

New Legislative Framework

Accreditation & Notification

Seminar on free movement of goods in the Western Balkans (HOT 4) 17 June 2010

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Unit C1: Regulatory approach for the free movement of goods and market surveillance



European Commission
Enterprise and Industry

New Legislative Framework

- **2 complementary instruments**
 - **Regulation 765/2008/EC** - requirements for **accreditation** and **market surveillance** relating to the marketing of products
 - **Decision 768/2008/EC** - a **common framework** for the marketing of products
- **Horizontal framework for Community harmonisation legislation = legislation fixing conditions for the marketing of products**
- **Objective:** Improve the functioning of the internal market in practice



European Commission
Enterprise and Industry

2 complementary legal texts

REGULATION 765/2008

- **Accreditation**
- Market Surveillance
 - Internal
 - Imported products
- **CE** General principles
- Financing elements

Applicable 1 Jan 2010

DECISION 768/2008

- Definitions
- Obligations for economic operators
- Conformity Assessment Procedures
- **CE** marking
- **Notified bodies**
- Safeguard mechanisms

Basis for future legislation



Regulation – Accreditation

Main principles

- What is accreditation?
- **Scope: no exemptions**
 - Accreditation relating to conformity assessment
 - Rules apply both to mandatory and voluntary areas
 - Apply to product and services
- **Not render obligatory**
- **Last level of control**



Regulation – Accreditation

- **Public authority activity**
- **Single national accreditation body**
- **Non competition principle**
 - ⇒ Strict cross border policy
- **Recognition of EA** (European co-operation for accreditation) as official European accreditation infrastructure
 - Management of the peer evaluation
 - EC can mandate to develop sectoral accreditation schemes

Regulation – Accreditation

- **Requirements for NABs**
 - Not for profit, not be involved in conformity assessment
 - Involvement of stakeholders
 - Member of EA and undergoes peer evaluation
 - ...
 - **Requirements for MS**
 - NAB fulfil requirements
 - Appropriate resources
 - Prove that CAB evaluated not using accreditation complies with requirements
 - ...
- structural + administrative changes & legal alignment

Decision – toolbox for future legislation

- **Objective:** ensure a more coherent and robust regulatory framework for the free movement of goods
- Lays down **general principles and reference (model) provisions** for the drafting of legislation
- European legislator (COMM, Council and EP) has **committed** himself to use it whenever possible
- Deviations need to be **justified**

Decision - Notified Bodies

- Where the Directives delegate conformity assessment to third parties, these are undertaken by 'Notified Bodies'
- Notified Bodies are officially 'notified' to the EC and MS
- Notification process :
accreditation vs other evidence

Decision – Notification

- Requirements for notifying authorities
- Requirements for NBs
- Subsidiaries and sub-contracting
- Accredited in-house bodies
- Electronic notification / de-notification
- Co-ordination GNBs

Web site addresses

- New internal market package:
http://ec.europa.eu/enterprise/regulation/internal_market_package/index_en.htm
- Questions:
Entr-reg-approach-for-free-circ@ec.europa.eu

**Thank you
for your attention**