

Key issues of the proposed EU Regulation for CABs

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- Regulatory approach to free movement of goods

Key issues of the proposed EU Regulation for CABs

PROBLEMS

- +/- 1800 Notified Bodies (NBs)
- Notification procedures & criteria
 - Need of more equal level playing field for CABs and manufacturers
 - Need of greater transparency
- Role of accreditation
 - No legal basis and common rules at Community level
 - Uneven use for notification of CABs in Member States
- Incoherence definitions & conformity assessment
- Relationship CE marking/others

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PROPOSED SOLUTION

- Clear overall policy
- 2 legislative instruments covering both New and Old Approach

REGULATION
directly and immediately applicable

DECISION (sui generis)
to be used for revision of sectoral legislation + drafting of new legislation

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REGULATION (COM 2007 – 37)

- Accreditation
- Market surveillance
 - internal
 - third country products
- Community financing for intercomparisons

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ACCREDITATION

- **Framework and principles for its operation:**
 - **Public authority activity**
 - **1 national accreditation body (NAB) per Member State**
 - **Prevention of competition between NABs and between NABs and accredited CABs**
 - **Set of requirements for NABs**
 - **Peer evaluation**
 - **Cooperation between national accreditation bodies => EA (European co-operation for accreditation)**
- **Rules applicable to mandatory & voluntary area**

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ACCREDITATION BODIES shall:

- **Be completely independent from commercial motivations;**
- **Be authoritative and impartial bodies;**
- **NOT be involved in conformity assessment activities for which they accredit other bodies;**
- **Demonstrate a high level of competence via participation in the EA peer evaluation system.**
- **SME issue and conformity assessment**

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DECISION (COM 2007 – 53)

- **Legislative framework**
- **Definitions & obligations for economic operators**
- **Notification (criteria & process & accred.)**
- **Conformity assessment procedures**
- **CE marking**
- **Safeguard mechanisms (& market surveillance)**

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COMMUNITY FRAMEWORK FOR NBs

- **Strengthening of the requirements for notifying authorities**
 - No conflict of interest, objectivity, impartiality
 - Competent personnel at its disposal
- **Strengthening of the requirements for notified bodies**
 - Always third-party bodies – independence, impartiality
 - Competent personnel for conformity assessment activities
 - Access to necessary equipment and facilities
 - Subsidiaries and sub-contractors to meet the same requirements as NBs
 - Information obligations
 - Participation in Groups of NBs

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- **Notification**
 - Accreditation = preferred way of demonstrating competence of CABs
 - Need of documentary evidence to demonstrate competence if accreditation not used
 - Procedure – electronic notification and online database of NBs
- **Accredited in-house bodies**
 - Separate and identifiable part of an undertaking
 - Services only for the undertaking of which it forms a part

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TIMETABLE

- **Adoption Commission:**
 - 14 February 2007
- **Adoption Council/EP? (end 2008?)**
- **Implementing measures**
- **Review of sectoral legislation**