



**European  
co-operation for  
Accreditation**

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## **ACCREDITATION UNDERPINNING THE DEVELOPMENT OF ECONOMY AND SOCIETY**

**Lorenzo Thione**

Chairman

**EA – European co-operation for Accreditation**

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# Accreditation

- Accreditation – as independent and authoritative attestation of the competence, impartiality and integrity of conformity assessment bodies (CABs) and bodies performing related activities and thus of the value and credibility of the corresponding attestations of conformity (calibration certificates, test reports, inspection reports, certifications of management systems, products and personnel, other attestations) – has, in the last two decades, definitely affirmed its major role and attained remarkable achievements in favouring the elimination of technical barriers to trade and contributing to the protection of the fundamental rights of people.

# Accreditation

- Confidence provided by accreditation has been recognized and valued as equally needed for both purposes of protecting public general interests and supporting the economic progress and accreditation is having and will have, in Europe and elsewhere, an increasing impact on economical and social policies and related implementation.
- Accreditation, both in Europe and worldwide, shall be fully exploited to the advantage of both regulated and voluntary sectors.

# Accreditation

- Accreditation rules and procedures are harmonized at supra-national level.
- Harmonization is achieved making reference to normative documents commonly accepted world wide – for accreditation bodies (ABs), for conformity assessment bodies (CABs) and for the objects of the conformity assessment (products, processes, systems, personnel) – and by proper control of the functioning of the accreditation bodies and related conformity assessment chains exerted by supra-national (regional and international) accreditation co-operation entities.

# The supra-national accreditation infrastructure

- Supra-national accreditation cooperation entities include:

At regional level (just to mention the main ones):

- **EA “European co-operation for Accreditation”**;
- APLAC “Asia Pacific Laboratory Accreditation Co-operation”;
- PAC “Pacific Accreditation Co-operation”;
- IAAC “Inter American Accreditation Co-operation”;
- SADCA “South African Development Community Accreditation”.

At world wide level:

- ILAC “International Laboratory Accreditation Co-operation”;
- IAF “International Accreditation Forum”.

# The Multilateral Recognition Agreements

- Assuring that ABs are properly following the applicable rules and duly enforcing their observance by the accredited CABs is performed by means of “peer evaluations” managed by the above cited supra-national co-operations, leading to the establishment of Multilateral Recognition Agreements or Arrangements (MLA or MRA).
- The Multilateral Agreements at world wide level (ILAC and IAF) are essentially based on the agreements managed by the regional organizations and the proper operation of regional agreements (e.g. the EA MLA) is a must for the effectiveness and credibility of the world wide accreditation system.

# The Multilateral Recognition Agreements

- The peer evaluations systems are the basis for the establishment and maintenance of the MLAs/MRAs.
- If properly organized and managed, based on solid and transparent criteria and procedures, they do guarantee that the ABs signatories to the Agreements operate accreditation systems that are equivalent, in terms of adequacy and effectiveness, and such to ensure that the attestations of conformity issued under the respective accreditations are equally reliable and can be trusted by the direct and indirect users of them (the “marketplace” in its broader meaning).

# The Multilateral Recognition Agreements

- The MLAs / MRAs are thus the basis for:
  - reinforcing the credibility of accreditation vis-à-vis the interested parties, by ensuring the proper operation of the signatories ABs subject to rigorous evaluations;
  - facilitating the free circulation of products and services, by ensuring the equal trustworthiness of the relevant attestations of conformity issued in any country and under any of the signatory's accreditation, regarding the ability of such products and services of fulfilling the applicable requirements, both defined by voluntary norms and specifications and established by mandatory regulations.

# EA – European co-operation for accreditation

- EA is the Association of the national European accreditation bodies providing accreditation of all conformity assessment activities in both voluntary and regulated spheres.
- EA was operationally formed in 1997, following the progressive merge of pre-existing European accreditation co-operations dating back to 1976 and was established as a legal entity in 2000.
- In November 2007, EA has celebrated its tenth Anniversary
- The organizational structure of EA consists of an Advisory Board (gathering all stakeholders categories), a General Assembly, an Executive Committee, 5 Committees (among which the MAC Committee ruling the EA peer evaluation system and the related Agreements (MLA, BLAs), and of a permanent Secretariat.

