



**NLA Test and Measurement 2009 Conference
Misty Hills Country Hotel - SA
September 13-16, 2009**

**An overview of past, current and future activities
of EUROLAB**

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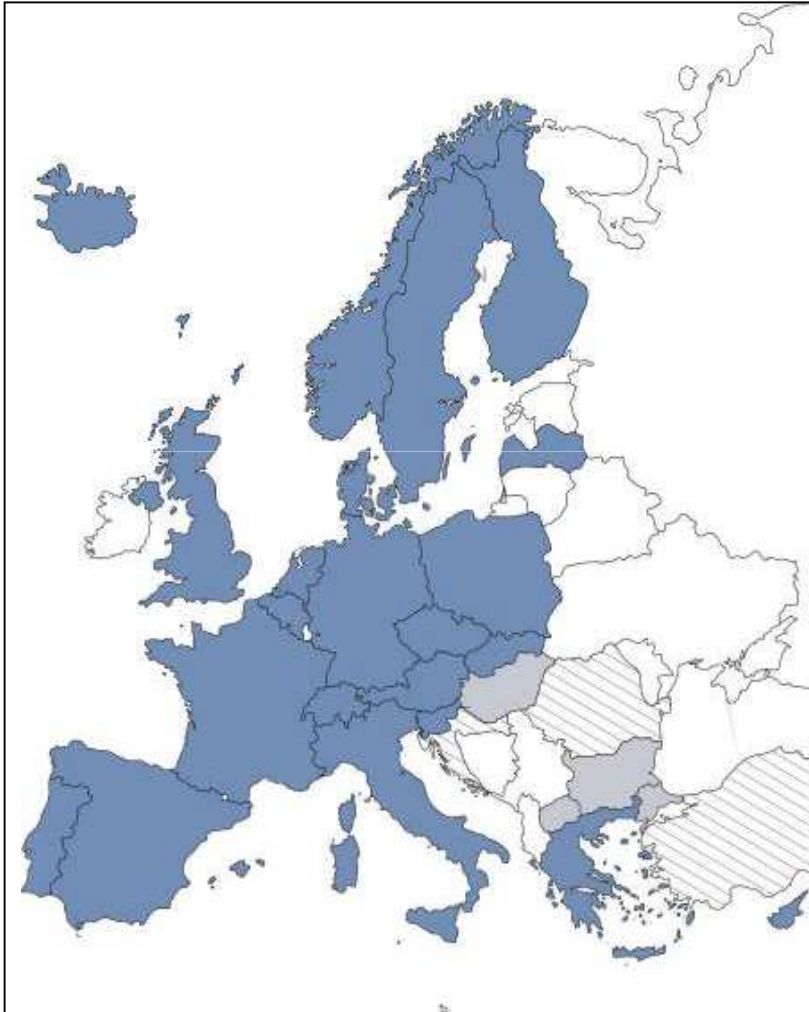
- is the European Federation of National Associations of Measurement, Testing and Analytical Laboratories,
- was formed as a network of the laboratory community in connection with the evolution of the European Union (EU),
- created in Brussels on 27 April 1990.



**EUROLAB is since 1998 a legal entity in the form of an international association under Belgian law:
*aisbl – association internationale scientifique sans but lucratif***

