



European Federation of National Associations of  
Measurement, Testing and Analytical Laboratories

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**EUROLAB:  
An International  
Forum for the  
Laboratory  
Community.**

**THE EUROLAB  
STRATEGY 2009-2013**

**Basic Document**

# **EUROLAB: AN INTERNATIONAL FORUM FOR THE LABORATORY COMMUNITY.**

## **THE EUROLAB STRATEGY 2009 - 2013**

### **Executive summary**

Eurolab was set up eighteen years ago in order to respond to a need for a forum for exchange and promotion for the laboratory community and its political, economic and technical partners in Western Europe. One of the basic aims was to be the voice of the laboratory community at European level in order to create an interface with the European Commission and the recently created European Association of Accreditation Bodies.

#### **1. The driving forces**

Some of the priorities of the founding members are still valid today, some other ones are the result of evolution of our environment. The major driving forces for the future development of EUROLAB are:

- The internationalisation and globalisation process forcing EUROLAB to be much more active in the international arena.
- The organisational and political changes induced by the European New Legislative Framework for Goods
- The integration of new EU member countries;
- The changing market situation requiring more attention to be paid to customer relationships, and development of new or improved services;
- The need to improve the technical competence and infrastructure of measurement, testing and analytical services in order to make the innovation process more effective;
- The increased emphasis on sustainable development, environmental issues and improved reliability and safety;
- The possibility to create or make use of novel R&D results, especially in some fields where crucial interests, risks and conformity assessment emerge from industry, economies and public authorities.

#### **2. The key objectives**

Taking this into account, the key objectives can be described as follows :

- Representation by formulating and voicing the opinion of laboratories regarding economic, political and technical issues having a direct impact on laboratories'activities both on the European scene and world-wide.

EUROLAB has exhibited a strongly European orientation in the past, but in the next ten years much more emphasis must be put on the international arena. In order to be successful, the number of international affiliates must be increased and the EUROLAB members must play a very active role, for example, in ISO, ILAC, IAF, etc.

- Co-ordination by interfacing with organisations having activities of interest to the laboratory community, and striving to avoid duplication of efforts and activities.

Accreditation has reached a mature stage but accreditation issues are still high on the agenda. For EUROLAB this means that the focus will be on harmonization of practices, implementation of flexible scope and issues related to technical development and customer relationships.

EUROLAB should be the major multisectorial and horizontal forum for the circulation and exchange of information and experience in the development of :

- Test, measurement and analytical methods,
  - The use of test and analytical results in the implementation of legislation and directives, in product certification and acceptance, and in technical evaluations,
  - New measurement and testing techniques for example within the EC framework programmes, as well as
  - Quality assurance measures.
- Action by providing adequate means for the exchange of information and experience including such activities as publications, seminars, working groups, inquiries, expressions of opinions, etc.
  - Promotion of cost-effective testing, calibration and measurement services, for which the accuracy and quality assurance requirements are adjusted to the actual needs.

In order to achieve this, EUROLAB must strengthen its relationship with sector-oriented organisations and groups, consequently avoiding duplication of activities and promoting coherence of action of the laboratory community. Due to the human resources and the financial situation in many European organisations, it seems realistic that co-ordination of and sharing of secretarial functions could be a cost-effective solution.

In summary, no single laboratory, country or region can maintain a testing and measurement system isolated from the rest of the World. All parties are increasingly dependent on international co-operation, co-ordination and recognition, and they need to present a common, transparent and customer oriented approach.

### **3. The short and medium term strategic issues**

The main and crucial issues that arise from the common interest of the laboratory community shared by EUROLAB members, from which specific and technical actions must be further derived on a short and medium term basis are:

- To look for and provide more added value to EUROLAB national members;
- To advocate and participate in the harmonization of procedures at European and international level via all available and suitable means;
- To address the economic, political and technical issues associated with the Regulation on Accreditation (Regulation 765/2008).

The Regulation sets new duties on the European accreditation bodies. These duties can result in stronger requirements and higher costs for European laboratories. A classic example of this is that the European cross-frontier accreditation policy is much more restrictive than the ILAC one. There is thus a risk of a two-tier system when a Regulatory Body acting under the European Multilateral Recognition Agreement relies on results by a test laboratory accredited under other rules. The new situation produced by the Goods Package should not be detrimental to the European CAB community.

