

The New Legal Framework, R&TTE Review and Market Surveillance

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The New Legal Framework

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
- 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

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

2 main thrusts

- Coherence
- Fill in missing chapters

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 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

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

Consequences for electro technical sectors

- NLF will result in better environment
 - more harmonised and intensified enforcement
 - financing is possible
 - more effective information system
 - Simpler Community procedures
- Since about 5 years: common campaigns
- Various projects financially supported by the EU (under the General Product Safety Directive)
- Common campaigns will continue with support under the NLF

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

New Legislative Framework - Texts

OJ L218 - 13.08.08 :

- Regulation 764/2008 - procedures relating to the application of certain national technical rules to products lawfully marketed in another Member State (Mutual recognition)
- *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

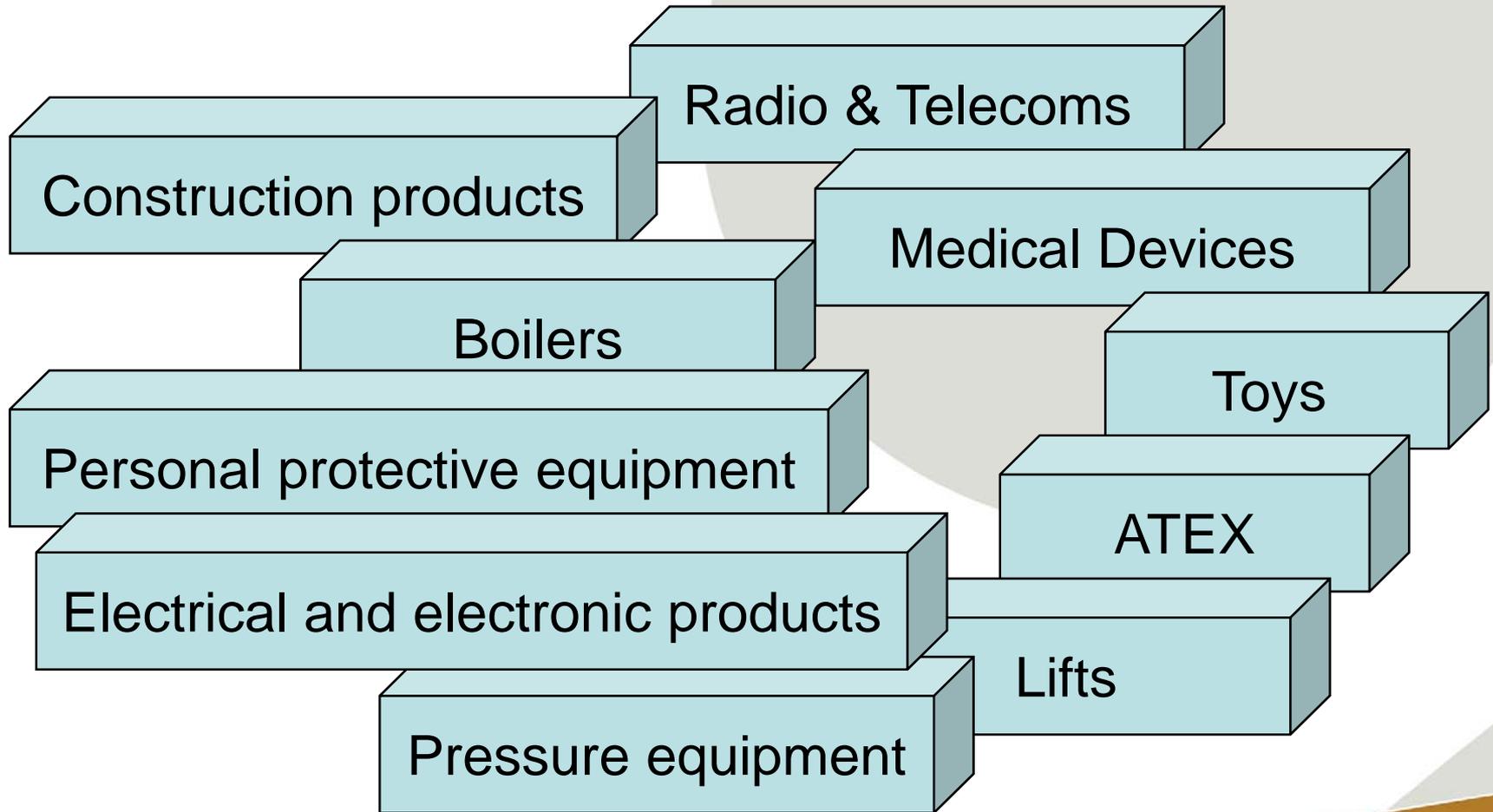
REGULATION

- 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

The Review of the R&TTE Directive

Time table for review and possible revision

Progress report to Council & European Parliament:

