



Letter from **EUROPE**

As we are entering a new decade, we also enter a new era for conformity assessment bodies in Europe. This is due to a new European legal framework on accreditation and market surveillance.



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Contributing Editor**

This first Letter from Europe in 2010 deals with: Strategies in the New Decade and Accreditation and Conformity Assessment.

- Accreditation: The new legal EU framework relating to the marketing of products, applying from January 2010.
- Conformity Assessment: The updated EUROLAB Strategy for measurement, testing and analytical services.

A general look at the interrelations between market, trade, conformity assessment, and accreditation

In today's global market and trade there is an increased need for conformity assessment, calibration, testing, inspection, and certification ensuring that products and equipment meet specifications. Along with the growing use of these conformity assessment tools goes the request for assurance of the competence of the conformity assessment bodies. An increasingly applied and recognized tool for this is accreditation. Figure 1 gives an overview of the interrelations between market, trade, conformity assessment, and accreditation.

To support market and trade, conformity assessment services play an important role. The primary goal of conformity assessment is to provide the user, purchaser or regulator with the necessary confidence that a product, service, process, system or person meets relevant requirements. The International Standards relevant for conformity assessment services are provided by ISO's Committee on Conformity Assessment (CASCO). The conformity assessment tools are listed in Table 1 with identification (x) on their use by first parties (suppliers), second parties (customers, regulators, trade organizations) and third parties (bodies' independent from both suppliers and customers).

The EU legal framework relating to the marketing of products

Before considering the new developments, a look back on the evolution of the European Economic Community should be made. Thanks are due to Anita Schmidt from BAM, the German Federal Institute for Materials Research and Testing, for her help in compiling the following overview on the EU legal framework and its new developments relating to the marketing of product.

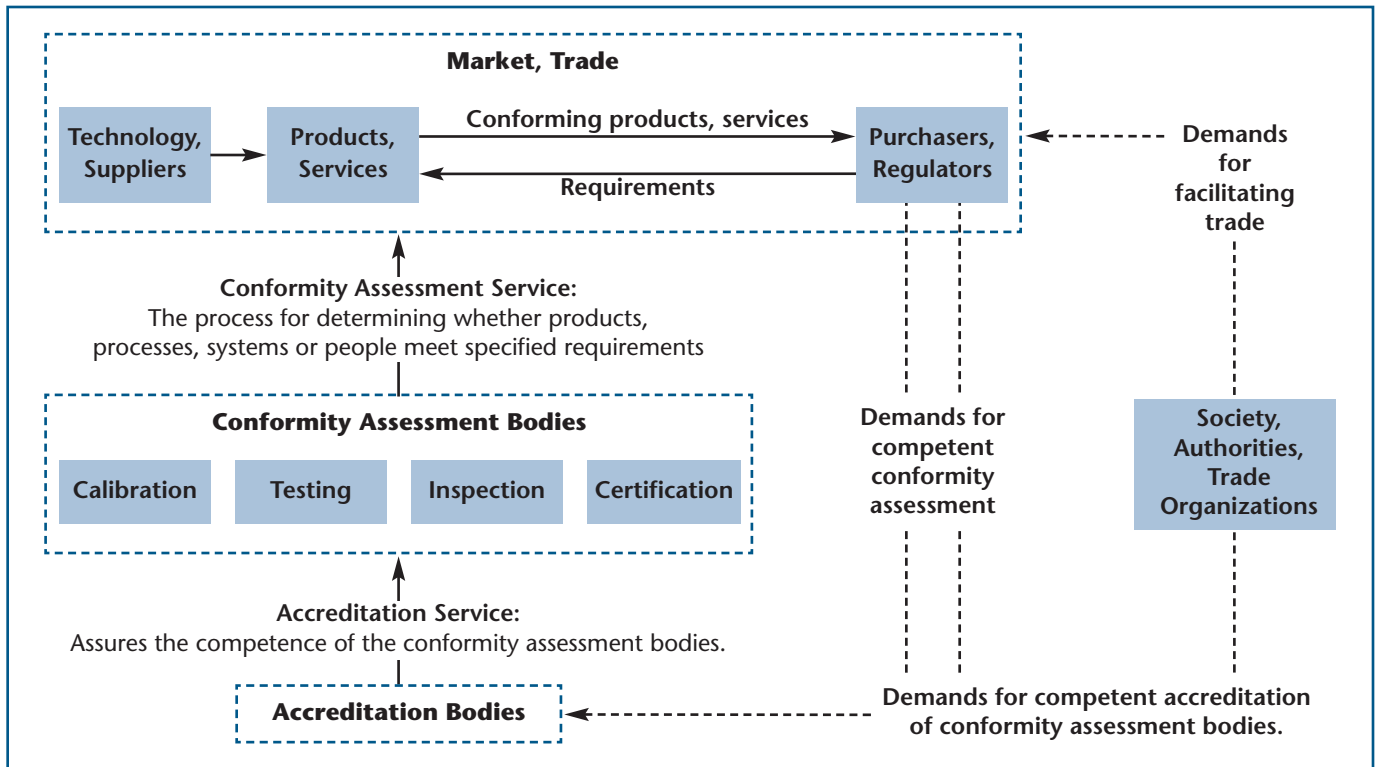


Figure 1. Overview of the interrelations between market, trade, conformity assessment, and accreditation.