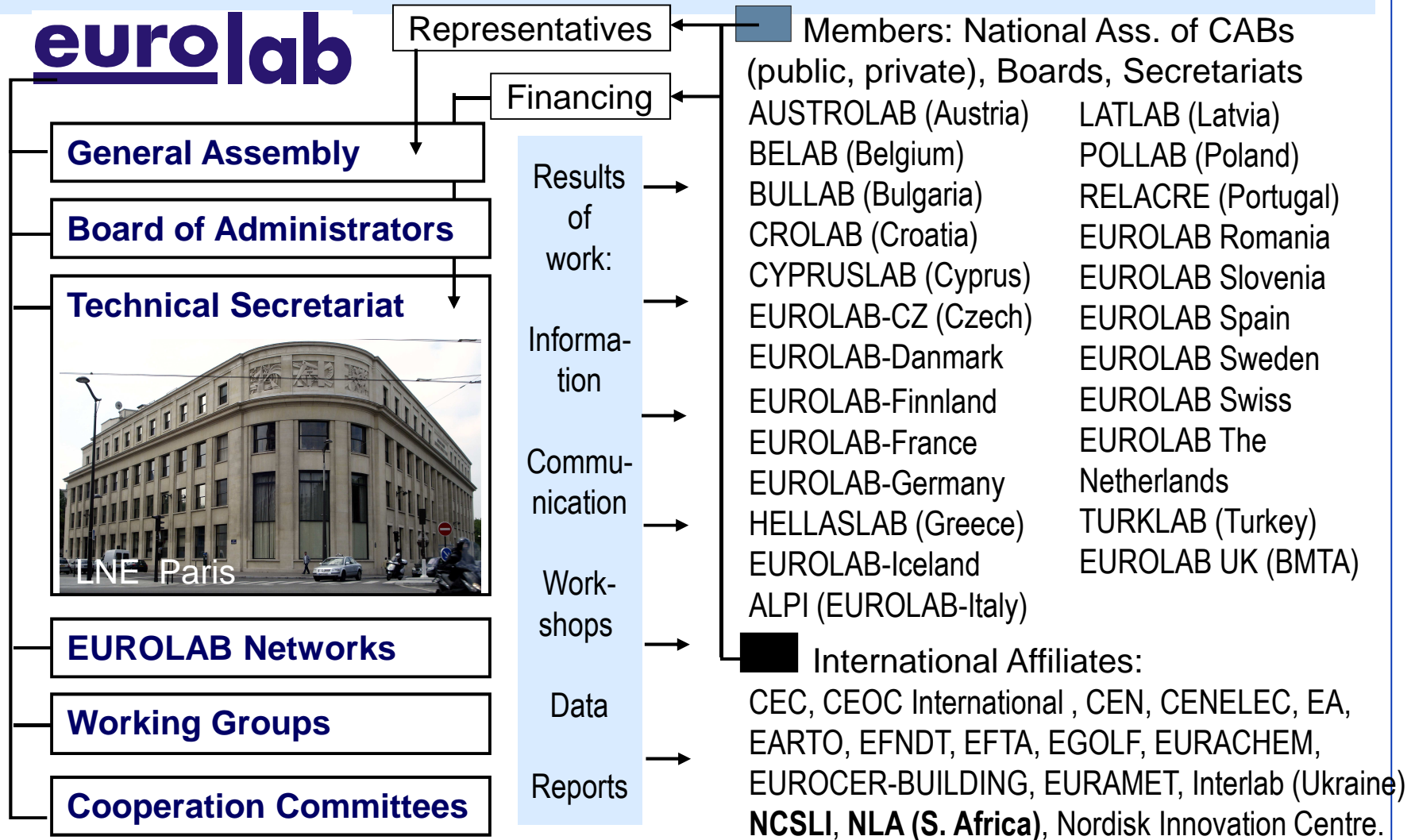
The European Union in 2009: an overview

European Union (EU): political and economic union of 27 member states (with 23 official languages for national regulations). It was established by the Treaty of Maastricht in 1993 upon the foundations of the pre-existing European Economic Community. With almost 500 million citizens, the EU combined generates an estimated 30% share of the world's nominal gross domestic product (WIKIPEDIA 2008).