- Closely follow the development of the accreditation requirements for Notified Bodies

Accreditation requirements are currently prepared at EA level. The basic approach is horizontal (covering all sectoral regulatory documents). EUROLAB welcomes the development which will help to improve consistency in the requirements for accreditation. Great care needs to be taken of the sectoral differences. For example laboratories notified under the Construction Products Directive have technical and administrative duties which are basically different from the duties of laboratories notified under the Low Voltage Directive. If all of them are mixed, this will produce undue and unnecessary burdens on the accredited notified laboratories. All necessary steps should also be taken to ensure the technical sectoral competence of the accreditation auditors. To be pro-active in requesting a coherent approach and a better harmonization EUROLAB could look at the existing situation and current practices in the member states. Once such a mapping is realized EUROLAB could benchmark the best practices and ask each of its members to address directly the recommendations to their relevant competent authorities in charge of the notification process.

- Promote practical implementation of flexible scope of accreditation

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 for national accreditation bodies and, in parallel, to allow them to keep different policies (e.g. some may accept flexible scopes and some may refuse). On the other hand the results of the EA enquiry indicate that real application of the concept needs supplements relevant to the particular sector and/or activity concerned (testing, inspection, product certification....). As EA is really involved in implementing and possibly enlarging accreditation with flexible scope EUROLAB could co-operate and participate in such a process more than just commenting on the EA document.

All details and relevant information on the background of the Eurolab strategy 2009-2013 can be found in this document.

**EUROLAB:  
AN INTERNATIONAL FORUM  
FOR THE LABORATORY COMMUNITY.  
THE EUROLAB STRATEGY 2009 - 2013**

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# **EUROLAB: AN INTERNATIONAL FORUM FOR THE TESTING COMMUNITY. THE EUROLAB STRATEGY**

## **Motto:**

Measurement and testing are of fundamental importance to science, technology and the economy. The Commission of the European Union has expressed this in the following way: "There is no science without measurements, no quality without testing and no global market without standards."

## **1. INTRODUCTION**

EUROLAB is the European Federation of National Associations of Measurement, Testing and Analytical Laboratories. It is a multiregional organisation bringing together almost 30 active and associated members (one per country) from western, eastern and central Europe. It represents nowadays more than 4000 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 for 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 groups 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, from 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 economic, political and technical issues having a direct impact on their activities 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**, as formed by the constitutions and consolidation of national associations of laboratories and by being recognised as such by 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 on standards and other documents, have demonstrated the need for a specific forum for 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 programmes 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 Committee 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. MEASUREMENT AND TESTING IN EUROPE AND WORLD-WIDE**

### **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. Consumer and user groups require measurement and testing services to survey and appraise the products on the market, and the public sector has a great interest in issues related to quality of life, safety, health, environment etc. Measurement and testing contribute to the development and implementation of legislation, directives, technical regulations, market surveillance and specifications in connection with the assessment of conformity.

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.

In this strategy, the word "laboratory" has been used. It should be interpreted as an organisation, however named, which performs measurements and testing, or in a technical sense participates in the conformity assessment process.

The positioning of laboratories in the economy and society is diverse and this enhances the need for collective action and representation, both at national and at international levels.

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 regulated and 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. A changing world for the laboratories**

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

- The globalisation of world trade leads to a harmonisation of requirements and standards as well as to the development of global markets for products and services. This globalisation process will of course also have repercussions on industrial and private testing laboratories.
- International agreements, such as GATT, WTO and mutual recognition agreements, dominated by the preoccupation of facilitating international trade, are aimed at avoiding unnecessary duplication of testing. Contrary to this, trade regions are trying to improve their competitiveness by increasing their exports and limiting their imports. In some cases new barriers including technical ones to trade are thus created.
- Further harmonisation of technical specifications and requirements as well as of the conformity assessment procedures will take place. Standards and technical regulations as well as conformity assessment procedures will increasingly be developed in the international arena.
- Fading of the borderline between public and private sectors in measurement and testing. The public sector will however in general continue to maintain authority over such testing activities

that are of great importance to health and safety, environmental issues, and the preservation of large economic values.

