Finnish Communications Regulatory Authority

Introduction to the New Legislative Framework (NLF)

WGRA Webinar

September 15, 2010

Mrs Kati Heikkinen

Deputy Head of Radio Inspection Unit, FICORA
Chairperson PT RA1

Introduction to the NLF – WGRA Webinar

1. Background and objectives of the NLF
2. Regulation (EC) No 765/2008 on accreditation and market surveillance
3. Decision (EC) No 768/2008 on marketing of products
4. Impact of the NLF on the revision of the R&TTE Directive
5. Sources of information

Finnish Communications Regulatory Authority

Background and objectives of the NLF

New Legislative Framework (NLF)

”Broad package of measures which has the objective of removing the remaining obstacles to free circulation of products”

”A major boost for trade in goods between EU Member States”

”Update of the New Approach”

New Legislative Framework (NLF)

- Regulation (EC) No 764/2008 – application of certain national technical rules to products lawfully marketed in another Member State
- Regulation (EC) No 765/2008 – requirements for accreditation and market surveillance
- Decision (EC) No 768/2008 – common framework for marketing of products

Problems in the background of the NLF

- Directives have not been functioning in the same way in the Member States
  - Different levels of import control and market surveillance in Member States
  - Different ways of controlling Notified Bodies
  - Unclear definitions
  - Unclear obligations for importers and retailers
  - ➢ Unequal treatment, distortion of competition
  - ➢ High levels of non conforming products on the market
  - ➢ Lack of trust in CE marking

Objectives of the NLF

- Improving the functioning of the internal market for goods
- Clarifying the conditions for placing products on the market
- Introducing better rules for accreditation of conformity assessment bodies
- Strengthening the enforcement of legislation
- Enhancing the credibility of CE marking
- Establishing tools to be used in future legislation

Main elements covered by the NLF

- Market surveillance
- Accreditation
- CE-marking
- Common definitions
- Common obligations
- Safeguard mechanisms

Finnish Communications Regulatory Authority

Regulation (EC) No 765/2008 on accreditation and market surveillance

Regulation (EC) No 765/2008

- Accreditation
- Market Surveillance
  - Internal market
  - Imported products
- General principles for CE marking
- Financing elements

- Date of application 1st January 2010

➢ Became law in all Member States

Regulation (EC) No 765/2008

- Covers elements that are not covered by the sectoral legislation

➢Lex specialis

- Creates direct rights and obligations with the objective of
  - ensuring uniform and transparent assessment of the competence of conformity assessment bodies
  - ensuring effective market surveillance
  - ensuring equal conditions for economic operators

Accreditation

= Assessment of competence of conformity assessment bodies

- Introduction of a horisontal framework for accreditation
  - Public authority activity, one accreditation body per Member State, no competition
  - Uniform requirements for accreditation bodies, European cooperation (EA)
  - Accreditation applied for in Member State of establishment to ensure effective monitoring

➢ Uniform application of accreditation

➢ Confidence in accredited certificates

➢ One accreditation certificate for whole EU

Market surveillance

= Activities and measures taken by national authorities to ensure that only safe and compliant products are placed on the Community market

- Obligations to have necessary powers, resources and knowledge to properly perform market surveillance
- Rights to organise inspections, require documentation from the manufacturers, take samples for testing, destroy products etc.
- Responsibility to withdraw and/or recall dangerous products and alert consumers

...

Market surveillance

...

- Obligation to implement and update market surveillance programme
- Obligation to evaluate the functioning of market surveillance
- Responsibility to inform European Commission and other authorities on market surveillance actions taken
- Responsibility to participate in European cooperation

Market surveillance

Control of products entering EU:

- Obligations for Customs to carry out inspections at external border
- Responsibility for Customs to suspend of release for free circulation if
  - product is not properly marked
  - product presents a serious risk
- Responsibility for Customs and market surveillance authorities to cooperate

Market surveillance

- Efficient, comprehensive and consistent market surveillance
- Adequate and equal protection to consumers regardless of the country they live in or the origin of the product
- Equal conditions for economic operators, reduction of unfair competition

General principles of CE marking

- General principles of CE marking in Regulation 765/2008 are complementary to legislation
- CE marking have to and can be affixed only on products for which it is foreseen in legislation
- Affixing CE marking = taking responsibility of conformity
- Obligation for Member States to protect the marking
  - ensure correct implementation of the CE marking regime
  - take action against improper use of CE marking
  - provide deterrent penalties for violations