EUROLAB Organisation

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EUROLAB Activities

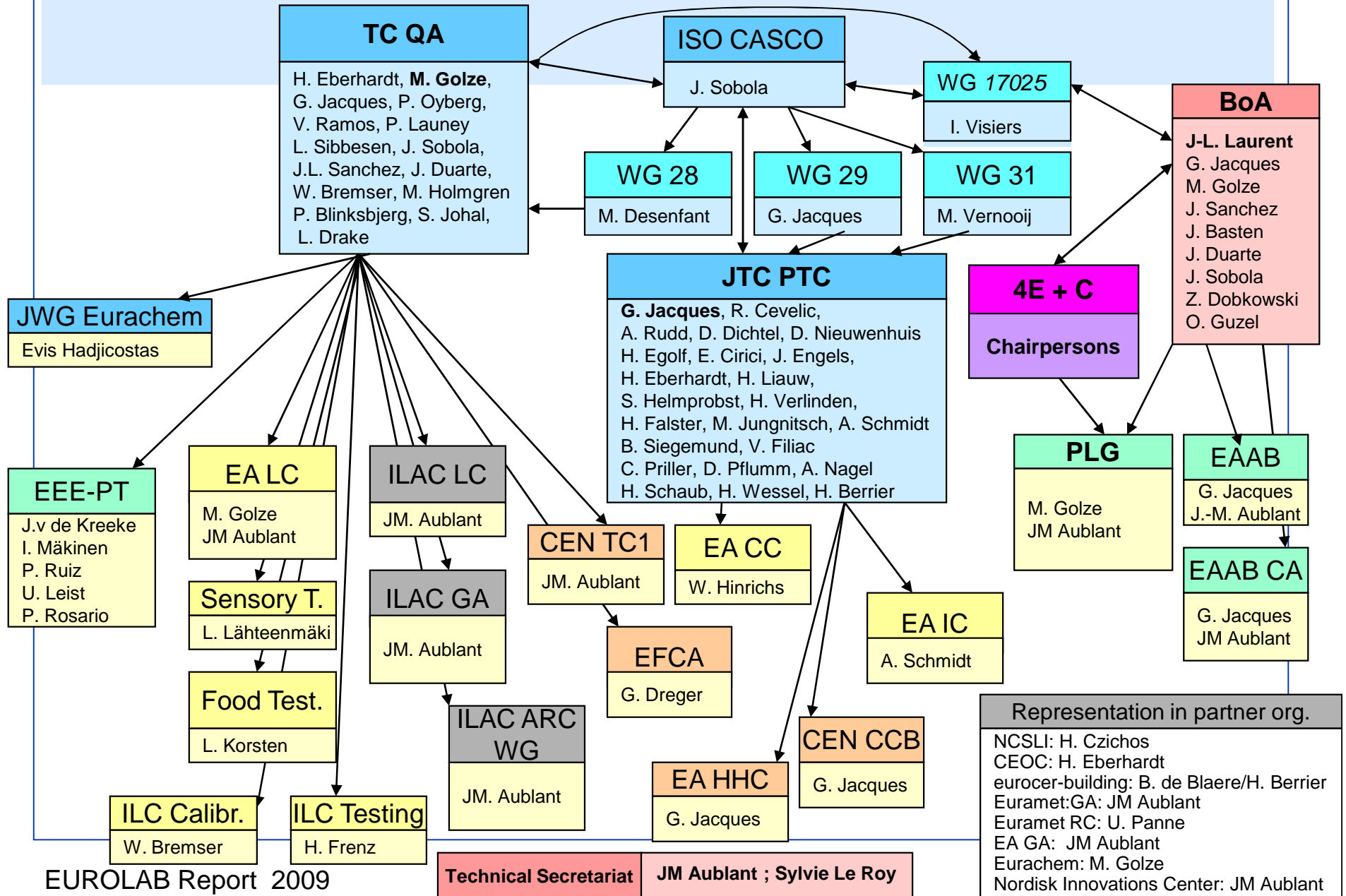
EUROLAB Working Groups and Cooperation Committees

- **TC QA** : EUROLAB Technical Committee on Quality Assurance
- **JTC PTC**: EUROLAB/CEOC* Joint Technical Committee on Product Testing and Certification
- **PLG** : Permanent Liaison Group *between*
 - EA, *European Accreditation Cooperation*
 - EURACHEM
 - EURAMET
 - EUROLAB
 - CEOC

* International Confederation of Inspection and Certification Organisations

EUROLAB GA

EL_07_01_09_179 (Rev19)
as of May, 2009



EUROLAB Cook Book

In recent years, EUROLAB has intensively discussed on its added value for its members with the following results:

- “Hands-on guidance for the daily work of laboratories” was identified as a helpful tool.
- Thus the TC QA, EUROLAB’s Technical Committee for Quality Assurance, started to develop a series of short guidance documents, the so-called EUROLAB “Cook Book”.
- It contains a set of informal EUROLAB documents intended to aid laboratories in their effort to comply with requirements of the ISO/IEC 17025 standard.
- They are based on experience and extensive discussion in the EUROLAB TCQA and will be published on the EUROLAB website (www.eurolab.org), but they are not in any way formally endorsed.

EUROLAB Cook Book



The EUROLAB “Cook Book”

A compilation of short documents on Quality issues for laboratory practitioners

EUROLAB Cook Book

Today, the EUROLAB Cook Book series comprises the following documents which are ready for publication*:

- Validation of test and calibration methods
- Criteria for the selection of a proficiency testing scheme
- Use of interlaboratory comparison data by laboratories
- Handling of untestable samples
- Management review in laboratories
- Conflict handling within the accreditation process
- Competence of personnel
- Determination of conformance with specifications or limiting values with particular reference to measurement uncertainty – possible strategies



* available and downloadable from the member area of the website

EUROLAB Cooperation Activities – an example

EURACHEM / CITAC / EUROLAB Joint Symposium on new developments in measurement uncertainty in chemical analysis

The Symposium with participants from 27 countries focused on two major topics:

- measurement uncertainty arising from sampling
- use of uncertainty information in compliance assessment.

