

The New Legislative Framework

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Unit C1: Regulatory approach for the free movement of goods



European Commission
Enterprise and Industry

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

Need for the Review

- Because experience has shown that the New Approach directives are not all functioning in the same way in all Member States
- As a result, manufacturers do not benefit from the original intention of full access to the Internal Market and dangerous products continue to appear on the market

The Review

- New Approach 20 years old
- Simplification of legislation / Better regulation
- Completion of the single market
- Risk of distortion of competition
- Lack of trust in conformity marking
- Lack of coherence in implementation and enforcement

Main elements covered by the Review

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

2 main thrusts

- Coherence
- Fill in missing chapters

Why introduce Accreditation?

- Currently operates in all Member States, however due to lack of common rules:
 - Different approaches to accreditation
 - Differing systems with uneven rigour
 - Uneven use in support of notification of conformity assessment bodies in the Member States
- Need to introduce a framework for accreditation and to lay down principles for its operation and organisation at Community level to ensure uniform application

Why strengthen Market Surveillance?

- Member State responsibility
 - Stop non-compliance / fraud / counterfeit
 - National officials in the marketplace
 - Check products / imported products
 - Corrective measures – safeguard clause

However levels / rigour of Market Surveillance
differ widely = distortion of control

Main elements of New Legislative Framework

- Common Market Surveillance requirements in all Member States / EFTA
 - Organisation of Market Surveillance
 - Oblige necessary controls
 - Co-operation mechanism
 - Improvement of safeguard clause mechanism & information procedure

Why strengthen requirements for Notified Bodies?

- Notification is a Member State responsibility
 - Different requirements for notification in different Member States
 - Ongoing verification
 - Corrective measures
- There is a need to create a level playing field for both Notified Bodies and manufacturers

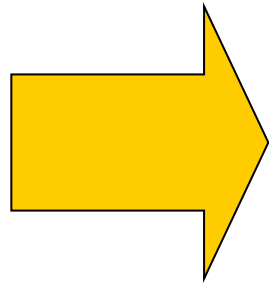
Why harmonise definitions?

- Different Directives use terms differently
- Some Directives have no clear definitions at all
- Obligations are not consistent
- Lack of clarity for stakeholders

Creates many problems

Need for clarification of terms

Why did we propose the review?



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

Main elements covered by the Review

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

**Strengthen the system
through a review of the
main features**

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

The Regulation & the Decision

REGULATION

- EU “law”
- Becomes law in all Member States at same time
- Directly Applicable
- Member States need to be ready to apply

Immediately enforceable

DECISION

- Also EU “law”
- *Sui Generis* Decision
- Applies to legislators themselves
- Model Articles “toolbox”

Applies ONLY when sectoral legislation is revised or to new legislation

Complementary legislative tools

REGULATION

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

Applicable 1 Jan 2010

DECISION

- Definitions / Obligations
- Notification (criteria / process / accreditation)
- Conformity Assessment Procedures
- Safeguard mechanisms (& market surveillance)
- **CE** marking

