



European Commission

Enterprise Directorate General

# ***Market access in the European Union The R&TTE and EMC Directives***

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- Introduction
- The EU policy on industrial products
- The EMC and R&TTE Directives
- Conclusion



- **Introduction**
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- Sector is rapidly globalising
  - *mobile communications: GSM, IMT-2000*
  - *Short range radio devices: IEEE 802.11, Bluetooth*
  - *Wired communication: xDSL, modem technologies*
- Globalisation forces regulatory reform:
  - *Wealth of technical regulation around the world hampers trade*
    - ✓ **Diverging administrative provisions**
    - ✓ **Diverging technical requirements**
    - ✓ **Diverging conformity assessment procedures**
  - *Regulators need to address non-tariff barriers*
  - *Rethink the proportionality of existing market access regimes*





- The EU has a lot of experience to share
  - ➔ *Single market forced the EU to resolve internal barriers*
  - ➔ *Although still imperfect most of the barriers have been removed*
    - ✓ **Customs Union**
    - ✓ **No import/export tariffs**
    - ✓ **No need for local establishment**
  - ➔ *Started in 1986 to address barriers caused by conformity assessment in EMC and R&TTE sectors*
    - ✓ **1986: Exchange of test reports for TTE (86/361/EEC)**
    - ✓ **1989: EMC Directive (89/336/EEC)**
    - ✓ **1991: Mutual Recognition of approvals for TTE (91/263/EEC)**
    - ✓ **1999: Deregulation: R&TTE Directive (1999/5/EC)**



## The basic policy for R&TTE and EMC:

- *The market players are the prime responsible: build your legal system on this*
- *Rely on horizontal liability and consumer protection*
- *A priori type approval regimes are an overkill to manage the risks caused by electronic, electrical and R&TTE products*
- *Mutual Recognition Agreements are only 2<sup>nd</sup> best, cost/benefit not always clear: Deregulate first*
- *It costs a lot of energy to reform legacy approval infrastructures*
- *Continue policy on unbundling terminal and service provision*



- Introduction
- The EU policy on industrial products
  - *New Approach: the policy*
  - *Standardisation: development of technical standards*
  - *Global Approach: conformity assessment principles*
- The EMC and R&TTE Directives
- Conclusion



- New Approach on technical regulation and standardisation: Council resolution of 1985
- Applied since resolution except certain areas:
  - *Foodstuffs,*
  - *Chemical products,*
  - *Pharmaceutical products,*
  - *Motor vehicles*
  - *Tractors*





## ● New Approach Directives

- Low voltage equipment (73/23/EEC, amendment 93/68/EEC)
- Simple pressure vessels (87/404/EEC, amendments 90/488/EEC and 93/68/EEC)
- Toys (88/378/EEC, amendment 93/68/EEC)
- **Electromagnetic compatibility (89/336/EEC, amendments 92/31/EEC and 93/68/EEC) (replaced by update mid 2007 by Directive 2004/108/EC)**
- Machinery (98/37/EC, amendment 98/79/EC)
- Personal protective equipment (89/686/EEC, amendments 93/68/EEC, 93/95/EEC and 96/58/EC)
- Non-automatic weighing instruments (90/384/EEC, amendment 93/68/EEC)
- Active implantable medical devices (90/385/EEC, amendments 93/42/EEC and 93/68/EEC)
- Gas appliances (90/396/EEC, amendment 93/68/EEC)
- Hot water boilers (92/42/EEC, amendment 93/68/EEC)
- Civil explosives (93/15/EEC)
- Medical devices (93/42/EEC, amendment 98/79/EC)
- Potentially explosive atmospheres (94/9/EC)
- Recreational craft (94/25/EC)
- Lifts (95/16/EC)
- Refrigeration appliances (96/57/EC)
- Pressure equipment (97/23/EC)
- In vitro diagnostic medical devices (98/79/EC)
- **Radio and telecommunications terminal equipment (1999/5/EC)**