➢ Clarifying the meaning and improving the credibility of CE marking

Finnish Communications Regulatory Authority

Decision (EC) No 768/2008 on marketing of products

Decision (EC) No 768/2008

- Common definitions
- Common obligations for economic operators
- Conformity assessment procedures
- Rules for affixing CE marking, form of CE marking
- Rules concerning Notified Bodies
- Safeguard mechanisms

➢ ”Toolbox” which applies to EU legislator, no immediate effects on Member States

Decision (EC) No 768/2008

- Covers elements already included in legislation
- Includes general principles and guidelines for legislator, template Articles and model provisions
- Applies to new legislation or revisions of legislation

➢Better regulation

Common definitions and obligations

- Definintions for placing on the market, manufacturer, authorised representative, importer, distributor, economic operator, technical specification, recall, withdrawal etc...
- Obligations of economic operators
  - manufacturers
  - authorised representatives
  - importers
  - distributors
  - cases in which obligations of manufacturers apply to importers and distributors
  - traceability provisions

Conformity assessment procedures

- 16 conformity assessment modules
- EC Declaration of Conformity (DoC)
  - model structure
  - updating DoC
  - language
- Formal objection to a harmonised standard

Rules concerning Notified Bodies

- Requirements for notifying authorities
- Requirements for Notified Bodies
- Notification procedure
- Operational obligations to Notified Bodies
- Subsidiaries and sub-contracting
- Accredited in-house bodies
- Challenge of the competence of Notified Bodies
- Coordination and cooperation

Safeguard mechanisms

Safeguard clause procedure

- Cases where safeguard clause is applied
- Possibilities to object
- Decision making process in case of objections
- Cases where all Member States are obliged to take actions on the basis of safeguard notification

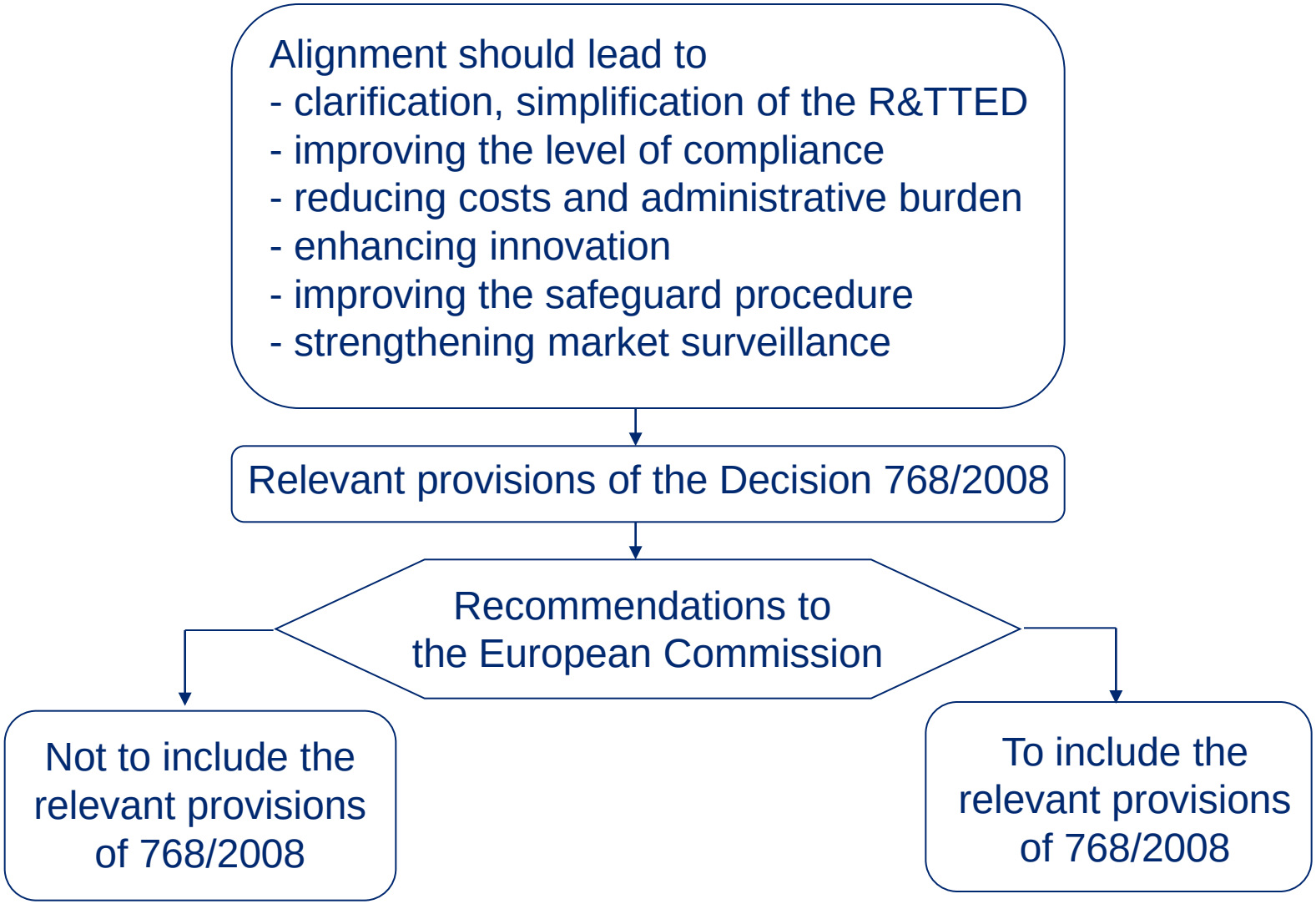
Finnish Communications Regulatory Authority

