending Regulation (EC) No 396/2005 to establish Annex I listing the food and feed products to which maximum levels for pesticide residues apply.

III. Directive 76/895/EEC, as amended, relating to the fixing of maximum levels for pesticide residues in and on fruit and vegetables.

IV. Directive 86/363/EEC, as amended, on the fixing of maximum levels for pesticide residues in and on foodstuffs of animal origin.

V. Directive 86/362/EEC, as amended, on the fixing of maximum levels for pesticide residues in and on cereals.

VI. Directive 2002/63/EC establishing Community methods of sampling for the official control of pesticide residues in and on products of plant and animal origin.

Lot 2: Analysis of food and animal feeds for the presence of metallic contaminants, including lead, mercury, arsenic, etc.

The principle equipment requirements are:

- a. Microwave digestion system for preparation of samples.
- b. Atomic absorption spectrometer with Zeeman background correction supplied with
 - 1) Graphite furnace atomisation system
 - 2) Autosampler suitable for use with the graphite furnace
 - 3) Accessory for hydride generation for the determination of arsenic etc., and for the determination of mercury by cold vapour generation

By providing this equipment the FSA will have access to the equipment necessary to check compliance with the limits set for metallic contaminants in EU Regulations and Directives controlling the occurrence of metallic contaminants in food and in animal feeds. This equipment will also be required should the FSA decide to undertake additional surveillance of the occurrence of metallic contaminants in foods and animal feeds, for the purpose of risk assessment. The corresponding EU Regulations and Directives are as follows.

I. Directive 2002/32/EC, as amended, on undesirable substances in animal feed.

II. Regulation (EC) No 221/2002 amending Regulation (EC) No 466/2001 setting maximum levels for certain contaminants in foodstuffs.

III. Regulation (EC) No 78/2005 amending Regulation (EC) No 466/2001 as regards heavy metals.

IV. Directive 2001/22/EC laying down the sampling methods and the methods of analysis for the official control of the levels of lead, cadmium, mercury and 3-MCPD in foodstuffs.

Lot 3: Analysis of food and animal feeds for mycotoxins, including aflatoxins B₁, B₂, G₁, G₂ and total aflatoxin (B₁, B₂, G₁, G₂), aflatoxin M₁, ochratoxin, patulin etc.

From the experts preliminary visits to laboratories it would appear that the enforcement authorities do not have the equipment available to detect mycotoxins at the low levels specified in EC regulations. In that case, they are unable to effectively enforce the EU limits that apply. A further consequence of this lack of suitable equipment will be the risk that consumers in Bosnia and Herzegovina will be exposed to unacceptably high levels of mycotoxins in particular categories of food, since there is no effective control of imports.

It is suggested that this area should be a priority for the FSA in any planned surveillance for the purpose of risk assessment. Special attention should be paid to the possibility of the occurrence of aflatoxin M₁ in milk and dairy products arising from the feeding of animals with feedstuffs that may be contaminated with aflatoxin B₁.

The principle equipment requirements are:

- a. Solid phase extraction unit, suitable for use with immuno-affinity columns for sample preparation and extraction.
- b. High performance liquid chromatograph equipped with a quaternary gradient pumping system, autosampler, column oven, fluorescence detector and post column derivatisation system.

The relevant EU Regulations and Directives are as follows.

I. Directive 2002/32/EC, as amended, on undesirable substances in animal feed.

II. Regulation (EC) No 257/2002 amending Regulation (EC) No 194/97 setting maximum levels for certain contaminants in foodstuffs and Regulation (EC) No 466/2001 setting maximum levels for certain contaminants in foodstuffs.

III. Regulation (EC) No 472/2002 amending Regulation (EC) No 466/2001 setting maximum levels for certain contaminants in foodstuffs.

IV. Regulation (EC) No 1425/2003 amending Regulation (EC) No 466/2001 as regards patulin.

V. Regulation (EC) No 401/2006 laying down the methods of sampling and analysis for the official control of the levels of mycotoxins in foodstuffs.

VI. Directive 2003/78/EC laying down the sampling methods and the methods of analysis for the official control of the levels of patulin in foodstuffs.

Lot 4: Analysis of food for veterinary drug residues.

Council Regulation No 2377/90 of 26 June 1990 lays down a Community Procedure for the establishment of maximum residue limits (MRL) of veterinary medicinal products in foodstuffs of animal origin.

There are a number of annexes to this regulation. These annexes are updated on a regular basis as is evident from the number of amendments published to the original regulation.

MRLs are set for a diverse range of chemical substances.

Given that Bosnia Herzegovina are experiencing difficulties in obtaining approval for export of poultry and honey to EU Member States there is an urgent need to establish laboratory facilities to enable a comprehensive survey of such products to be undertaken. If such analyses were also undertaken on imported animal products, the combined data would be available to the FSA and so enable them to perform a risk analysis in respect of the occurrence of such residues in food consumed in BiH.

The analysis for veterinary drug residues requires additional equipment:

- Equipment for use with screening tests such as those based on inhibition of bacterial growth or ELISA techniques
- HPLC-MS-MS to determine the presence of specific residues and to confirm the results of initial screening tests.