- Local and regional networking of industry and service providers is taking place, the aim being to conquer international markets. As a result, the challenge for the laboratories is to achieve recognition/acceptance of their reports outside the national borders and thus increased visibility and impact.
- In order to promote innovation and competition, measuring and test methods must be further developed and their capabilities tailored to fit the anticipated needs. Continued R&D activities are required.
- The quest of customers and society for improving the quality and safety of products is resulting in a greater awareness of the importance of market surveillance. Market surveillance is also requested by industry concerned with the fairness of competition between producers. This may infringe the increased openness of free trade. In measurement and testing, there is a need to obtain comparable results in the determination of the characteristics irrespective of the organisation performing the market surveillance.
- The predictability of technical development becomes more difficult as the rate of development, from designing a new product to marketing the final product, is considerably accelerated and industry is eager to create new markets.
- Sustainable development, environmental protection, human-centred technologies and increased attention to quality of life and human well-being are strong driving forces and will influence development in all sectors.

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.

In summary, developments 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 changes envisaged are seen as a continuous evolution of the present situation.

### **2.3. Technical development**

Over 4,000 organisations are linked to EUROLAB. They employ about 100,000 staff, operate equipment and facilities representing several billions of Euros and provide services to more than 100,000 customers in all sectors of the economy. The EUROLAB members have different roles, aims, sizes and scopes, but they are all affected by, or involved in, the developments taking place. Many of them undertake conformity assessment activities other than measurement and testing and they may also be involved in production. Several bridge the borderline towards product certification and inspection.

As EUROLAB members have very different company profiles, they consequently expect different things from EUROLAB. EUROLAB must therefore balance its services and support to the different categories of laboratories as, for example, small laboratories may have completely different interests compared to large national organisations.

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, which repeals Council Decision 93/465/EEC and Regulation (EEC) No 339/93 and sets out the requirements for accreditation and market surveillance relating to the marketing of products, have a direct impact on the technical and economic conditions of the operation of laboratories in Western Europe including those in the EFTA countries and, increasingly 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 required harmonisation.

For the future, owing to the growing importance of operations at the international level, it is essential for EUROLAB to increase its involvement with international organisations in order to have strong legitimacy during discussions. With regard to the issues to work on, standardisation work concerning conformity assessment will continue to require a strong involvement from EUROLAB. R&D issues, at the European level, will increasingly require an efficient networking of R&D and testing bodies, and EUROLAB could be more active on that topic, in close relation with the

European Commission. As national EUROLABs intend to work at the national level, a challenge for EUROLAB would be to extend its scope of competence more explicitly towards new domains, such as biological, medical and environmental activities. There are currently a few major laboratories involved in EUROLAB coming from these sectors, but the areas could be positively developed.

Development of new or improved measurement and testing methods is the result of scientific and technical development taking place in conjunction with the evolving needs of industry and more generally, of the users of test results. Testing of materials and final products is experiencing normal evolutionary improvement whereas production control and monitoring of products and systems in operation are expected to develop rapidly due to the technical progress anticipated. This is triggered by the use of cheap sensors and automatic decision-making logics, which provide the possibility to observe what is happening in the surroundings (changes in chemistry, temperature, mechanical impact, etc.) and in the product or the system (expected/ predicted stresses, etc.). The logics used can respond effectively to changes to optimise for example, the effect on remaining lifetime, degradation of properties or production rate.

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. The environmental, biotechnology and food control areas will also 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. Forensic and customs laboratories especially are in need of more effective methods. Other areas, in which there is a well defined need for further improvement, are fast screening tests for food and beverages as well as rapid, cost-effective on-site tests and measurements to be used outside the laboratories.

The 7<sup>th</sup> EU framework programme with integrated projects and networks of excellence offers a possibility to tackle both practical and theoretical R&D issues and standardization issues. EUROLAB associated laboratories should use that possibility for technological enhancement. In certain areas foresight studies should be conducted.

One of the crucial questions is how to build and finance the further technical development of measurement and testing. There is no longer, neither on a European nor on a national level, a co-ordinated long-term R&D approach for measurement and testing. The ongoing R&D projects are fragmented, and it is difficult to get an overall view of the situation.