Basis for future legislation

Why 2 ? a Regulation & a Decision

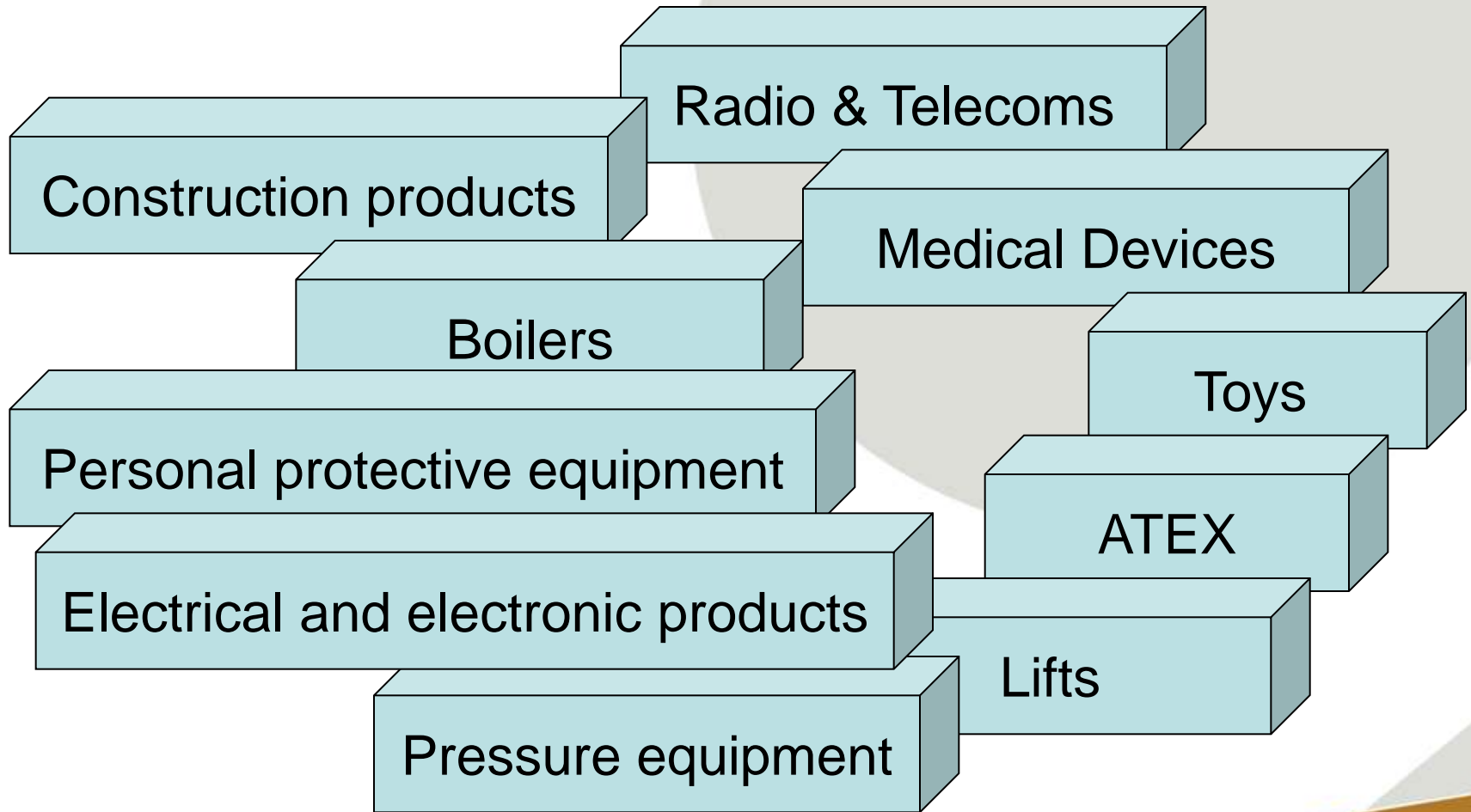
REGULATION

- Covers elements not already included in sectoral legislation e.g. accreditation / market surveillance etc
- Common elements to facilitate the internal market

DECISION

- Covers elements already included in legislation e.g. notification / safeguard clause mechanisms etc
- BUT sectors will be able to deviate according to specificities of the sector

Sectors covered by CE marking



Scope of the package

- Accreditation
 - No exclusions
- Market Surveillance
 - Exclusions for : food, feed, human blood, cells, tissues and agricultural products via the product definition in Article 15 (4)
- Other Sectors
 - *Lex specialis* Art 15(2) : pharmaceuticals, aviation, medical devices and motor vehicles – given as examples in recitals

Scope of the Decision

Recital 6 ...

“ Whenever legislation is drawn up, the legislator may depart, totally or partially, from the common principles and reference provisions laid down in this Decision on account of the specificities of the sector concerned. Any such departure should be justified.”

Regulation – Overall framework (1)

- Accreditation
 - Single accreditation body
 - Non-competition / public authority
 - Requirements for accreditation bodies
 - Peer evaluation
 - Information obligation / transparency
 - EA (European co-operation for accreditation)

Regulation – Overall framework (2)

- Strengthen Market Surveillance framework
 - Scope
 - Organisation / Surveillance measures
 - Restrictive measures
 - Communication and co-ordination
 - Control of products entering the Community

Regulation – Overall framework (3)

- **CE** marking – General principles
 - Clarification on use
 - Clarification on meaning
 - Clarification of role ‘v’ other marks

Decision –

Toolbox for future legislation (1)

- Definitions / obligations for manufacturers
 - 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
 - Co-ordination GNBs

Decision –

Toolbox for future legislation (2)

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

And Community Collective trade mark

Timeframe / process

- Commission adopted proposal 14 Feb 07
- Approved EP Plenary 21 Feb 08
- Formal Council adoption 23 Jun 08
- Published in OJ L218 on 13 Aug 08
- Entry into force 20 days after publication
- Date of application of Regulation 1 Jan 2010
- Decision “*sui generis*” can be used now

Implementation phase

- Work plan to ensure consistent application
- Consultation with all colleagues ENTR, SANCO, TREN, ENVI, TAXUD, AGRI, COMP, MARKT, LS, etc
- Implementation measures – Accreditation
- Initiatives for Market Surveillance
- Review of Sectoral Directives to align with Decision

Web site addresses

- New Approach:

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

- Questions:

Entr-reg-approach-for-free-circ@ec.europa.eu