

# **An overview of past, current and future activities of EUROLAB, the European federation of national associations of measurement, testing and analytical laboratories**

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## **Abstract**

EUROLAB has been deeply involved in the construction of the new European legislation on Accreditation (Regulation 765/2008 “Goods package”) that addresses economic, political and technical issues. This Regulation sets new duties on the European accreditation bodies which make things different from the rest of the world. Main concerns of EUROLAB are dealing with harmonization of practices should they be from a technical point of view as well as political and economical ones when applied by the laboratory practitioners, national, regional or international authorities and accreditation organizations.

The presentation will give an overview of the EUROLAB activities over the past, current and coming years. The drafting process and content of the new EUROLAB strategy 2009-2013 will be presented including the relevant topics to be tackled on a short and medium term basis, i.e. Accreditation (new status of “EA”, ILAC, flexible scope in calibration and testing activities, cross frontier policy), Effects of globalisation on the European laboratory community, Recruitment, competences, quality and education of laboratory practitioners, Technical issues (validation, uncertainty, ILC/PT) and Standardisation (ISO CASCO, revision of ISO 17000 series).

## **1. Introduction**

EUROLAB is the European Federation of National Associations of Measurement, Testing and Analytical Laboratories. It is a multiregional organisation gathering almost 30 active and associated members (one per country) from western, eastern and central Europe. It represents nowadays more than 4 000 laboratories spread over these regions. Its member institutions provide conformity assessment services such as measurement, testing, analysis, inspection and certification.

### **1.1. Creation and status**

EUROLAB was formed in 1990 as a forum of exchange and promotion for the laboratory community and its political, economic and technical partners in Western Europe. It was not an easy task considering the very large number of laboratories, their diversity and that no national comprehensive associations pre-existed. In January 1997, EUROLAB was consolidated into a legal entity in the form of an international not-for-profit association (a.i.s.b.l) under Belgian law forming the European Federation of National Associations of Measurement, Testing and Analytical Laboratories.

### **1.2. Organisation and means**

The organisation adopted for EUROLAB is based on:

- the General Assembly composed of:

- active members, namely one association by country of the EU and EFTA, representative of the public and private laboratory community of their country,
  - associated members, namely one legal entity by country from countries that are eligible for membership of the European Union, and representative of its laboratory community,
  - international affiliates, being entities or associations or group of organisations not eligible for active or associated membership but being interested in measurement, testing and analytical activities.
- the board of administrators, composed of eight administrators representing the active members and one representing the associate members, elected by the General Assembly, amongst which a President and a Vice-President are elected.
  - the secretariat, split into an administrative secretariat located in Brussels and a technical secretariat hosted by one national laboratory.
  - technical committees, whose mandates and Chairmen are approved by the General Assembly.

A number of European co-operations have been established in the field of testing, measurement, metrology and conformity assessment. Five of these (EA, EUROLAB, EURACHEM, EURAMET and CEOC International) have agreed to arrangements ensuring a closer co-ordinated approach to issues of common interest and concern.

### **1.3. Objectives and major achievements**

The objectives of EUROLAB are today as follows:

- Representation by formulating and voicing the opinion of laboratories regarding economical, political and technical issues having a direct impact on their activity both on the European scene and world-wide.
- Co-ordination by interfacing with organisations having activities of interest to the laboratory community, and striving to avoid duplication of efforts and activities.
- Action by providing adequate means for the exchange of information and experience including activities such as publications, seminars, fora, workshops, working groups, inquiries, expressions of opinions, etc.
- Promoting cost-effective testing, calibration and measurement services, for which the accuracy and quality assurance requirements are adjusted to the actual needs.