# EA – European co-operation for accreditation

- EA has, at present, **35 full members**, these being Accreditation Bodies (or systems) of countries member of EU and EFTA or candidate to join them. Among these, there are **32 Bodies signatories** to the EA MLA out of which **18** have signed for all accreditation activities presently covered by the EA MLA.
- EA has currently **17 contracts of cooperation** with ABs of European countries not yet fulfilling the requisites for full membership and of non European countries.
- **10** of such contracts have developed into **Bilateral Agreements** (BLAs) that convey the same benefits, in terms of mutual recognition, as the EA MLA.
- The mission of EA is to provide Europe with an effective and reliable accreditation infrastructure serving at best the needs of the European economy and society.

# The new European legislative package

## General

- This package consists of two main complementary documents (\*) that have been approved by the European Parliament on February 21 2008, formally adopted by the Council of the EU on June 23 2008 and published on the OJEU on August 13 2008, namely:
  - a **Regulation** setting out requirements for accreditation and market surveillance (EC 765/2008);
  - a **Decision** on a common framework for the marketing of products (768/2008/EC).
- The Regulation is directly and immediately applicable. The Decision (sui generis) is the base for the future sectoral legislation (e.g. issuance of new Directives and revision of the existing ones).
- (\*) The package also includes a third document (Regulation EC 764/2008) laying down procedures relating to the application of national technical rules to products marketed in another Member State not being subject of harmonization at the Community level.

# The new European legislative package

## General

- This set of legal acts – and in particular the Regulation setting out the requirements for accreditation – is a good example of how technical tools that have been developed essentially based on voluntary choices of “private” operators can be valued and exploited in the frame of the regulatory policies of a given social and economical context (in this case Europe).
- The Regulation on accreditation – aiming at formally regulating the operation of accreditation at Community level, enhancing its rigour, effectiveness, transparency and uniformity – is briefly outlined in this presentation since it represents a central pillar for the development of the European “Quality Infrastructure” and a model to be possibly followed by other similar regional contexts.

# The new European legislative package

## The Regulation on Accreditation

- As European Regulation it is **effectively a law** and is directly applicable to Member States and to national accreditation bodies.
- It applies to **accreditation of all conformity assessment activities** in both voluntary and regulated sectors.
- **Main provisions** are:
  - one national AB per Member State (this preventing to have more national ABs competing among them);
  - ABs act with public authority in the public interest (this representing a juridical recognition of accreditation);
  - ABs shall be independent of commercial motivations, being not-for-profit organizations;
  - ABs shall not be involved in conformity assessment and consulting activities;

# The new European legislative package

## The Regulation on Accreditation

- **Main provisions (cont.):**
  - Member States shall ensure that the national ABs have appropriate resources;
  - national ABs shall be member of EA;
  - ABs shall enable effective and balanced participation of the interested parties;
  - being accreditation the preferred way, Member States not resorting to accreditation in their authorization processes shall provide evidence of the equivalence of the procedures used;
  - cross-frontier accreditation is restricted to specific cases and cooperation among ABs is required;
  - Member States shall monitor their national ABs and take the necessary measures;
  - national ABs shall subject themselves to the peer evaluations conducted by EA, under the responsibility of the Member States;
  - the Commission shall oversee the proper functioning of the peer evaluation system in cooperation with the Member States.

# The new European legislative package

## The new role of EA

- Pursuant to the Regulation, EA is recognized as the official European accreditation infrastructure (Article 14 and Annex I of the Regulation).
- This recognition is being implemented by:
  - the establishment of Guidelines defining the principles for the cooperation between EA and EC, EFTA and competent National Authorities and providing criteria for the effective and timely implementation of the new role;
  - the stipulation of a Partnership Agreement between EA, EC and EFTA that will place EA in the same position of other organizations of major European interest, such as the European Standardization Bodies, the JRC and similar.

# The development of accreditation

## General

- The main principle underlying such development is that accreditation shall be the ultimate level of control of the adequacy of the conformity assessment services in both voluntary and mandatory areas.
- This principle has been at the basis of the EA's "accreditation model" from the very beginning.
- It has duly inspired the new European Regulation in establishing a legal base for accreditation, ratifying its juridical recognition as public authority service with monopolistic character and fostering, although not making obligatory, the use of accreditation in the mandatory area.
- It is foreboded that a similar approach be adopted in other similar contexts worldwide.

