Report and recommendations on EU CRL visit to the Veterinary Diagnostic Laboratory in Serres, Greece, the Greek National Reference Laboratory for group A1, A3, A4 compounds, 7-8 June 2005

Introduction
On June 7-8 2005 a EU CRL representative, Drs. S.S. Sterk (NL) visited the Veterinary Diagnostic Laboratory in Serres in the north of Greece. The purpose of the visit was to stimulate and assist the laboratory on technical and quality issues. The CRL expresses its appreciation to the director, Dr. Th. Dabalis and the staff of the laboratory for their open discussions and their kind hospitality.

General management
The Laboratory in Serres is located in the north of Greece. The laboratory facilities are currently being rebuilt. A new sample reception and storage room is being created. Laboratory rooms are available and a new room was created for LC-MS/MS analysis.
In general, facilities are good as the equipment and housing is concerned.
The staff situation however, is more complicated.
During my visit only the Director of the NRL, Dr. Th. Dabalis, had a permanent position. Two analytical chemists worked on contract basis for 8 months per year and were due to start again after the summer. One veterinarian was also appointed on a permanent position. For the actual work in the NRL this means that only 1 person was able to perform analyses during this period. Functions as Director, QA-officer, technician performing the actual analysis were all in one person combined.
This situation was also mentioned in the FVO report of a mission carried out from 4-8 April 2005. Under these conditions, complying with the requirements for accreditation according to ISO 17025 becomes a difficult task.
Further, being a NRL and also being responsible for the routine sample analysis within the Greek National Plan is not a desirable situation. During one of the EU CRL workshops held in Bilthoven, the NRLs already supported the conclusion that the combination of NRL and RFL tasks is not a desirable one. Especially with the situation in Serres where permanent staff appointments are not the case, fulfilling both tasks becomes very difficult.
The NRL received funding from the EU to prepare for accreditation, but here too, the availability of staff to prepare for this accreditation is the limiting factor.

Recommendations:
In the situation of the NRL in Serres it is strongly recommended that staff is appointed on a permanent basis. The minimal number of staff necessary to fulfil the NRL and RFL tasks is 1 director, 1 veterinarian, 2 analytical chemists, two
Specific comments and recommendations
During the visit to the laboratory several topics were discussed. Below an overview of the comments and recommendations per subject are given.

Sample reception and handling
During the visit building activities were ongoing to build a separate reception room for samples. Also refrigerated and freezer storage facilities for the samples will become available in the new sample reception room.

Samples are received and information is written in a logbook. Also a unique sample code is generated for the sample. However, there is no SOP on sample reception and on acceptance criteria for the samples. Visual inspection of the sample is performed.

In practice a lot of samples are not sent in with good containers or are thawed upon arrival. Samples are not split in a sample for contra-expertise or for different methods. Samples are sent in for one specific method.

There is no limit to the reporting time. The outcome of the analysis is not something to take actions upon.

In the first six months of 2005 no samples were received. In total 900 samples have to be analysed in 2005.

Recommendation:
- Description of procedure for sample reception and acceptance criteria for samples.

Analytical methods
Not all methods of analysis used are fully validated. For DES analysis a new method was developed and validated and described in a SOP format with version numbers and dates. Control of instruments before analysis is not performed according to a prescribed procedure. Control charts are available with the equipment.

There are no SOPs on how to prepare, check quality and keep standard solutions. The availability of standards is difficult due to a strong governmental involvement in the buying procedures.

Standards have no expiration date and are used until they are finished.

Criteria for acceptance of analytical runs and non-compliant samples are not written down. During a mini-audit 0.2 ppb trenbolon was shown in an unknown sample but this was not reported and no actions were undertaken.

Recommendations:
- Procedure for preparation and control and acceptance of standard solutions.
- Procedure for acceptance of analytical runs and non-compliant samples.
- Support or own responsibility for buying standards and consumables is needed.
- Training of chemists and
technicians in the CRL would be helpful but this can only be done when permanent staff is appointed.

Quality system

In the NRL the function of independent Quality Assurance officer is fulfilled by the director. Combination of these two functions can lead to a conflict of interest. Extension of the staff of the laboratory with a QA-officer is urgently needed. Especially in the period of preparation for the ISO 17025 accreditation. A QA-manual, audit scheme, archiving procedure and staff education plans are some of the items missing in the organisation.

Recommendation:
- Appointing an independent QA-officer is urgently needed.
- Extending the appointment of a QA-officer during the accreditation phase is needed. After accreditation is vested the amount of time spent on QA business can be lower. However, maintaining a QA-system within a NRL will cost approximately 15% of the time.

National Plan

Data in the National Plan with regard to laboratory methods and detection limits are not reflecting the actual used methods and detection limits. Example given DES detection limit is not 0.2 ppb but 2 ppb.
For natural hormones the detection limits are higher then the levels of actions.

Concluding remarks and priority recommendations

A lot of the things that need attention can be dealt with faster when the situation with regard of the personnel is solved. Staff with permanent positions and more laboratory technicians are necessary to fulfil all tasks that need to be fulfilled by a National Reference Laboratory and Routine Field Laboratory. Combination of both NRL and RfL is not a preferable thing but when this is the case extra attention has to be paid that there is enough time to develop and validate methods next to the routine analysis of the samples.
Also ISO accreditation, including all QA requirements, can only be handled adequately when an independent QA-officer is installed. The laboratory staff in Serres has good potential to fulfil the NRL and RFL tasks very well in the future, but the items indicated need consideration urgently.

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