

The New Legislative Framework

**Workshop “New regulatory requirements
for accreditation and market surveillance”
Athens, 5 November 2008**

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Unit C1: Regulatory approach for the free movement of goods



European Commission
Enterprise and Industry

New Legislative Framework - Texts

OJ L218 - 13.08.08 :

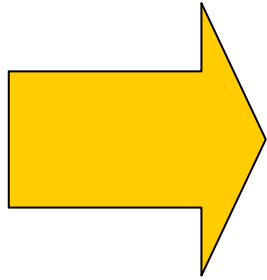
- Regulation 765/2008 - requirements for accreditation and market surveillance relating to the marketing of products
- Decision 768/2008/EC - a common framework for the marketing of products

Why did we propose the review?

Experience shows Directives do not function in the same way in all Member States

- Risk of distortion of competition
- Unequal treatment
- Lack of trust in conformity marking
- Lack of coherence in implementation and enforcement

Why did we propose the review?



Manufacturers do not benefit from the original intention of full access to the Internal Market

New Legislative Framework

Regulation 765/2008 & Decision 768/2008/EC

- Form common rules for placing products (covered by harmonisation legislation) on the Community market
- No fundamental change to technical / sector specific safety requirements
- Updated and strengthened the horizontal elements

Main elements covered

- Market surveillance / Accreditation
- Notified Bodies
- Role and significance of CE marking
- Common definitions & obligations

**Strengthened system
through enhancement of the
main features**

Complementary legislative tools

REGULATION

- Accreditation
- Market Surveillance
 - Internal
 - Imported products
-  General principles

**Overall framework
applicable 1 Jan 2010**

DECISION

- Definitions
- Obligations for economic operators
- Notified bodies (criteria / notification / obligations)
- Conformity Assessment Procedures
- Safeguard mechanism
-  marking

**Toolbox: Basis for future
legislation**

Regulation – Market surveillance

Scope

- Products = Substances , preparations and goods produced through a manufacturing process, except food, feed, human blood and tissues, living plants and animals
- Exemptions
 - via product definition Art 15(4)
 - via *lex specialis* Art. 15(2): pharmaceuticals, drug precursors, civil aviation, motor vehicles, medical devices
 - Authorities may take more specific measures as provided for in GPSD Art. 15(3)

Regulation – Market surveillance

Common minimum requirements in all Member States

- Organisational/operational requirements
- Restrictive measures
- (Safeguard clause - Decision)
- Co-operation at European level
- Exchange of information
- External border control

Regulation – Accreditation

Main principles

- Scope: no exemptions
 - Accreditation relating to conformity assessment
 - Rules apply both to mandatory and voluntary areas
 - Apply to product and services
- Why introduce accreditation?
- Not render obligatory
- Strengthening the use of accreditation in the regulated area
 - Accreditation vs. alternative assessment

Regulation – Accreditation

- Last level of control
- 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
 - Operate on a not for profit basis
 - No competition between NABs and between NABs and accredited CABS
 - Be a member of EA and participation in peer evaluation
- Requirements for Member States

Regulation – CE

General principles

- Clarification on use
- Clarification on meaning


Decision –

Toolbox for future legislation (1)

- Definitions / obligations for economic operators
 - Manufacturers / distributor / importer etc
- Notification
 - Requirements for notifying authorities
 - Requirements for NBs / role of accreditation
 - Subsidiaries and sub-contracting
 - Accredited in-house bodies
 - Electronic notification / de-notification
 - Participation in Groups of notified bodies

Decision –

Toolbox for future legislation (2)

- Conformity of the product
 - Assessment procedures
- Market Surveillance
 - Safeguard procedures
-  Marking
 - Rules and conditions for affixing – form of the marking

And Community Collective trade mark

Implementation – Member States

- Need for action: only for Regulation
- Structural and organisational alignment
 - accreditation
 - Single national accreditation body, exercise of public authority, appropriate financial resources
 - Market surveillance
 - (Market surveillance authorities)
 - Communication mechanism between national authorities
 - Procedures in order to react to complaints, monitor accidents, verify corrective action
 - Market surveillance programmes
- Legal alignment
 - removal of inconsistent provisions

Implementation – EC Market surveillance

- Functioning of *lex specialis*?
- Extension of RAPEX
- Database for exchange of information – ICSMS?
- Operation of safeguard clauses: integration in exchange of information
- Co-ordination infrastructures

Implementation – EC Accreditation

- Political guidelines – EC, EFTA, MS & EA
- Framework partnership agreement for EA
- Inter-service steering group for accreditation
- Publication list of NABs (NANDO?)
- Peer evaluation: rules for small MS
- Follow national legislative evolutions in MS

Implementation – EC Decision

- Decision *sui generis*
- “automatic alignment” in case of revision of sectoral Directives
 - currently: toys, construction products
- What about sectoral directives not under revision?
 - By issue? Separate Directives? Omnibus?
- Practical aspects
 - NANDO

Web site addresses

- New Approach review:

http://ec.europa.eu/enterprise/newapproach/review_en.htm

- New internal market package:

http://ec.europa.eu/enterprise/regulation/internal_market_package/index_en.htm

- Questions:

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