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.

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 does not support 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. Furthermore the accreditation bodies also 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 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.

The laboratory community favours a so-called functional approach. This means that the elements that can be identical in different conformity assessment standards should really be so. For example, handling of equipment must be the same, no matter whether the equipment is used for testing, inspection or product certification.

In many areas technical progress is relatively slow and this will lead to incremental improvements in testing capabilities. Many testing standards do not, for example, provide any information on the

measurement uncertainty related to the test results. The laboratory community asks the standardisation bodies to include such requirements when the standards are updated.

The total number of tests performed is not expected to decrease, but structural changes in the testing patterns and volumes are foreseen. Continuous quality control during the whole manufacturing process is expected to grow because manufacturers are keen on eliminating as early as possible those materials, items and products which will not pass the final acceptance controls. The monitoring of products, equipment and production systems will also increase as unforeseen interruptions and outages are very expensive. Further, the equipment manufacturers may even give guarantees that a certain production capacity is reached continuously.

The influence of market surveillance on the volume of testing is difficult to judge as the market surveillance activities are not so well developed even should a new regulation come into force. There seems to be differences in approach and ambition between European and national authorities. The role for private laboratories in market surveillance must also be clarified.

Although the manufacturers or importers are ultimately responsible for their products, the involvement of third-party testing for the public sector will probably slightly increase. The request for very specialised testing services is growing and they may be supplemented by calculations, modelling and simulations. Accreditation will probably be developed for such activities.

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

Cost of accreditation has been discussed for many years. Although decreasing, there still exist differences between countries. As testing, inspection and certification are commercial activities, differences in accreditation costs may favour some of the organisations in the competitive field. The new monopoly situation of the national accreditation bodies and the possibility for them to transfer almost all costs, including their contribution to EA and ILAC, to their clients, is of major concern.

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? Accreditation should be the best way to demonstrate competence if such accreditation is 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 of accreditation.

The public sector will not surrender the right to accept products solely on the basis of information supplied by manufacturers; there will always be public sector interest, often in the form of third-party laboratory involvement when issues of great importance for general safety (pressure vessels, nuclear energy, chemicals, etc), health (food, drugs, etc.), environment (pollution, emissions, sustainable development etc.) and important economic values are concerned. There is definitely a need to develop legislation related to the acceptance of test results, especially to clarify when third-party involvement is required.

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. Why is accreditation so little known in industry when certification of quality systems and products has been well established? If accreditation is going to have a great influence on the voluntary (non-mandatory) sector a promotional campaign should be launched soon by the relevant stakeholders, especially the accreditation bodies.

It seems obvious that there will always be differences in the way results are accepted in the mandatory sector compared to the voluntary sector. More competition and market-tailored specific solutions will be seen in the voluntary sector.

The users of test results, i.e. industrial companies and public authorities, have not really been involved in developing the acceptance process. The market and market forces are expected to have a much stronger influence in future and for the testing community it is important to listen carefully to the needs and views of its customers.

, There are several issues concerning the acceptance of test results that are being discussed in some detail today and a pragmatic solution has to be found. These issues are accreditation vs. certification, third-party laboratory involvement, opinions and interpretations, measurement uncertainty, mandatory proficiency testing schemes, traceability, use of computerised systems,

grading of non-conformities, etc. Some of the questions are related to accreditation, some are related to a more general acceptance of the test results. Different parties have different views on these issues. The general acceptance of test results should be handled at an authority or public acceptance level. Accreditation procedures should be handled by the accreditors and the technical issues should be handled by the laboratories with the best expertise in the subject.

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

Laboratories are still experiencing multiple assessments of their competence. There is accreditation, certification of the quality system, GLP and GMP assessment, customer evaluations, peer assessment type activities, etc. All these take time and cost money and there are examples where the different assessments end in contradictory views or recommendations. In future it must be possible to have only one assessment procedure covering all those options indicated by the laboratory. Accreditation of multi-site, multi-functional and multi-disciplinary organisations with integrated quality management systems generally results in multiple assessments. Co-ordination between different assessments must be achieved in a cost-effective way and the whole conformity assessment process stream-lined.

