

Twinning-Project Bosnia-Herzegovina  
Project title: Support to the State Veterinary Office  
EU-Project number: BA05/IB/AG/01

16.11.2006

Short-Term Mission on

**Activity 1.1 “Assessment, analysis and follow-up of key factors for  
functional organisation and training  
- Laboratory-**

**Mission report**

**Names of experts**

1. PD Dr. Lüppo Ellerbroek, BfR, Berlin, Germany
2. Dr. Michael Djuren, LAVES Veterinärinstitut Oldenburg, Germany

**Objective and task of the mission:**

The objective of the activity is to carry out a gap analysis of the regulatory and institutional framework of Bosnia and Herzegovina (BiH) for acquis alignment in the veterinary sector regarding the analysis of present organisation, structure and technical capacity of the veterinary laboratories and assessment of inspection bodies organisation and quality assurance for testing laboratories. The ongoing education and technical updating schemes will be considered as well.

Date of visit: November 05 – 09 November, 2006

05<sup>th</sup> November 2006: Arrival at Sarajevo ; Briefing with the RTA Dr. Schollmeyer

06<sup>th</sup> November 2006: State Veterinary Office (SVO);  
Veterinary Institute of Veterinary Faculty Sarajewo

07<sup>th</sup> November 2006: Veterinary institute “Dr. Vaso Butozan”, Banja Luka

08<sup>th</sup> November 2006: Veterinary Institute Mostar

09<sup>th</sup> November 2006: Final meeting in Sarajewo; Departure

## Identification of activities during the visit

### a. Meeting at the SVO

Dr. Sc. Nihad Fejzic – Deputy Head of SVO

### b. Visit at Veterinary Institute of Veterinary Faculty Sarajevo

Preliminary discussion

Prof. Jazic Adnan – Deputy Head of the Laboratory

DVM Sanin Tankovic, assistant SVO

DVM Zorana Mehmedbasic, assistant SVO

Dr. Karoline Schollmeyer, RTA

DVM Edin Lendo, RTA-assistant

Visit in the laboratories

Prof. Abdulah Gagic, Head of laboratory for poultry diseases

DVM Davor Alagic, senior assistant, Food Hygiene and Food Technology

DVM Muhamed Smajlovic, senior assistant, Food Hygiene and Food Technology

MSc DVM Maid Rifatbegovic, Department of Microbiology

DVM Ramiz Velic, Head of Laboratory for epizootiologie

### c. Visit at Veterinary Institute “Dr. Vaso Butozan” in Banja Luka

Preliminary Discussion with following visit in the laboratories

Mr. Branko Bjelajac, General Manager

Mr. Rodoljub Trkulja, Head of the Laboratory

DVM Aleksandra Babic , Dairy and Quality System

DVM Radovan Babic, epizootiologie and microbiology, pathology, laboratory for BSE

DVM Violeta Santrac, DVM, serology

DVM Kalaba Vesna, Food Hygiene and Residue Control

DVM Sanin Tankovic, assistant SVO

DVM Zorana Mehmedbasic, assistant SVO

Dr. Karoline Schollmeyer, RTA

DVM Edin Lendo, RTA-assistant

### d. Visit at Veterinary Institute Mostar

Preliminary discussion with following visit in the laboratories

Mr. sci. DVM Milan Adrijanic, Director of the Institute

DVM Sanin Tankovic, assistant SVO

DVM Edin Lendo, RTA-assistant

### e. Final Meeting at the Veterinary Faculty Sarajevo

Dr. Sc. Nihad Fejzic – Deputy Head of SVO

DVM Sanin Tankovic, assistant SVO

DVM Zorana Mehmedbasic, assistant SVO

Dr. Karoline Schollmeyer, RTA

DVM Edin Lendo, RTA-assistant

DVM Sanin Tankovic, assistant SVO

Representatives of the laboratories in Sarajevo, Banja Luka, Mostar and other laboratories.

## Introduction

International/world wide trade with food and animals has a tendency for globalisation. In 2000, business volume for food extends to 1.000 billion EURO, which was approx. 10 % of the world market (only 30 commercial enterprises). Further on it has a tendency for merger. All foodstuffs are available around the year world wide.

These trade attitude has a high potential for internationalisation of pathogens and a risk of spread for residues and contaminants.

Many international organisations like OIE, WHO, FAO, Codex Alimentarius work on security of global trade in animals and animal products together with surveillance and control of animal diseases. Harmonisation of health standards for international trade concerning animals and products can be found in the International Animal Health Code of the OIE to assist the development of health regulations in Member states.

The EU follows their principle „Safe food from healthy animals“. This principle includes measures on the whole food chain, beginning at the animal health status, including slaughter, processing and retail.

It can be summarised that Global trade increases tremendously and food safety aspects are of high concern (FAO, WHO, OIE). Regulations regarding the global trade and food safety aspects are implemented by WTO, Codex Alimentarius Commission, OIE.

According to a statement of the CVO of Bosnia-Herzegovina (BiH), currently 8 veterinary laboratories were authorised by a BiH-decision.

Three National Reference Laboratories (NRL) in BiH are authorised according to a BiH-decision for 12 elected diseases. A sampling/work plan is established by CVO. For each sample of the 12 elected diseases, the state of BiH payed a fixed charge to the NRLs. A National Residue Plan is compiled by the CVO. Sampling and laboratory work is financed by a state budget.

Following the discussion with the heads of laboratories, the implementation of decision (which is in force since a few month) for staffing, budget, equipment is pending.

Chain of command for NRLs is from the CVO to the state vet administration at the NRL and Border Inspection Posts(BIP). Regional Laboratories are authorised by the entities.