Since its creation in April 1990, EUROLAB's major achievements have been:

- representation of the laboratory community at large in Europe, materialised by the constitution and consolidation of national associations of laboratories and by being recognised as such by the major stakeholders such as EA, EC, EFTA, CEN/CENELEC/ETSI, JRC-IRMM, etc.
- exchange of experience and information: the success of the newsletter, of symposia and of workshops, the publication of position papers and technical reports, as well as active commenting of standards and other documents, have demonstrated the need for a specific forum of exchange between laboratory practitioners across technical fields and EUROLAB's ability to provide it;

- influence on the rules for conformity assessment and accreditation in Europe and worldwide by developing a working relationship with other organisations of interest to the laboratory community: ISO, ILAC, IAF CEN/CENELEC/ETSI, EURACHEM, EURAMET, CEOC International, EGOLF, NICE, EA;
- demonstration of the usefulness and ability of EUROLAB to conduct studies requiring the consultation and co-operation of the laboratory community;
- contribution on the evolution of the EC R&D framework programme, in particular for the content, operation and funding of programme dealing with European standardisation activities;
- support to the EU Commission in the evaluation and assistance of the infrastructure for conformity assessment in Central and Eastern European countries, e.g. through the PHARE and PRAQ programmes;
- setting up horizontal technical committees to formulate the opinion of the laboratory community and exchange ideas and experience, e.g. TCQA (technical committees on quality assurance), JTCPTC (joint technical committee on testing and product certification together with CEOC), whilst we have joined forces in PLG (permanent liaison group) with other organisations such as EA, EURACHEM, EURAMET, EUROLAB, EEE-PT and CEOC International;
- increased international influence by participating in international organisations, for example ISO, ILAC, by increased contacts with regional measurement and testing organisations and by accepting international affiliates;
- participation in a thematic network (Metrotrade) to provide metrological support to international trade.

## **2. The European and international environment**

### **2.1. A New European legislation**

In July 2008 the New Legislative Framework (NLF) was finally adopted in the form of Regulation (EC)765/2008 1 and Decision 2008/768/EC 2. Regulation 765/2008/EC which will come into force on 01/01/2010 in all Member States as a step forward to boost the role of market surveillance and custom controls and the obligations for Member States to carry them out.

This new legal package on the marketing of goods in the European Union was approved by the Council of Ministers and European Parliament on a co-decision principle. One part of this package is a regulation on accreditation and market surveillance which will apply with effect on 1 January 2010.

The provisions on accreditation of this regulation apply in relation to bodies carrying out conformity assessment in both the regulated and non-regulated areas. Member states should not maintain more than one national accreditation body which should operate independently of commercial conformity assessment activities. Conformity assessment bodies should in principle request accreditation by their national accreditation body. Cross frontier accreditation will be possible only in a limited number of situations.

In order to ensure that the national accreditation bodies fulfil the requirements of the regulation and to ensure an equivalent level of competence of the conformity assessment bodies EA, the European Co-operation for Accreditation, will get the mandate from the European Commission to manage a peer evaluation system among the national accreditation bodies.

As according to the regulation an effective participation of the interested parties is required both at the national and the European levels it will be an important issue for EUROLAB and its national members to take an active role in the representation of the accredited organisations within the accreditation structures. In particular in the coming years it will be essential to follow the new rules and procedures in the regulated areas and to voice the views and experiences of the respective conformity assessment bodies.

## **2.2 Measurement and testing in Europe and world-wide**

### **2.2.1 Key issues for industrial competitiveness and sustainable development**

Measurement and testing play a major role in the economy and society, and they are closely related to various fields from R&D to the production, use and final disposal of materials, items or products. They are referred to by various parties in the context of commercial transactions and fulfilment of requirements.

Measurements and test results are a key element for defining and implementing regulations and standards related to the protection of the environment or to health and safety issues.

The contribution of the laboratories is at four levels:

- the provision and execution of test, calibration and analytical services to all members of the economy;
- the implementation of standards and technical regulations, which usually includes assessment of conformity to performance, safety, health or environmental requirements usually based on measurements and tests;
- the development and validation of new test and measuring methods, adapted to the evolution of R&D methodologies in science and technology and to the needs of industry, and, more generally, of the users of test results;
- the production of standards, which often contain test and measurement methods.

Laboratories usually do not just deliver plain results to their clients, but they also provide various forms of technical and scientific assistance. They contribute their expertise to accreditation, certification, inspection and, more generally, to conformity assessment both for the regulated and the non-regulated areas. Many conduct such activities in the same organisation and are therefore an integral part of the infrastructure that supports the achievement and control of quality and safety.