Based on general principles/requirements, the different technological or industrial sectors may interpret what the specific principles or requirements in that particular area are. However, the sectoral solutions should be kept to a minimum, as otherwise there will again be a proliferation of requirements. Consequently, there is a need for an overall horizontal level to express the laboratory community's view on the arrangements. The sectoral organisations should not deal with issues which can be handled at a general level.

The New Legal Framework, the modernisation of the New Approach for marketing of products was adopted finally in Council on 23<sup>rd</sup> June 2008. This broad package of measures which has the objective of removing the remaining obstacles to free circulation of products represents a major boost for trade in goods between EU Member States. It will bring particular benefits for small and medium sized enterprises (SMEs), who will no longer be discouraged from doing business outside their domestic markets. Existing market surveillance systems for industrial products will be strengthened and aligned with import controls. These measures will reinforce the role and credibility of CE marking.

The objective of the package is to facilitate the functioning of the internal market for goods and to strengthen and modernise the conditions for placing a wide range of industrial products on the EU market. The package builds upon existing systems to introduce clear Community policies which will strengthen the application and enforcement of internal market legislation. European accreditation (EA) will play a bigger role than today because its development will take place to become a mature activity used predominantly in the mandatory area. Its role will mainly be to verify that the statements of notified bodies with respect to scope and competence are correct.

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. interlaboratory comparison tests or proficiency tests and surveillance frequency/volume, should be possible. EUROLAB believes that it is necessary to address everything that is included in ISO/IEC 17025 standard, no more no less.

National accreditation bodies will have a monopoly position in the near future. The laboratory community recommends that this situation should be looked at carefully for three reasons: costs, schedules and available expertise. The accreditation bodies have been considered as non-profit organisations and a part of the public sector. However, they have been free to pass on all costs including those related to European and international co-operation, procedure development, etc. to the laboratories ; in the near future all these costs will probably increase. Although laboratory representatives are represented on the boards of accreditation bodies, their ability to influence the costs and the fees are limited. There are still significant differences in Europe with respect to these fees.

Two of the major criticisms of accreditation today are first, slow handling of accreditation applications and secondly the access to accreditation with flexible scope. This might be due respectively to a shortage in assessors and to the capabilities or policy of the national accreditation

body regarding the flexible scope accreditation. Considering the time/work in general spent on the accreditation process, it should be expected that the accreditation certificate could be issued within a few months. Therefore<sup>[2]</sup>, it is absolutely necessary to provide, at least in some cases, the possibility for cross-border accreditation to avoid unfair competition between laboratories from different member countries. Technically this should not be a problem since the accreditation bodies have signed the mutual recognition agreements meaning that the results should be equivalent. The laboratories view cross-border accreditation positively as new experts can be brought in and it will speed up the accreditation process and minimize its costs. The accreditation bodies should focus their interest on streamlining the accreditation process and make it more efficient based on a cost/benefit/quality approach.

A crucial question is about the added value of accreditation. It must be judged in accordance with 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 matter between the laboratory and the customer. 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. FUTURE DIRECTION

#### 3.1 Key objectives

The overall objectives may stay unchanged even if there is a need to accentuate certain ones so that EUROLAB can better respond to the challenges outlined above. EUROLAB has demonstrated that sharing the work load between members can be cost-effective as a collective knowledge base can be used and not everyone has to develop his/her own solution. In order to serve better the laboratory community, EUROLAB should regularly enquire of its members their needs for further guidance and information.

These objectives are still up-to-date and could be consolidated in details as follows:

- **Representation by formulating and voicing the opinion of laboratories regarding economic, political and technical issues having a direct impact on their activity both on the European scene and world-wide.**

In the past EUROLAB has exhibited a strongly European orientation but in the next ten years much more emphasis must be put on the international arena. In order to be successful, the number of international affiliates must be increased and EUROLAB members must play a very active role, for example, in ISO, ILAC, IAF, etc. But in parallel, co-operation with EA will probably increase in light of the new EA status and the recent EC package. The Permanent Liaison Group (PLG) between EA, EUROLAB, EURACHEM and EURAMET will reconsider its scope and missions as major technical issues are likely to be discussed at the European level. CEOC International is invited to join the PLG. Additional participants could be invited upon request to discuss on specific matters. It is, however, important to have a joint European position.