To evaluate the current situation concerning key factors for functional organisation an training of the laboratories, three laboratories working as National Reference Laboratories (NRL) for BiH were visited:

1. Veterinary Institute of Veterinary Faculty Sarajewo (S) representing 7 NRL
2. Veterinary Institute "Dr. Vaso Butozan" in Banja Luka (BL) representing 5 NRL
3. Veterinary Institute Mostar (M) representing 2 NRL

## **The overall findings can be summarised as follows:**

### **Legal basis**

Decision concerning NRL seems to be practically not in force. Legal base of laboratories is based partly on legislation of the entities as well as on legal grounds of former Yugoslavia and not uniform in BiH. The competence of SVO in matters of food hygiene is not given. The Food Safety Agency (FSA), which is founded some month ago, is responsible for matters of food hygiene. There is no cooperation established between SVO and FSA.

#### **Recommendations concerning the legal basis of laboratories:**

Legal base has to be clarified and more transparent concerning food hygiene and animal disease. Co-ordination between SVO, FSA and laboratories to determine tasks, resources and strategies seems to be necessary.

### **Administration/Organisation**

Chain of command for laboratories between SVO and laboratories is not clear (except residue control in the frame of the National Residue Control plan). In the organigrams, presented NRL and responsible persons were not defined and organigrams are not reflecting the actual conditions (i.e. performance of residue controls in BL in the department of serology).

#### **Recommendations concerning the administration and organisation:**

Personal structure of NRL should be visible in organigrams of the respective laboratories including introduction of the head of NRL and staff. Designation of further NRL in the field of food hygiene relevant hazards (e.g. Salmonella, Trichinella, TB) seems to be necessary.

### **Layout of laboratories (rooms); maintenance of rooms**

Important and relevant safety deficiencies were seen in the layout of laboratories used. In one case (avian disease department) substantial efforts are taken, to correct this situation, but lack of financial resources has delayed the finalisation of the room equipment. Pathology units had direct access to outside, thus protection against pathogens may not be sufficient. Waste control and control of infectious waste needs to be improved. Separation of „black/white“ areas (i.e. rooms for lunch and coffee were not clearly separated from laboratories, where pathogens were investigated and processed. Biosecurity level (BSL) 2 requirements are not fulfilled (i.e. walls, ceilings, tables etc. not appropriate to BSL 2).

#### **Recommendations concerning the layout of laboratories:**

A fundamental and conceptional review (potentially from an external reviewer) of the layout of all laboratories to fulfil BSL 2 seems to be necessary (at least for the NRLs).

### **Staff / education**

During the visit, great deficiencies in practical and daily hygiene performance could be noticed (use of cleaning and disinfection procedures, use of protective clothing, access authorisation etc.). For personnel working in the laboratories detailed competence profiles are needed.

#### **Recommendations concerning staff:**

Enforcement of continuing education and advanced training should be implemented in routine laboratory work.

### **Performance of laboratory tests**

Methods are dependent on/oriented towards equipment currently available in laboratories and with respect to NRL not always according to international standard. Especially for analysis of samples and confirmation tests equipment is not adequate (residue control: i.e. lack of HPLC, GC, MS; microbiology: i.e. molecular techniques rarely applied).

Written technical instructions and methods (SOPs) should be at hand in NRLs to ensure continuous and uniform application of laboratory methods. No or rarely ring trials or exchange of test material between BiH laboratories were carried out.

#### Recommendations concerning the performance of laboratory tests:

Introduction of standardised methods layed down in NRL laboratory manuals including regular actualisation on latest scientific standards (AOAC, CEN, EU etc.). Laboratory equipment to run NRLs both for microbiology and residue control should be modernised. Ring trials should be established in every laboratory.

### **Quality Management (QM)**

QM procedures were (with the exception of some areas of work) rarely in place.

#### Recommendations concerning quality management:

Immediate implementation of QM measures for laboratory tests is indispensable. QM-Manager has to be appointed in every laboratory. Note: The director of an institute can not be the QM-Manager.

### **Accreditation**

Accreditation is foreseen, but still there is no plan to reach the status of accreditation. Uncertainties on the organisation of accreditation for BiH resulted in further delay. No working group(s) existing within laboratories and between laboratories in BiH to prepare for accreditation procedure.

#### Recommendations concerning accreditation:

Immediate appointment of state accreditation organisation (potentially it is the Institute for Accreditation of Bosnia and Herzegovina - BATA) according to ISO 17025 standard in BiH, should call meetings for preparation of first steps for accreditation and preparation of check list for duties to reach accreditation.

In a first step all laboratories should have a consulting about accreditation. After implementation of the requirements necessary for accreditation, the laboratories should apply for accreditation at the state accreditation organisation.

### **Short term / medium term /long term perspectives for laboratories**

The current situation concerning the financial budget, the equipment and personnel needed and the competence profile as well as the specific area of work seems to be unsatisfactory.

#### Recommendations concerning short term / medium term /long term perspectives of laboratories:

In the first step, an intensive co-ordination between SVO, FSA and laboratories is needed. A current and future strategy for laboratories in BiH with respect to competence and area of work and work plan should be developed. This should include clarification on the financial budget necessary for NRLs.

Further on, additional resources are needed with respect to laboratory equipment and personnel.

Additional laboratory activities in relation to current food hygiene and animal hygiene hazards (i.e. Brucella, AI, TB, Leucosis, Trichinella etc.) are needed.

**General remarks and conclusions**

- coordination between SVO, FSA and NRL laboratories is needed (legal basis, work plan etc.)
- accreditation status is essential for all laboratories
- conceptional review of all laboratory layout (safety aspects, biosecurity etc.) necessary
- improvement of technical equipment needed (molecularbiology, chemical analysis etc.)

----- (Signature)  
PD Dr. Lüppo Ellerbroek

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Dr. Michael Djuren