- Imminent
- Based on public consultation in 2007, experience, inputs from TCAM and other inputs
- Draft has been shared with Member States

Revision of the Directive

- External study for Impact Assessment started
- September 2009-December 2009: Completion Impact Assessment
- 1st Quarter 2010: Basic Decision on a proposal
- 4th Quarter 2010: Adoption by Council and European Parliament

Progress report to Council & European Parliament

Basic conclusions: Policy does not require change

- Light conformity assessment procedures justified
- Standardisation works satisfactory
- Overall the essential requirements OK

Finetuning however required

- Alignment with New Legal Framework
- Optimisations of operations
- Especially need for better tools for surveillance authorities

Alignment with NLF

Largely an administrative change:

- Standardisation of definitions
- Clarification on obligations for market players
- Changes on requirements for Notified Bodies (accreditation)
- Codification in law of good practices for applying New Approach Directives

As regards market surveillance:

- Strengthening of obligations on importers of goods
- They need to assure that only compliant products are placed on the market
- Simplification of procedure to render decisions EU wide

Policy fine-tuning (Observations)

Basic observations:

- We manage a market of 90B€ with a regime that is less burdensome on the market than other economies
- It reaches its objective:
 - No problem with interference
 - High level of safety for users
 - Integrity of networks are ensured
- Together with the spectrum Decision sound legal basis for internal market

Policy finetuning (New Technologies)

Elements to introduce new technologies are NOT working :

- Notified Body route was defined to enable marketing of new technologies
- Lack of confidence of spectrum regulators
- Cultural divide
- We risk to stifle innovation
- Discussions on flexible use of the spectrum demonstrate there is an issue
- For license free/exempt use: only point of regulatory control is the equipment that reaches the market
- Procedure needs to be changed: elements to enable spectrum regulators to have confidence

Policy finetuning (New Technologies)

Role of notified bodies for products that do NOT follow harmonised standards:

- Option 1: regulators to give opinion
- Option 2: introduce scrutiny procedure for regulators to look at NB opinions
- Option 3: status quo, don't change
- We need your input to study these options

Policy finetuning (Simplification)

Administrative provisions :

- 17 administrative provisions is too much
- Individually we can justify all of them, but confusion with market players remain
- Notification procedure: scope remains messy
- In practice used by regulators as a tool to get visibility of market
- We need to rationalise things

Policy finetuning (Surveillance)

We need more effective tools:

- We have a single procedure to get products on the market, but
- We have 27+1 procedures to get them off the market when they don't comply
- Campaigns have demonstrated too high non-compliance statistics in certain areas
- Legal tools to deal with non-compliance not effective
- Surveillance in a single European market should have direct effects in that whole market
- NLF alignment will simplify Community procedures
- We feel that this may not be enough

Policy finetuning (Equipment Register)

Traceability remains a problem for surveillance:

- Market surveillance spends too much time on finding a legal entity to address compliance with
- Too much focused on national measures
- Better communication tools required
- Too easy to duck the rules and to get away with it

Policy finetuning (Equipment Register)

Equipment Register:

- Oblige registration and identifier on equipment
- Rationalise at the same time administrative provisions
 - No DoC in manual
 - No information that is in fact for authorities
 - No 3 CE marks!
 - Replace 6.4 notification procedure
- Non-registered products or products that fake IDs are illegal and action can directly be taken
- By streamlining information flows, overall cost saving for society and level playing field for industry

Policy finetuning (Public interest requirements)

Article 3.3:

- Used for functional safety requirements for specific product groups
- Even where not used, give a signal to the market to ensure certain things
- Discussions around harmonisation of battery chargers demonstrate the need for tools
- Enlargement of the scope of the article should be discussed

Market Surveillance

Conclusions

- The NLF will optimise the EU policy on the internal market for goods
- It is likely that the Commission will propose to amend the R&TTE Directive
- Not substantially though as the policy works
- Need to make this a more effective tool for spectrum managers: cultural gaps to be bridged though!
- Key point for discussion:
 - Would a registration system on balance create benefits?
 - We are studying therefore the impact of such a move in economic terms to be able to make an informed decision.