Laboratory associations have been and are being created in other regions of the World. Co-operation with these regional associations is conducted in some places such as ILAC LC which will be able to voice the opinions of the global laboratory community. EUROLAB should be instrumental in voicing the opinions of the European laboratory community in such places where these opinions are sometimes different from the others.

In order to achieve this, EUROLAB must strengthen its relationship with sector-oriented organisations and groups, consequently avoiding duplication of activities and promoting coherence of action of the laboratory community. Due to the human resources and the financial situation in many European organisations, it seems realistic that co-ordination of, and sharing of, secretarial functions could be a cost-effective solution.

EUROLAB has become quite influential in political matters. In the near future, emphasis must be placed on further developing EUROLAB's influence on economic, technical and legislative matters. Improved and close contacts with the Commission must be developed.

The recent enlargement of the European Union is a great challenge for EUROLAB in incorporating them fully into its activities. It should be a mutually beneficial interaction where on the one hand information and experience are exchanged and on the other hand there is the possibility to shape future development in the field of testing and analytical measurements as

well as in conformity assessment. Fair rules of competition and ethical behaviour in the market must be followed. Ethical questions have to be addressed in a code of conduct. EUROLAB could also support the candidate countries in their programmes aiming at developing their infrastructure.

EUROLAB should consider further integration of Europe and start to build bridges with, e.g., Baltic countries, former Soviet republics (SSR), etc. Special attention has to be paid to Eastern European countries and especially to Russia, as they will be neighbours of the enlarged European Union. Russia has huge natural and energy resources and her trade with Europe is expected to grow. The earlier the harmonisation in testing and measurements as well as in conformity assessment between Russia and Europe starts the better.

- **Co-ordination by interfacing with organisations having activities of interest to the laboratory community, and striving to avoid duplication of efforts and activities.**

Accreditation has reached a mature stage but accreditation issues are still high on the agenda. For EUROLAB this means that the focus will be on harmonization of practices, implementation of flexible scope and related issues to technical development and customer relationships. But as far as harmonization and accreditation are concerned it should be of crucial importance that at first national EUROLAB representatives be invited and enter as stakeholders in the board of their respective national accreditation bodies if not yet incorporated.

The EUROLAB representatives to EA AB, the Technical Committee on Quality Assurance (TCQA) and the Joint Technical Committee on Product Testing and Certification (JTCTPC) will continue their routine activities within their respective mandates. Nonetheless the scope and work programme of TCQA and PLG should be expanded to a certain extent to deal with economic and new technical issues. The interface between EUROLAB's representatives in different working groups and EUROLAB (Board and Secretariat) must be strengthened so that the representatives speak with one voice.

Support for the development of the national EUROLAB members is important in order to strengthen the laboratory community and its influence at the national level. Simultaneously, EUROLAB's representativeness must be encouraged and promoted and its members must be willing to appoint high-level influential persons to actively participate in global activities.

In order to respond to EUROLAB members' wishes and needs, EUROLAB must carefully activate its members to give their views on issues of interest to them. Close contacts with the national secretariats are important but also other ways to convey the messages must be developed. In certain cases inquiries may be used as they have proved successful in the past. In other cases a discussion forum on the EUROLAB website homepage may be more appropriate.

In conclusion EUROLAB should be the major multisectorial and horizontal forum for the circulation and exchange of information and experience in the development of :

- Test, measurement and analytical methods,
- The use of test and analytical results in the implementation of legislation and directives, in product certification and acceptance, and in technical evaluations,
- New measurement and testing techniques for example within the EC framework programmes, as well as quality assurance measures.

- **Action by providing adequate means for the exchange of information and experience including such activities as publications, seminars, working groups, inquiries, expressions of opinions, etc.**

As EUROLAB's financial resources are limited, external financing is needed. One crucial issue during the next few years is the consolidation of EUROLAB's financial situation. A possible solution to the financing problems should be to adjust the level of EUROLAB's activity to that which the members are prepared to pay for. This could lead to an increase in membership fees but also to a greater added value of the services provided by EUROLAB as well as an increase in activity among members who benefit from the services. In addition to the membership fees, other financial resources have to be exploited.