Both topics are also subject of two EURACHEM / CITAC Guides which are available from the EURACHEM website (www.eurachem.org).

The lectures of this symposium are published on the website of EUROLAB-Germany (www.eurolab-d.bam.de).



New developments
in measurement uncertainty
in chemical analysis

Programme

Sampling uncertainty
and
Uncertainty for compliance
assessment

Symposium at BAM, Berlin
15-16 April 2008 

EUROLAB and the New Legislative Framework

Legislation in Europe was revolutionised in 1985 by the "New Approach":

- Four basic freedoms for movement of goods, persons, services, capital.
- Flexible regulatory framework providing access to the common market while protecting essential public requirements, e.g. safety, health, environment.
- "Essential requirements" defined in EU-Directives: from machinery to toys.
- Harmonised EN Standards define the technical details
 - ENs must be transposed into national standards and conflicting standards withdrawn (Cassis Agreement).
- CE marking: the manufacturer declares that the product is safe and in conformity with the relevant EU Directives.

EUROLAB and the New Legislative Framework



OJ L218 - 13.08.08 :

- [Regulation 765/2008/EC](#) - requirements for accreditation and market surveillance relating to the marketing of products
- [Decision 768/2008/EC](#) - a common framework for the marketing of products

EUROLAB and the New Legislative Framework



Timeframe/Process

- Adoption : 9 July 2008
- Publication in OJEU – 13 August 2008
- Entry into force 20 days after publication
- **Date of application of Regulation 765/2008 is 1 Jan 2010**
- Decision '*sui generis*' = by issue/by sector

EUROLAB and the New Legislative Framework

Why did EC propose the review?



Experience shows Directives do not function in the same way in all Member States

- Different levels of controls in Member States
- Unequal treatment, distortion of competition
- Many non conforming products bearing CE marking
- Lack of trust in marking
- Different ways of controlling notified bodies - no transparency
- Differing definitions, unclear obligations for importers, distributors...

EUROLAB and the New Legislative Framework

Main elements covered by the Review



- Market surveillance
- Accreditation - Notified Bodies
- Role and significance of CE marking
- Common definitions & obligations
- Safeguard clause

EUROLAB and the New Legislative Framework

Regulation –main objectives



- Accreditation
 - Enhance mutual confidence in certificates and quality of conformity assessment bodies
 - Common transparent rules for assessing the competence of conformity assessment bodies
- Market surveillance
 - Make our internal market legislation more effective by ensuring better control of this legislation
 - Ensure equal conditions for economic operators
 - Common minimum requirements
 - Enhanced cooperation and information exchange amongst market surveillance authorities of MS

EUROLAB and the New Legislative Framework

Regulation – Accreditation (1)



Objectives are

- to create confidence in accredited certificates thus establishing trust in the market place
- to ensure ONE accreditation certificate for whole territory of EU
- to introduce a horizontal framework for accreditation and to lay down principles for its operation and organisation at Community level to ensure uniform application

EUROLAB and the New Legislative Framework

Regulation – Accreditation (2)



- Accreditation = Assessment of competence of conformity assessment bodies (laboratories, testing and inspection bodies..)
- Scope: no exemptions – accreditation of all conformity assessment bodies
- Organisational framework: no general obligation to be accredited
- Single accreditation body per Member State

EUROLAB and the New Legislative Framework

Regulation – Accreditation (3)

- Accreditation - a public authority activity
- No competition
- Accreditation in the Member State of establishment
- Requirements for accreditation bodies
- Peer evaluation
- EA (European co-operation for accreditation)



EUROLAB and the New Legislative Framework

Regulation – market surveillance (1)



- Scope
 - “harmonised products”
 - exceptions: food, feed, human blood, cells, tissues and agricultural products
 - lex specialis
- Organisational requirements
 - Infrastructures, resources, powers
 - complaint procedures, monitoring of accidents
 - Market surveillance programmes

EUROLAB and the New Legislative Framework

Regulation – market surveillance (2)



- Surveillance measures
 - appropriate product checks on “adequate scale”
 - Right to enter premises, ask for documentation
 - Warning of users
- Restrictive measures
 - Withdrawal/recall products posing a “serious risk”
 - Rapid information of all Member States
 - Hear economic operator
 - Possibility to destroy products
 - Penalties

EUROLAB and the New Legislative Framework

Regulation – market surveillance (3)



