European Directives and Regulations

Accreditation in Support of Market Access

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Outline

- Overview of the regulatory and accreditation "landscape" in Europe – the New Legislative Framework
- European accreditation policy in support of market access
- Implementation of the New Legislative Framework

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
- Need for growth in trade

Evolution of Regulatory Policy

- Phases:
  - “Old Approach”
  - “New Approach”
  - Development of conformity assessment instruments
  - New Legislative Framework

Old Approach

- “Traditional”
- Detailed
- Slow
- Unwieldy

New Approach

- 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 (1)

- 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)

- Focuses on marketing of products
- 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 legal basis for accreditation in Europe
- Establishes a common legal framework for future legislation

New Legislative Framework (3)

- Considers all economic operators in the supply chain - manufacturers, authorised representatives, distributors and importers, for their respective roles
- Emphasis on “making available” to the market

New Legislative Framework (Summary)

- Essential requirements
- Product standards
- Standards for competence of conformity assessment and accreditation bodies
- Standards for quality management and certification processes
- Conformity assessment procedures
- CE marking
- Accreditation policy
- Market surveillance policy

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
- Options for legislators in choice of conformity assessment required

Conformity Assessment (2)

Decision 768/2008 - 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 …… 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 it complies 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 areas
- Regulation recognises European cooperation for Accreditation

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

Recognition of Accreditation (2)

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

Recognition of Accreditation (3)

- Mandatory Conformity Assessment area:
  - National authorities of EU Member States:
    - must 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

Implementation of New Legislative Framework

- Risk?
  - Medical Devices - Implementing Regulation for existing Directives and proposed new Regulations
- Awareness of Accreditation?
  - Energy Efficiency Regulations, End of Waste Regulations, Roadworthiness testing, Revision of EMAS (Eco-Management and Audit Scheme)
- Engagement:
  - EU Emissions Trading Scheme, organic farming, Alignment Package of existing Directives

Conclusions

Thank you

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