EUROLAB seems to be well suited for managing and operating networks of excellence, as well as projects of a general and/or generic nature, in the field of measurement and testing. EUROLAB should, on a project-by-project basis, seek financial support from existing sources, for example, for support of technical development, for improved conformity assessment

activities, for more reliable trade and for responding to EU enlargement. This will be done with relevant competent partners also in the international market.

Where EUROLAB plays a key role on the long term, it is essential that it brings together the different types of laboratories, small and large, public and private, testing and analytical, and deals with a wide range of economic areas. This means that EUROLAB will permanently face a great variety of expectations. The only way to reconcile such different expectations is to combine the European and the national levels in a complementary way.

Although small laboratories form the majority in EUROLAB, big laboratories have been very crucial for EUROLAB as they share their knowledge and participate in the creation of laboratory guidance material. The large laboratories often act as national "reference" laboratories as they form the link between the international community and the national one. In many countries, they also arrange interlaboratory comparisons and proficiency testing exercises. As competition is now the "rule of the game" even for testing services directly linked to major health or safety issues under European regulations, it reinforces the need for a European network of laboratories, with a strong involvement of "reference laboratories", as has been the case since the inception of EUROLAB. Competition will probably encourage laboratories to offer services that include expert judgement". This should not be discouraged, but there will be a need for rules of transparency. Limits will need to be set to ensure that financial pressures do not give rise to problems and compromise confidence in the conformity assessment bodies. It will work only if these "reference" laboratories, often partially funded by public subsidies, accept continuing to contribute to the running of EUROLAB (both financially and in terms of involvement of their experts) beyond their importance from the economic point of view, as a part of their missions.

Periodic conferences and specialised workshops will still be important but the biggest change is expected in the area of information dissemination. Many more technical reports dealing with different aspects of testing and conformity assessment should be produced for the benefit of the laboratory practitioners and the users of test results. At the same time, this technical information can be used to support EUROLAB's more political statements to officials.

The EUROLAB network should also be used for training, education and assistance for the benefit of present and future members of EUROLAB. EUROLAB does not have to do everything itself but it can provide information to the laboratories on the availability of other organisations' services related to proficiency testing exercises (EPTIS), existence of reference materials, etc. Better links with the Joint Research Centre (JRC), and especially the Institute for Reference Materials (IRMM) established via the MoU could be beneficial in that respect.

- **Promoting cost-effective testing, calibration and measurement services, for which the accuracy and quality assurance requirements are adjusted to the actual needs.**

Information and publication activities are important both for internal communication within EUROLAB and for external communication to make the voice of EUROLAB heard. The volume of the activities will be determined by the available resources, not by the large demand. The major channels for EUROLAB are the web-site, position papers, technical reports, newsletter, conference presentations, and normal correspondence. Position papers are used to express EUROLAB's opinion on crucial questions and this is also done in EUROLAB's correspondence with officials. Technical reports serve also an educational role and EUROLAB should encourage its members to use more frequently the EUROLAB channel to spread the technical information. There is also a growing need to create EUROLAB "standards" (guidelines). This service is expected to be especially valued by small laboratories. EUROLAB should to a larger extent than before ask individuals to contribute to all information and publication activities. An expected service is that someone should read/comment/evaluate existing relevant technical documentations, and in a nutshell, give a professional judgement of the usefulness and relevance of the document for EUROLAB's members.

In summary, no single laboratory, country or region can maintain a testing and measurement system isolated from the rest of the World. All parties are increasingly dependent on international co-operation, co-ordination and recognition, and they need to present a common, transparent and customer oriented approach.