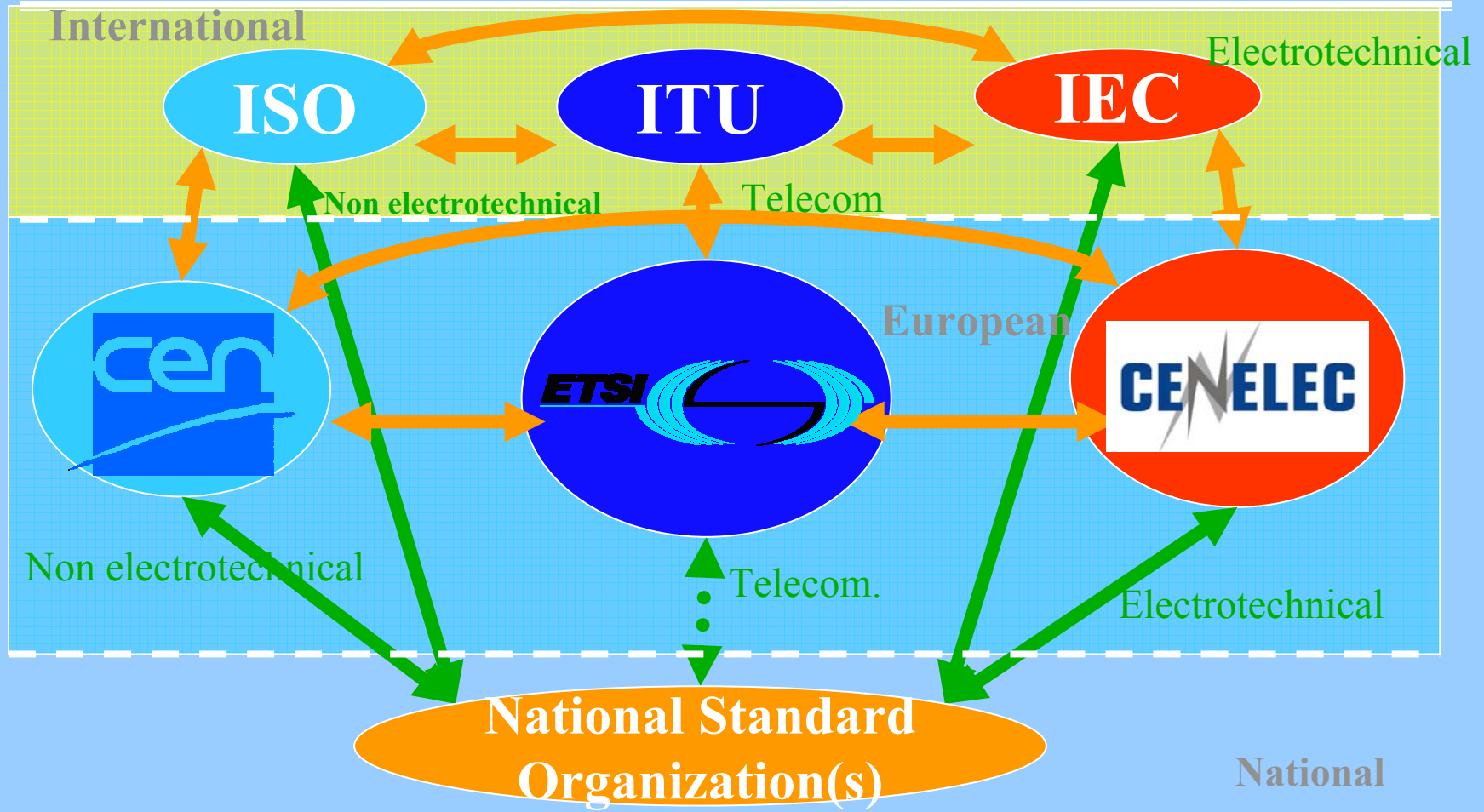
- Principles:

- *limited to harmonisation of safety, health and environmental essential requirements*
- *requirements are legal, not technical*
- *technical solutions to meet these requirements laid down in harmonised standards developed by European Standardisation Organisations*
- *Harmonised standards remain voluntary and manufacturers can use other methods*
- *When complying with harmonised standards presumed to comply with the Directive and hence free circulation within the EU*



