

Mission Report on Activity 5.4 “Preparation for accreditation“ within CARDS Twinning Project BA05 IB AG 01 Sarajevo, Banja Luka from 17th – 20th of June 2008

Names of experts:

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The purpose of the training activity was to give assistance in the establishment of quality management systems in BiH laboratories so they can complete process of accreditation as soon as possible

Report on the visit of the veterinary institute ‘Dr. Vaso Butozan’ in Banja Luca (BL) in June 18th 2008

During an introductory meeting, the head of the institute, Dr. Despotovic, and the quality manager, Dr. Violetta Sandrac, informed about the progress and improvement towards the accreditation process since the last visit and the study visits of experts in the LAVES institute in Oldenburg and vice versa.

Afterwards the laboratories were visited together with the leaders of the respective laboratories.

During the final meeting in the institute the situation was reviewed as follows:

A quality manager (QM) is already appointed and first steps for the accreditation have been made. The achievements are based on the experience of the LAVES-Institute in Oldenburg made especially by Violetta Santrac, the appointed QM in BL, by studying quality management documents. Plans were made to establish two departments for food hygiene and zoonoses/animal disease control to concentrate the laboratory activities in BL.

At the beginning documents were presented by the QM and discussed. Good progress was seen to initialise the accreditation procedure in BL. Activities are currently concentrated to certain methods in laboratories and areas of work but not for the BL laboratories in general. The chosen procedure (accreditation of methods and not of laboratories in general) may imply additional formal bureaucracy with the accreditation body, because every single change in an accredited method has to be announced to the accreditation body and is subject to a new "accreditation" or permission by the accreditation body. Further discussion on the chosen accreditation procedure with the national accreditation body (BATA) with respect to this is encouraged. As a help a copy of the technical competence profile of the Veterinary Institute Oldenburg was presented.

The technical competence profile and the organigram of BL is currently not available but in process. Master SOPs are also under preparation as well as technical forms on devices and equipment. Examples of SOPs technical forms for devices and equipment were shown. Together with the structure of the institute technical competence profiles have to be established. For all methods used for investigation a SOP has to be prepared. The different laboratories should use the same form for the SOPs. First SOPs have been developed.

The status of the BL outpost Bijeljina was discussed. According to our recommendations and experience in LAVES institutes, Bijeljina should be an integrated part of the BL institute and therefore subordinated to the BL institute director and the two departments. The organisation in the BL institute should be transparent including tasks and personnel of Bijeljina branch.

With regard to the laboratory practice and consultancy of customers in the field, all laboratory samples should be treated and investigated on an independent base. Consultancy of customers - which is currently done by persons who are involved at the same time in laboratory investigation of field samples - can lead to conflict of interest if customers receive private consultancy from persons who are involved in official sampling and analysis at the same time. It is advised to follow the guidance given by ISO/IEC 17025 (see paragraph 4.1.4) where interference between private consultancy and official control activities should be avoided in any case.

During the visit of the laboratories some deficiencies are still to be seen. The sample reception is well structured and centralised for both departments (animal disease control and food hygiene) of the institute.

The visited laboratories for pathology and TSE-diagnostic revealed some deficiencies while the rooms used for necropsy and the autoclaves seemed to be not on the state of the art. The BSE laboratory has practised approx. 6.000 samples per year but no national regulations are available for BSE/TSE investigation in BiH. It is recommended to follow the detailed directives of the EU with respect to safety issues. In case of a positive sample it seems to be difficult to sanitise the laboratories under the given circumstances.

In the laboratory for serology many samples were handled due to a high turnover. Due to the aerial structure of the laboratory and given safety facilities in this laboratory biological safety measures could be improved. Pathogen organisms are processed in rooms which have to be passed by personnel to reach other rooms and working positions. This may result in cross contamination and may pose an occupational risk. *Brucella melitensis* (which is currently present in the field samples in a frequency of 5-7%) is classified in the risk category 3. The presence of this pathogen requires special precaution measures towards occupational risks and work places with directed air flow is recommended (see also Directive 2000/54/EC of the European Parliament and of the Council of 18 September 2000 on the protection of workers from risks related to exposure to biological agents at work).

In **summary** progress in accreditation is seen together with a positive attitude towards accreditation.

For future activities it has to be mentioned that after implementation of accreditation procedures have to be implemented practically too and should not remain theoretical demands. Furthermore an achieved and established quality laboratory level should be continuously practised. The director of the institute should encourage the QM and help the QM in her tasks. Since not all rooms are currently in an accredited status some improvements are necessary.

Report on the visit of the University of Sarajevo in Sarajevo in June 19th 2008

During an introductory meeting, the head of the university (dean) was absent but her deputy (Professor Dr. Adnan Jaszic, head of the fish department), the quality manager Dr. Aida Kavazovic and Prof. Dr. Amina Razidbegovic informed about the progress and improvement towards the accreditation process since the last visit and the study visits of experts in the LAVES institute in Oldenburg and vice versa.

Afterwards the poultry disease and food hygiene laboratories were visited together with the leaders of the respective laboratories.

The institute (which is equivalent with the laboratories performing official control) is integrated in the university. Out of the existing laboratories situated in the different university departments four centres are planned: Laboratories for poultry disease, food control, veterinary drug control and animal health. A central laboratory outside the university campus (in Stub) is planned to concentrate all animal disease laboratories. The head/dean of the university is currently appointed as head of the institute which is seen as not practical because of double loading in University (political decisions, education, administration, research) and in the Investigation Institute. The last job alone is more as a fulltime job.

Another problem is the conflict of interest between official tasks and private consulting for customers. This issue is already mentioned in the context of the Banja Luca laboratories.

A quality manager (QM) and heads and deputies of the laboratories have already been appointed. In this year only a few laboratories will apply a application for accreditation (poultry diseases, fish diseases, parasitology, bacteriology and virology).

Few accreditation documents are prepared and presented in a premature state. An organigram of the institute will be prepared but is at the moment not available. Sample reception is still distributed and every separate laboratory/department has its own solution. It is planned to centralise the sample reception for the whole institute (at the latest in the new building in Stub).

The reception documents in the laboratory for poultry disease are structured but they are not in the food department, where sufficient documentation on the routine analysis of samples is not available.

Quality assurance documents are currently in process as well as master SOPs. Methods and documents for devices are not available but in process. New methodical SOPs exist only in the laboratories for poultry and fish diseases.

A technical competence profile of the institute is currently not available. Master SOPs are also in development as well as technical forms on devices and equipment. Together with the structure of the institute technical competence profiles have to be established.

To **summarize** the current activities in the university, two main handicaps were identified:

1. The planned institute will be still an integral part of the university which will initiate conflict of interest between independent sample analysis and private consultancy with customers.
2. The institute is still subordinated to the head/dean of the faculty which may anticipate the full attention of the dean for the institute, which is necessary especially during the initial phase of institute establishment.

Although efforts are made in construction of rooms for the poultry department insufficient progress was seen in the formal accreditation process (preparing of documents, infrastructure and responsibilities).

A hard working QM alone can not perform all the accreditation work. She must have the active help of her superior and all co-workers and not only in the phase of accreditation.

Implementation of accreditation procedures are indispensable for National Reference Laboratories for food control and an identification for foreign acceptance of their results in analysis. Accreditation procedures have to be implemented also practically and should not remain as theoretical procedures. Furthermore an achieved and established quality laboratory level should be continuously practised. It seems to be questionable whether the dean of the university has the time and energy to encourage the QM and help the QM in her tasks. While only few rooms are visited and not all rooms are currently in an accredited status further structural improvements are necessary.