Impact of the NLF on the revision of the R&TTE Directive

TCAM ad hoc working group on NLF

- Established in TCAM 28
- Member States, market surveillance authorities, industry, ETSI, R&TTE CA, ECO
- Cooperation with TCAM ad hoc WG TRAC
- Introduced its final report to TCAM 30
- Identified the NLF issues (768/2008) that should be included in the revised R&TTE Directive
- Issued 53 recommendations

NLF -> R&TTED (TCAM ad hoc WG NLF)



Recommendations (TCAM ad hoc WG NLF)

- All recommendations are explained in detail with justifications in the final report of TCAM ad hoc WG NLF (doc. TCAM (30)09)
- 16 articles from Decision 768/2008 should be included without changes in the revised R&TTE Directive
- The remaining provisions of Decision 768/2008 need modifications to be included in the revised R&TTE Directive
  - Clarifications, making text more R&TTE specific
- Some clarifications are needed in general level
  - The revised Blue Guide?

Recommendations (TCAM ad hoc WG NLF)

- New conformity assessment modules
  - Module A: Internal product control
  - Module B+C: EC type examination + conformity to type based on internal product control
  - Module H: Full quality assurance

  - Regarding electrical safety and EMC the manufacturer should have a choice to use modules from R&TTE, EMC or LVD Directives

  ➢ conformity assessment would be linked to the phenomena to be assessed and not any more the type of the equipment

...

Recommendations (TCAM ad hoc WG NLF)

…

- An EC type examination certificate would be issued by an involved notified body (not anymore an opinion)
- Inclusion of the EC type examination certificate and DoC in the technical documentation
- A change in the applicable harmonised standard during the lifecycle of the product shall lead to a re-assessment of the compliance of the product, even if the manufacturer didn't apply harmonised standards
- Possibility for national market surveillance authorities to charge testing costs from manufacturer

Finnish Communications Regulatory Authority

Sources of information

General information

Single market for goods; New legislative framework:

http://ec.europa.eu/enterprise/policies/single-market-goods/regulatory-policies-common-rules-for-products/new-legislative-framework/

CE marking makes Europe's market yours:

http://ec.europa.eu/enterprise/policies/single-market-goods/cemarking/

Regulations

Regulation (EC) No 764/2008 – application of certain national technical rules to products lawfully marketed in another Member State

http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:218:0021:0029:en:PDF

Regulation (EC) No 765/2008 – requirements for accreditation and market surveillance

http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:218:0030:0047:en:PDF

Decision 768/2008

Decision (EC) No 768/2008 on marketing of products

http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:218:0082:0128:en:PDF

Public TCAM documents

http://circa.europa.eu/Public/irc/enterprise/tcam/library

ECO meeting document server

http://www.ero.dk

Finnish Communications Regulatory Authority

Thank you for your attention!

Kati Heikkinen
Radio Inspection Unit
Finnish Communications Regulatory Authority
P.O.Box 313
FI-00181 Helsinki
tel. +358 96 96 64 76
kati.heikkinen@ficora.fi
www.ficora.fi