### **2.2.2 A changing world for the laboratories**

There are several major trends which have a considerable impact on the overall technical and technological development and consequently also on the development in the field of measurement and testing. These are:

- The globalisation of world
- International agreements, such as GATT, WTO and mutual recognition agreements
- A further harmonisation of technical specifications and requirements
- Fading of the borderline between public and private sectors
- Local and regional networking of industry and service providers
- The quest of customers and society for improving the quality and safety of products
- The difficult predictability of the technical development
- Sustainable development, environmental protection, human-centred technologies and increased attention to quality of life and the human well-being.

Laboratories must be valued for their contribution to the improvement of quality and their role for making sure that the liberalisation of trade is not detrimental to health, safety and

environmental protection. They assist industry in bringing "good" products to the market and in ensuring the fairness of competition in a global economy.

### **2.2.3 Technical development**

Recent developments in the European Union, in the context of the decision No 768/2008/EC of the European Parliament and of the Council of 9 July 2008 on a common framework for the marketing of products, and repealing Council Decision 93/465/EEC associated with the regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93, have a direct impact on the technical and economic conditions of the operation of laboratories in this part of the world, including those in the EFTA countries and, more and more in the future, those of Central and Eastern Europe. The last enlargement of the European Union will require special effort in order to support the needed harmonisation.

The fastest technical development is expected to take place in the area of life sciences and nanotechnologies in which bioinformatics and new instrumentation will provide a completely new basis for novel measurement and testing methods. The major applications will be in the medical, pharmaceutical and pharmacological fields, but also the environmental, biotechnology and food control areas will see a technology push.

Special attention has to be paid to the need to further develop measurement and testing capabilities related to the supervision and control of doping, fraud, crime and illicit trafficking. Especially forensic and customs laboratories are in need of more effective methods. Other areas, in which there is a well defined need for further improvement, are fast, screening type tests for food and beverages as well as rapid, cost-effective on-site tests and measurements to be used outside the laboratories.

International standardisation bodies have set up a comprehensive programme for new or improved standards related to testing materials, items, and products. Accreditation bodies have shown a great interest in participating in the development of technical testing and conformity assessment standards. The laboratory community and their customers are aware of the real needs and have the expertise and competence required. They are also able to judge what is feasible and appropriate and whether the proposed measures are cost-effective. The laboratory community and its customers should have a strong influence on the technical guidance needed and they should participate in the practical work related, for example, to reference materials production, proficiency testing provisions, measurement uncertainty determination, traceability, use of computers, etc.

### **2.2.4 Cost-effectiveness, acceptance of test results and accreditation**

The quest for cost-effectiveness in testing and wide acceptance of test results are going to be dominant factors in finding a compromise between market forces and public interference. The laboratory performing tests must be competent but how should this competence be demonstrated? The accreditation should be the best way to demonstrate the competence if reliable, harmonized, peer assessed and widely and mutually recognized. As many testing laboratories work for different customers in different sectors, the laboratory community strongly supports a common system.

World-wide acceptance of test results has not been achieved so far. For example, there are still problems with the acceptance of European results in the American market and the problems are not only related to legislation but also to technical issues. Accreditation is not well known in industry and as a consequence results from accredited laboratories are not being valued accordingly.

Although accreditation has been operational for almost two decades, there is still a need to better define the role of accredited laboratories in relation to product certification, inspection and notification.

In ten years' time the most crucial factors for achieving reliable test results, i.e. quality of testing, must better be understood and realised than today. Proficiency testing activities have shown in some cases no significant difference in the performance of accredited and non-accredited laboratories. It automatically leads to the question whether the present accreditation process focuses on the right issues. Can a better result be achieved by doing just a few things very well and forget the less important issues? A sound and comprehensive balance between good performance in, e.g. inter-laboratory comparison tests or proficiency tests and surveillance frequency/volume, should be possible.