- **Harmonised Standards:**

- *Commission mandates harmonised standards from the European Standardisation Organisations (CEN, CENELEC and ETSI)*
- *Standardisation process open and transparent*
- *Before vote, public enquiry*
- *Adoption based on a national weighted vote*
- *After adoption, publication in the Official Journal. Only after publication they give presumption!*
- *Directives provide for safeguard procedures against faulty standards*





- Global Approach on conformity assessment: Council Decision 93/465/EC concerning the modules for the various phases of the conformity assessment procedures and the rules for the affixing and the use of EC conformity marking which are intended to be used in the technical harmonisation directives
- Defines standard conformity assessment procedures to be used in new approach Directives
- Hierarchy from Module A (Manufacturers Declaration) to Module H (Full Quality Assurance)
- Choice linked to the risk which is regulated



A	Internal control of production	Covers internal design and production control. This module does not require a notified body to take action.
B	EC type-examination	Covers the design phase, and must be followed up by a module providing for assessment in the production phase. The EC type-examination certificate is issued by a notified body.
C	Conformity to type	Covers the production phase and follows module B. Provides for conformity with the type as described in the EC type-examination certificate issued according to module B. This module does not require a notified body to take action.
D	Production quality assurance	Covers the production phase and follows module B. Derives from quality assurance standard EN ISO 9002, with the intervention of a notified body responsible for approving and controlling the quality system for production, final product inspection and testing
E	Product quality assurance	Covers the production phase and follows module B. Derives from quality assurance standard EN ISO 9003, with the intervention of a notified body responsible for approving and controlling the quality system for final product inspection and testing set up by
F	Product verification	Covers the production phase and follows module B. A notified body controls conformity to the type as described in the EC type-examination certificate issued according to module B, and issues a certificate of conformity.
G	Unit verification	Covers the design and production phases. Each individual product is examined by a notified body, which issues a certificate of conformity.
H	Full quality assurance	Covers the design and production phases. Derives from quality assurance standard EN ISO 9001, with the intervention of a notified body responsible for approving and controlling the quality system for design, manufacture, final product inspection and testing



- Introduction
- The EU policy on industrial products
- **The R&TTE and EMC Directives**
  - *Market in Europe*
  - *Philosophy*
  - *Details*
  - *Implementation*
  - *International aspects*
- Conclusion



- Total sectors covered by EMC Directive: 250 b€
- R&TTE equipment: 90 b€ /year in the EU in 2003
  - *Machinery market: >250 b € /year*
  - *Telecommunication Services: 200 b € /year in 1999*
- Diverse industry
  - *The Big Boys (Nokia, Ericsson, Motorola, Siemens, Philips, Alcatel, Nortel)*
  - *Many SMEs in e.g. Short Range Radio markets*
- Before R&TTE Directive: highly fragmented
  - *> 1000 national regulations, around 30 harmonised EU regulations*
  - *fragmentation of radio frequency spectrum*
- After R&TTE Directive: less fragmented
  - *fragmentation of radio frequency spectrum*





- Scope R&TTE: terminal equipment + all radio equipment (harmonised and non-harmonised frequency bands) with some minor exceptions
- Scope EMC: electrical equipment causing EMC disturbance
- No further national approval regulations
  - *but remember: the R&TTE Directive does **NOT** harmonise spectrum use!*
- Community principles applied: free movement unless a MS has good reasons to bar products (notably radio)
- New approach Directives:
  - *requirements are legal, not technical*
  - *technical translation of requirements delegated to the market through ETSI*
  - *voluntary standards giving presumption of conformity*
- Safeguards for protecting the radio frequency spectrum



- No ex ante market access controls on R&TTE and Electrical products
  - *ex post market surveillance to deal with incompliant products*
  - *market self regulation*
  - *liberalisation of testing market: no accreditation of test houses required!*
- Redefinition of role of equipment regulation in addressing the public interest
  - *Less protection for networks*
  - *Leave technical details to the market players and voluntary standardisation*
  - *Obligation on operators to publish their interfaces*
  - *Liability for products and consumer protection laws deterrent*
  - *Relies on market surveillance*



