European co-operation for Accreditation

Accreditation and Market Access in Europe

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Economic Drivers in Europe

- Trade Policy
  - Promotion of free trade
  - More open trade and investment
  - More growth and jobs
  - Lower consumer prices
- Size of European economy
- Dependency on trade for employment
- Growth in world trade

Internal Market in Europe

- Contribute to WTO TBT Agreement obligations
- Do not create or maintain barriers to intra-EU trade
- Apply specific rules for certain products (e.g. New Approach and New Legislative Framework)

Prevention of TBT

- Principle of free movement of goods
- Internal EU notification procedure for new technical regulations related to products and services
- Flexible regulatory framework while protecting essential public requirements

New Approach Legislation

- Product legislation restricted to essential requirements, conformity assessment procedures and CE marking
- Enables essential requirements to be combined with technical specifications/harmonised standards
- Standardised conformity assessment
- More flexibility
- Helped innovation

New Legislative Framework

- Focused on marketing of products
- Includes market surveillance and accreditation
- Retains flexibility of approach
- Published August 2008
- Came into force on 1 January 2010

The New European Legislative Package

- Regulation (EC) 765/2008
  - Sets out requirements for accreditation and market surveillance
- Decision 768/2008/EC
  - A common framework for the marketing of products
- Regulation (EC) 764/2008
  - Procedure for application of national technical rules

New Legislative Framework (2)

- Better rules on market surveillance
- Reinforced and clearer rules on the requirements for notification of conformity assessment bodies
- Enhances the credibility and clarifies the meaning of CE Marking
- Establishes a common legal framework for future legislation

Conformity Assessment

- The essential requirements governing the characteristics of the products covered
- Conformity assessment procedures required to demonstrate that a product, before it is placed on the market, conforms to the essential requirements of the directive that apply to it

Conformity Assessment (2)

Decision 768 - Presumption of conformity

- Where a conformity assessment body demonstrates its conformity with the criteria laid down in the relevant harmonised standards ……. …… it shall be presumed to comply with the requirements set out in Article [R17 - Requirements relating to notified bodies] in so far as the applicable harmonised standards cover those requirements

Notification & CE Marking

Notification

- Where a Member State informs the EC and the other Member States that a body, which fulfils the relevant requirements, has been designated to carry out conformity assessment according to a Directive

CE marking

- A key indicator of a product's compliance with legislation - by placing CE marking on a product, manufacturers declare that the products comply with all the legal requirements in force in Europe

European Accreditation Policy

- Regulation 765/2008 provides a common legal basis for accreditation
- Enhance mutual confidence in accredited certificates
- Accreditation recognized as the ultimate level of control of the adequacy of the conformity assessment services in both the voluntary and mandatory area

Main Principles

- One National Accreditation Body (NAB) per Member State (MS)
- Non-competition
- Public authority activity
- Non-profit, impartial, objective
- Balanced participation of interested parties
- Formal recognition of EA as the official European accreditation infrastructure

European cooperation for Accreditation (EA)

- Association of European National Accreditation Bodies of EU/EFTA/candidate countries
- 35 Full Members
- 13 Associate Members
- 33 Signatories to the EA Multilateral Agreement (26 of which are for all activities covered by the MLA)

Role of EA

- To define, harmonise and build consistency in accreditation as a service in Europe
- To maintain a multilateral agreement on mutual recognition between the accreditation schemes
- To provide Europe with an effective and reliable accreditation infrastructure to serve the needs of the economy and society, representing the last level of control of conformity assessment services in both voluntary and mandatory areas

EA Accreditations - 2011

Calibration Laboratories	2,598 (2,543)
Testing Laboratories	12,833 (11,989)
Medical (ISO 15189) Laboratories	1871 (869)
PT Providers	88 (80)
Product CBs	974 (967)
Management System CBs	1,113 (1,018)
Persons CBs	319 (307)

Greenhouse Gas Verifiers	84 (78)
Inspection Bodies	4,788 (4,569)
Organic Farming CBs	167 (125)
Occupational H&S Management CBs	203 (171)
Information Security Management System CBs	105 (91)
Food Safety Management System CBs	173 (172)

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Recognition of accreditation

- Accredited reports and certificates issued under the accreditation of an ILAC or IAF accreditation body signatory are considered to be equally reliable by EA to those issued under accreditation within the EA MLA

- When using accreditation for notification purposes or for the recognition of conformity assessment bodies, Member States' authorities and the European Commission should pay particular attention that the accreditation bodies providing the certificates comply with the Regulation or are a peer evaluated by a member of ILAC/IAF complying with EN ISO/IEC 17011.

Acceptance of accredited conformity assessment attestations in the EU

- Voluntary Conformity Assessment area:
  - Specifiers and the marketplace are free to decide on acceptability

Acceptance of accredited conformity assessment attestations in the EU

- Mandatory Conformity Assessment area:
  - National authorities of EU Member States:
    - must generally accept attestations of conformity issued under accreditation from an EA MLA signatory
    - may accept attestations of conformity issued under accreditation from non-European accreditation bodies that are signatories to IAF or ILAC MLA/MRA

➢ except where an EU to Country MRA is in place

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