# The development of accreditation

## General

- For accreditation being able to duly perform its strategic role of major promoter and ultimate guardian of the credibility of the conformity assessment services worldwide, continuous improvements are necessary.
- Accreditation principles and practices must be constantly developed to meet the evolving needs of economy and society and their effective and uniform adoption must be continuously and rigorously ensured, to maintain and consolidate stakeholders confidence, particularly in those sectors where the credibility of accredited conformity assessment services is being seriously challenged.

# The development of accreditation

## Focusing on the output

- In particular, accreditation must be able to ascertain and confirm in depth that CABs have the specialist knowledge and expertise required to operate in the different technical sectors and that such know-how is properly and consistently applied to the assessments.
- In few words, accreditation and accredited conformity assessment services shall become more “**output focussed**” and this can be achieved only making a definite “**move from the culture of procedures to the culture of results**”, this being indeed the basic commandment that should inspire the best accomplishment of the very role of accreditation.
- Cooperation with stakeholders – as CAB organizations, National Regulators, industry and society at large – is essential for the effective pursuance of the above objectives.

# The development of accreditation

## Towards an “output focussed” accreditation

- Major areas, where problems still exist and improvement efforts are to be concentrated, include:
  - the competence of AB assessors who must be able to follow a process oriented approach and be knowledgeable of the pertinent technologies, products and process;
  - the conduct of the assessment that should be focussed on assessing the performance of the CABs looking, in particular, to the quality of its results;
  - the surveillance mechanisms that shall be reinforced strengthening the witness activities and introducing a direct monitoring based on collection of quality indicators and on suitable forms of direct market surveillance;
  - the sanction measures that shall be enhanced by adopting more rigorous and harmonized sanctions policies;
  - the complaint handling by the ABs that shall be rendered more timely and effective;

# The development of accreditation

## Towards an “output focussed accreditation”

- Areas for improvement (cont.):
  - the control of cross-frontier accreditations that should be enhanced by enforcing the observance of the existing rules and fostering the cooperation between the foreign AB and the local AB;
  - the feedback mechanisms; ABs shall have in place distinct and proper mechanisms to search for and obtain feedbacks from the direct and indirect users of the accredited conformity assessment services and shall integrate these feedbacks in their accreditation policies and practices;
  - the harmonization of the behaviour of ABs that needs to be enhanced by a better enforcement of the observance of the rules through improving the effectiveness and consistency of the peer evaluations. At regional level the process shall be rendered more incisive and continuous and chiefly focussed on the performance of the ABs and of the accredited CABs. At the international level, optimal use shall be made of the regional MLAs enhancing the monitoring of their operation.

# The development of accreditation Toward “performance based” accredited certifications

- The reinforcement of the effectiveness of accreditation as described above will, by definition, significantly contribute to the improvement of the quality of the accredited conformity assessment services. In addition and with particular reference to management system certifications, the following main aspects are to be considered:
  - the competence of the certification bodies (CBs) auditors and the effective use of auditors by the CBs;
  - the conduct of the audit (preparation, execution, reporting);
  - the contrast to “price” competition among CBs;
  - the “metrics” to be used by CBs to measure initially and to keep under continuous monitoring the performance of the certified organizations.

# Conclusions

- A robust and trustworthy third party conformity assessment infrastructure, delivering credible attestations of conformity to mandatory regulations and voluntary standards, is needed for both purposes of protecting public general interests and supporting the progress of the economy.
- Accreditation has proved to be a valuable tool for the development, consolidation and optimal exploitation of such infrastructure.
- It is the task of the supra-national organizations coordinating the operation of national accreditation bodies, at both regional and international level, to consolidate and further expand such achievements, ever better responding to the demands from the economy and society.
- EA will certainly make its part as surely will do the other regional co-operations and the international organizations, the latter essentially in terms of subsidiarity to the former, to contribute to the creation of a world where quality, as ability of satisfying needs, is the motor of economical and social relations.