A crucial question is about the added value of accreditation. It must be judged based on the views expressed by the laboratory community and their customers. It must be more than a logo or a stamp on a report or certificate. Market forces are strong and they will partly shape the future development. It is good to remember that the accreditation bodies do not have any responsibility in the case where something goes wrong, and it is a case between the laboratory and the customers. Quality in conformity assessment is a much more difficult question than quality in calibration, which is relatively well established. The quality in conformity assessment is very seldom a small measurement uncertainty or accreditation. The real attributes have to be found from the customer's interface where added value of accreditation could be evaluated.

### **3. The new EUROLAB strategy 2009-2013: short and medium term strategic issues**

As regards the common interest of the laboratory community given by the EUROLAB members it arises that the main and crucial issues from which specific and technical actions must be further derived on a short and medium term basis are:

#### **3.1 Economical, Political and technical issues associated with the regulation on accreditation (Regulation 765/2008)**

##### **3.1.1 Political and technical issues**

The regulation sets new duties on the European accreditation bodies. These duties can induce stronger requirements and higher costs to European laboratories. To give a very classical example, the European cross-frontier accreditation policy is much more limitative than the ILAC one.

##### **3.1.2 Economical issues**

Besides political and technical issues where a better understanding and harmonization is expected there is another field where the European Laboratory community asks for a more coherent and harmonized approach. It concerns the routine practices of the national ABs as regards the overall costs borne by the accredited laboratories. The laboratory community reasonably asks for an equivalent treatment over Europe whatever the local AB ruling its day-to-day activities.

#### **3.2 Requirements for Notified Bodies**

Accreditation requirements are currently prepared at EA level. The basic approach is horizontal (covering all sectorial regulatory documents). EUROLAB welcomes the development which will help to improve consistency on the requirements for accreditation.

As far as national practices of accreditation are is not yet harmonized enough over Europe it should be of high probability that the national practices and requirements set up by the

national authorities as regards the notified CABs under the Goods Package will be different. The notified CAB community should be very attentive and might anticipate the proliferation of various and additional requirements to be set up by the national authorities.

### **3.3 Flexible scope**

EA recently produced a Top level document on flexible scope : "EA-2/15 – EA Requirements for the Accreditation of Flexible Scopes". As stated by EUROLAB at a very preliminary stage, it is not adequate to ensure a monopolistic situation to national accreditation bodies and, in parallel, to allow them to keep different policies (e.g. some may accept flexible scopes and some may refuse). EUROLAB is really interested in having accreditation with flexible scope in calibration activities as it has been demonstrated at the Boras General Assembly. It should be useful for the European laboratory community on one hand and reinforce the impact of the ILAC document about flexible scope in other field than testing when being issued on the other hand.

## **4. Conclusion**

The European Federation of National Associations of Measurement, Testing and Analytical laboratories, EUROLAB, is the major stakeholder representing the European laboratory community. A new strategy has been drafted to lead further activities over the years 2009 to 2013 in continuation of the ongoing development dedicated to the interest of conformity assessment bodies and laboratories, should it be in technical, scientific, economical and political fields at European and international levels.

In summary, the development in the field of measurement and testing over the next ten years will predominantly be determined by market forces, but for example, in the life science area societal forces will be strong. Although new directives, regulations and standards have been or are being developed, the envisaged changes are rather seen as a continuous evolution of the present situation.

The international standardisation programme is very ambitious and the number of proposed new standards in the field of testing and conformity assessment is large. The laboratory community is not supporting a proliferation of standards as the laboratories can only operate one quality system and cannot in the testing area differentiate between the same test for different applications or uses. Besides the accreditation bodies produce guidance documents. The laboratory community strongly advocates that these guidance documents should only explain the present requirements or give acceptable solutions. They should not add new requirements. For instance the future revision, if any, of the standard ISO/IEC 17025 must be in line with the latest version of the ISO 9001. Additionally, the guidance documents must be exposed to a transparent process, in which all parties can express their views.

Finally EUROLAB is strongly involved in and will keep doing involvement in the implementation of the harmonization in accreditation practices as broad as possible world-wide.