- Communication and co-ordination
 - Exchange of information
 - ✓ Rapid information on dangerous products
 - ✓ Comprehensive database
 - Cooperation
 - ✓ Obligation to cooperate with other MS
 - ✓ Mutual assistance
 - ✓ Joint initiatives, training programmes, sharing of resources

EUROLAB and the New Legislative Framework

Regulation – market surveillance (4)

Control of products entering the Community



- Customs must carry out checks at external borders on an adequate scale
- Suspension of release for free circulation if product
 - is not properly marked
 - presents a serious risk
- Information of market surveillance authorities
- Possibility of destruction

The New Legislative Framework

Key points of the new legislation relevant to Conformity Assessment Bodies (CABs):

- One national accreditation body per country only, no competition with conformity assessment bodies.
- No commercial profit from accreditation activities.
- No cross-border accreditation in principle.
- Peer evaluation system for accreditation bodies, operated – on the basis of a mandate from the European Commission – by EA, the European Cooperation for Accreditation (legal entity).



→ As according to the EU regulation, an effective participation of the interested parties is required, EUROLAB took and still takes an active role in the representation of the accredited organisations within the accreditation structures.

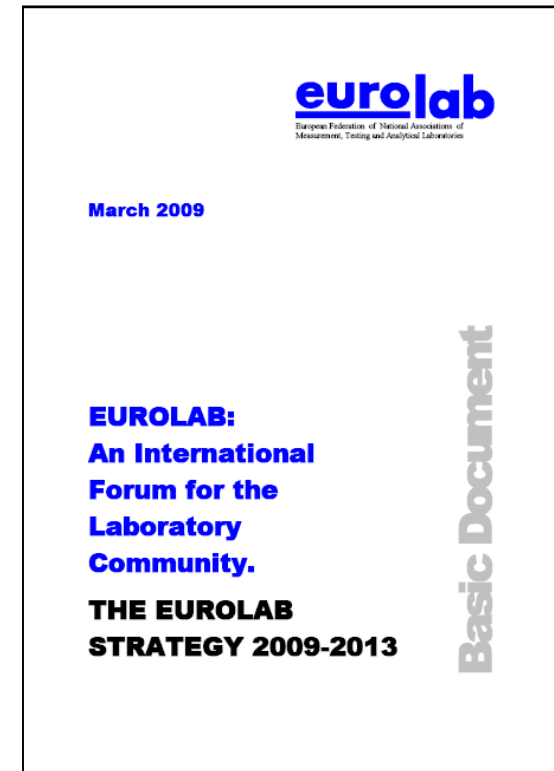
EUROLAB: The new Strategy 2009 - 2013

The EUROLAB Strategy 2009-2013*

has been drafted and

finally approved in March 2009

** Downloadable from the website*



Considering the following driving forces:

- 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 the customer relationships, and development of new or improved services

Considering the following driving forces:

- the need to improve the technical competence and infrastructure of measurement, testing and analytical services also 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 and conformity assessment emerge from industry, economy and public authorities

EUROLAB: The new Strategy 2009 - 2013

The EUROLAB key objectives are:

- Representation by formulating and voicing the opinion of laboratories regarding economical, political and technical issues
- Co-ordination by interfacing with organisations having activities of interest to the laboratory community
- Action by providing adequate means for the exchange of information and experience
- Promotion of cost-effective testing, calibration and measurement services, for which the accuracy and quality assurance requirements are adjusted to the actual needs

EUROLAB: The new Strategy 2009 - 2013

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.

EUROLAB: The new Strategy 2009 - 2013

The short and medium term strategic issues are:

- look for and provide more added value to EUROLAB national members
- advocate and participate in the harmonization of procedures at European and international level
- address the economical, political and technical issues associated with the regulation on accreditation (Regulation 765/2008)
- Closely follow the development of the accreditation requirements for Notified Bodies
- Promote practical implementation of flexible scope of accreditation

EUROLAB: The way forward

(1)

The new EUROLAB 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.

It addresses technical, scientific, economical and political fields at European and international levels

The development in the field of measurement and testing over the next ten years will predominantly be determined by market forces, then new directives, regulations and standards need to be developed, but the envisaged changes are rather seen as a continuous evolution of the present situation.

EUROLAB: The way forward

(2)

The international standardisation programme is very ambitious and the number of proposed new standards in the field of testing and conformity assessment is large. Besides the international, European and national accreditation bodies produce guidance documents.

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. EUROLAB strongly advocates that these guidance documents should only explain the present requirements and not add new requirements to standards. 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.

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.

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And last but not least:

Best Greetings from Europe



Thank you for your attention!

Visit us at www.eurolab.org

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