### **3.2 Strategic issues**

The main and crucial issues that arise from the common interest of the laboratory community shared by the EUROLAB members from which specific and technical actions must be further derived on a short and medium term basis are:

➤ **Economic, Political and technical issues associated with the Regulation on Accreditation (Regulation 765/2008)**

Political and technical issues

The Regulation sets new duties on the European accreditation bodies. These duties can result in stronger requirements and higher costs for European laboratories. A classic example of this is that the European cross-frontier accreditation policy is much more restrictive than the ILAC one. There is thus a risk of a two-tier system when a body acting in the regulatory field under the European Multilateral Recognition Agreement relies on results by a test laboratory accredited under other rules. Four situations have been identified so far for which clarification with EA and EU must be established, if possible, by the 1<sup>st</sup> of January 2010:

- Some conformity assessment bodies have multiple accreditations from various national accreditation bodies for some good reasons but mainly for commercial ones and market requirements. According to the new Regulation it will not be possible anymore for these CABs to have multiple accreditations in spite of the demands of their customers. How could these CABs meet satisfactorily their client requirements within the new Regulation ?
- Some CABs have multi-site facilities. In some cases these laboratories belonging to the same CAB, work in the same conditions with the same quality system under the same quality manual conditions and management. The secondary laboratory being run abroad could be faced with difficulties and be required to be accredited by the local AB without any co-operation with the AB which is located in the country of the primary laboratory.
- EA and its MLA members will be considered as signatories to ILAC MRA and IAF MLA. Attestation of conformity issued under accreditation by AB signatories of ILAC MRA and IAF MLA but which are not signatories to EA MLA or BLA and not complying with requirements of the EU Regulation will be considered by EA to be equally reliable. But acceptance in the EU of conformity assessment attestation certificates issued under accreditation by non European ABs does not depend on the recognition between ABs. The situation needs clarification. For instance in the voluntary CA area vs. mandatory CA area on the one hand and if MRAs are not modified for the time being, what could be done for new MRAs or revision of existing MRAs in the future on the other hand ?
- ABs are not obliged to provide accreditation with flexible scope. If whatever the reasons, should it be internal policy or lack of suitable competence, an AB does not want to provide flexible scope at its national level, how, under the cross frontier policy, can a local CAB look for such an accreditation abroad to avoid the risk of unfair competition.

These elements should be clarified at EA and at EU level. JTCPTC in co-operation with EA AB and TCQA could be entrusted to deal with these issues. These have also to be elaborated in relation to the effects of globalisation on the laboratory community. The new situation as produced by the Goods Package should not be detrimental to the European CAB community.

Economic 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. A survey needs to be conducted amongst the EUROLAB national associations to establish the existing situation as it is now in the different member states before any further actions towards the European accreditation world are taken. The starting point should be to work together with its representatives<sup>[J3]</sup> in order to have better transparency and harmonization of economic issues to devise an equivalent treatment for all European accredited CABs.

➤ **Requirements for Notified Bodies**

Accreditation requirements are currently prepared at EA level. The basic approach is horizontal (covering all sectoral regulatory documents). EUROLAB welcomes the development which will help to improve consistency in the requirements for accreditation. Great care needs to be taken of sectoral differences. For example laboratories notified under the Construction Products Directive have technical and administrative duties which are basically different from the duties of laboratories notified under the low voltage directive. If all of them are mixed, this will produce undue and unnecessary burdens to the accredited notified laboratories. All necessary steps should also be taken to ensure the technical sectoral competence of the accreditation auditors.

As national practices of accreditation are not yet harmonized sufficiently across Europe it is very probable 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.

To be pro-active in requesting a coherent approach and a better harmonization EUROLAB could look at the existing situation and current practices in the member states. Once such a mapping is realized EUROLAB could benchmark the best practices and ask each of its members to address directly the recommendations to their relevant competent authorities in charge of the notification process.

➤ **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 for national accreditation bodies and, in parallel, to allow them to keep different policies (e.g. some may accept flexible scopes and some may refuse). On the other hand the results of the EA enquiry indicate that real application of the concept needs supplements relevant to the particular sector and/or activity concerned (testing, inspection, product certification....). As EA is really involved in implementing and possibly enlarging accreditation with flexible scope, EUROLAB could co-operate and participate in such a process more than just commenting the EA document.

For instance EUROLAB is really interested in having accreditation with flexible scope in calibration activities as was demonstrated at the Boras General Assembly. To advocate and support this expectation it would be very valuable if TCQA and PLG were to collect examples, bad and good, which could be used as arguments and models for best practices and learning process of ABs not yet implementing flexible scope in calibration. It could be useful for the European laboratory community on one hand and could reinforce the impact of the ILAC document on flexible scope in fields other than testing, when issued, on the other hand.