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Constraints in CEEC countries to Achieving International Laboratory Accreditation

The Republic of Lithuania, in common with other countries of Central and Eastern Europe, is currently undergoing a transition period from a centrally planned economy to a market based system and is in the process of restructuring public sector institutions and revising former legislation. In 26 of the countries of Central and Eastern Europe and the Commonwealth of Independent States (CIS), this process is underway in a variety of stages and approaches, or has been completed. A wide range of reforms has been necessary in all sectors of the economy including agriculture and food production. Important legislative, institutional and administrative changes have been identified that must take place in a number of key sectors including the laboratories sector in order to facilitate the implementation of Agreements such as the European Free Trade Agreement and other EU requirements. In the case of the Republic of Lithuania, a Free Trade Agreement between the European Union (EU) and the Republic of Lithuania was signed in 1994, which later was changed by the Association (Europe) Agreement.

Public interest has increased significantly regarding the reliability and quality of test results performed by laboratories on food products during the last 20 years. Laboratory accreditation is considered by the public to be a demonstration of competence.

One of the exceptional traits of the post-socialist countries laboratory system was to have very strong external control and very strict requirements to follow the standards as defined by the state (government). For example, standards of the former Soviet Union included the phrase that nonobservance of the requirements of the standard was punishable by law. It was very important that each analysis method used in a laboratory be approved by a high-level government official (for example by a Minister) and at the same time the initiatives of the laboratories were restricted. The methods that had been expertly prepared and validated by the laboratories did not have legal authority until there was an official legal national document officially confirming the methods. External control of the laboratory had preference over any internal quality control system.

The inherited infrastructure of the state metrology system, which is totally different from metrology systems in use in EU countries, creates many problems. The basis of such a system is total legally obligatory official registration and verification of all laboratory and measurement equipment (i.e., gas chromatograph, pH-meter and other equipment), which laboratories in EU countries routinely calibrate themselves. This obligatory system creates problems in purchasing modern equipment made in Western countries due to the additional requirements for equipment and documents, which are not applied in Western countries. Due to the high level of official attention to legally obligatory verification the most important accreditation requirements, such as calibration of the equipment, use of certified reference materials, internal standards and other important quality measures, are not taken into consideration. Therefore, legally obligatory verification should be abandoned or should be restricted to those instruments for which the measurement results are directly of crucial importance to trade, health, safety or environment.

A further constraint is encountered in creating a laboratory accreditation system which fulfils the requirements of EN 45003. Despite strong efforts in this direction among former Soviet Union republics, only the Lithuanian Accreditation Bureau has been accepted to the organization of European Accreditation.

In the educational system of many universities of post-communist countries, students are still receiving insufficient training on requirements for the most modern quality systems and other aspects of activities of accredited laboratories. This situation relates to the more demanding analytical requirements for food products that are being exported to EU markets and the training required for the operation of highly sophisticated new laboratory equipment. Due to this problem there is a shortage of specialists who are able to work as quality managers to implement quality systems and to accurately describe these actions and procedures in the Quality Manual and to prepare the laboratories for accreditation. During recent years another problem has appeared. Many well-educated young specialists are leaving for work in Western countries and it becomes problematic to find qualified young specialists who are able to prepare the laboratories for accreditation.

The most important factor is the human factor. It is very important that personnel have a full understanding of the essence and necessity of the accreditation and quality system. At the beginning, laboratory workers believed that only managers needed the added training and they questioned the necessity of the many extra tasks. This attitude was very difficult to change. An additional problem was to train staff to operate the new and sophisticated equipment. As most of the most sophisticated systems are computerized, this required additional training to improve computer skills, which proved a hardship for some staff members.

The decision of the laboratory to seek accreditation is determined largely by the financial resources allocated to the laboratory for upgrading equipment and facilities and for participation in international proficiency testing schemes and training of personnel. This is one of the most important factors related to why some regional laboratories are not presently seeking accreditation. While staff is fully willing and capable of being trained to meet accreditation requirements, the costs of the process are too great for many laboratories.

EU funds (Phare) have supported and helped very much in the implementation of the accreditation system and the actual accreditation of laboratories. Experts from EU countries have evaluated the Lithuanian accreditation scheme and they provided practical recommendations on how to change or improve activities in different fields. A PHARE project

was carried out for the National Veterinary Laboratory of Lithuania by a team of German and Lithuanian experts, co-ordinated by the German company.

The goals of the project were:

- to supply proposals for the compliance of Lithuanian food legislation with EU requirements;
- to upgrade a national state controlled food and feeding stuffs laboratory;
- to assist with accreditation for the laboratory in accordance with EN 45001.

The overall budget of the accreditation project amounted to 2 Million Euro. One and one-half million Euro have been allotted for the acquisition of modern equipment and training of the staff in institutes and laboratories of EU countries. From the budget of the Lithuanian Government nearly 800 000 Euro were allocated for renovation of the laboratory. At present the equipment has been delivered, with most apparatus coming from EU countries. Members of the staff of the laboratory have undergone practical training in different institutes, training centres and laboratories in EU countries and the laboratory has been accredited by the German accreditation body, DAP, according to the requirements of EN 45001. Only with the substantial investments from EU funds and the government and the help of EU experts, could the National veterinary laboratory achieve accreditation.