The establishment of a common European market depends upon an adequate level of technical harmonization. To this aim, EU legislation was revolutionized in 1985 with the so-called “New Approach to harmonization and standardization.” This “New Approach” is based on a few key principles:

- EEC legislative harmonization (e.g. EEC Directives for product groups: toys, construction products, machinery etc.) ensures the free movement of products throughout the Community.
- Corresponding technical specifications are described in harmonized standards.

- Products manufactured in conformity with harmonized standards are presumed to be conformant to the essential requirements.
- CE marking allowing the manufacturer to declare that the product is in conformity with the legislative requirements and may be placed on the market.
- Safety clauses require the Member States to take all appropriate measures to withdraw unsafe products from the market.

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2010 The New EU Internal Market Package for Goods

Modernizing the “New Approach,” in 2008 a new legislative framework for marketing of products was adopted, which applies from January 1, 2010. The new measures consist of the following three legal acts:

- Regulation (EC) No. 765/2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products.
<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:218:0030:0047:EN:PDF>
- Decision No. 768/2008/EC on a common framework for the marketing of products

Tools for Conformity Assessment	First Party: (suppliers, users)	Second Party: (customers, regulators, trade associations)	Third Party: (bodies independent from first and second parties)	ISO Standards
Supplier's Declaration	x			ISO/IEC 17050
Calibration Testing	x	x	x	ISO/IEC 17025
Inspection	x	x	x	ISO/IEC 17020
Certification			x	ISO 17021 ISO Guide 65

Table 1. Tools for Conformity Assessment.

- Regulation (EC) No. 764/2008 laying down procedures relating to the application of certain national technical rules to products lawfully marketed in another Member State.

Of the three acts, Regulation No. 765/2008 on accreditation and market surveillance is the most important for the conformity assessment bodies. In order to enhance the confidence in and quality of conformity assessments of products it contains clear rules on the requirements for notification of conformity assessment bodies. The accreditation system is chosen as a major tool.

Herewith, for the first time a legal framework for the provision of accreditation services across Europe applies. It covers the operation of accreditation in support of both voluntary conformity assessment as well as conformity assessment required by legislation. Important aspects are:

- accreditation as public authority activity
- responsibility of the member state
- one national accreditation body per country permitted
- conformity assessment body must use its national accreditation body

- cross frontier accreditation is generally not possible and restricted to exceptional cases
- the European co-operation for Accreditation (EA) to coordinate European accreditation infrastructure.

In essence, the Regulation will require National Accreditation Bodies:

- to operate on a not for profit basis
- to be objective and impartial
- to employ competent personnel for the tasks to be carried out
- to be independent from the conformity assessment bodies they accredit
- not to offer services offered by conformity assessment bodies.

To improve the consistency of accreditation services across Europe, the Regulation sets common requirements for national accreditation bodies, to be monitored by Member State governments. The Regulation also recognizes the European co-operation for Accreditation (EA) as the coordinating organization for the national European accreditation infrastructure. National accreditation bodies will be required to be members of EA and to participate in the peer evaluation program operated by

EA as the preferred means of demonstrating compliance with the legal requirements.

Developments in conformity assessment: The EUROLAB strategy in 2010

With the evolution of the European Union, the conformity assessment bodies in Europe gathered together to form EUROLAB as an international forum for the laboratory community.

EUROLAB's general objectives are:

- Representation by formulating and voicing the opinion of laboratories regarding economical, political and technical issues on the European scene, and also worldwide.
- Coordination by interfacing with organizations 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 actual needs.



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For the future development of EUROLAB major driving forces are:

- the changing market situation requires more attention to be paid to the customer relationships, and development of new or improved services
- 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 the field of life sciences and nanotechnologies
- the integration of new EU member countries
- the internationalization and globalization process forcing EUROLAB to be much more active in the international arena.

As a result of the EUROLAB strategy, the following key goals should be achieved:

- improved cost-effectiveness in the whole value chain of measurement and testing
- more added value from accreditation
- stronger influence on legislation by expressing the views of the laboratory community
- more differentiation in the services provided to national EUROLABs and their members with increased two-way communication
- enhanced information activities, especially in support of technical advice to the laboratory community.

Concluding this overview on developments in accreditation and conformity assessment, a statement on the importance of measurement and testing by the Commission of the European Union will be quoted:

There is no science without measurements, no quality without testing and no global market without standards.

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