- Which legislation applies to a product?
- Which requirements does a product need to meet?
- What standards are available?
- What conformity assessment procedure to follow
- What are the other administrative provisions to comply with?
  - ➔ *Notification obligations*
  - ➔ *User information*
  - ➔ *Marking*



## What has changed with the R&TTE Directive?

- Before: mixed structure of EU and national rules



**Electromagnetic compatibility (89/336/EEC)**

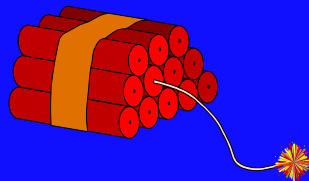
**Electrical safety requirements (73/23/EEC)**



After: single market with national spectrums

## R&TTE Directive (1999/5/EC)

### National interface regulations (radio only)



BE	DA	DE	EL	ES
FR	IE	IT	LU	NL
A	PT	SF	SV	UK
N	IS	CH		
CZ	HU	EE	SK	

LVD+EMC Directive conformity assessment procedures can continue to be used)



- Protection requirements of the EMC Directive:
  - *Limited your emissions*
  - *Be immune to those emissions*
- How to meet those requirements?
  - *Comply with harmonised standards*
  - *Obtain a competent body report*



## • Essential requirements of the R&TTE Directive:

- *Electrical Safety and health (as in Low Voltage Directive, 73/23/EEC),*
- *ElectroMagnetic Compatibility (as in EMC Directive, 89/336/EEC)*
- *Spectrum use (effective use so as to avoid harmful interference)*
- *possibility to define some additional public interest requirements:*
  - ✓ **End-to-end interworking**
  - ✓ **No network harm**
  - ✓ **privacy protection**
  - ✓ **avoidance fraud**
  - ✓ **access emergency services**
  - ✓ **Features for the disabled**
- *Needs to operate properly in nationally defined radio spectrum (access via R&TTE website)*

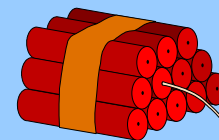
**Decisions on application for:**  
**maritime equipment**  
**inland waterways**  
**avalanche beacons**





## How to meet radio requirements?

- *Member States have to publish the rules for accessing the spectrum (Art.4.1). High level description of intended transmissions:*
  - ✓ frequency band, transmission power, channel spacing etc.
  - ✓ EFIS considered a tool to improve transparency
  - ✓ TCAM-RIG defines borderline between R&TTE and national regulations
  - ✓ Regulations should be compatible with the Treaty and are scrutinised in 98/34 procedure
- *R&TTE Essential requirements to ensure that other users of the spectrum are not disturbed (non-intended transmissions):*
  - ✓ spurious emissions, out of band transmission etc.
- *Where Harmonised Standard is available it provides the easiest route to market*
- *Usability in a Member State can only be declared if equipment abides by the national frequency plan*







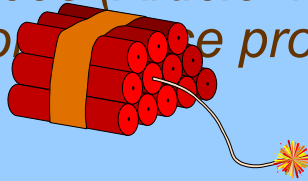
## How to meet the requirements for wired telecommunication equipment?

→ *Level of regulation will be reduced but this doesn't guarantee interworking:*

- ✓ **no physical harm to the network or disturbances**
- ✓ **no further telecommunication specific requirements**

→ *Similar depth of regulation as e.g. US FCC Part 68*

→ *To ensure interworking, operators have to publish the characteristics of their interfaces (Article 4.2), in their own interest to be complete, so that products do not cause problems*





- Technical interpretation of the essential requirements delegated to standardisation
- The European Commission, after consultation of the Member States, formally asks the development of standards interpreting the essential requirements of the Directive
- 3 recognised European Standardisation Organisations:
  - ➔ *CEN (not active in R&TTE area, a few EMC standards)*
  - ➔ *CENELEC (Safety standards, including RF hazards, EMC standards)*
  - ➔ *ETSI (Radio standards, EMC standards for R&TTE)*



# Details (Harmonised standards 2)

- Harmonised standards are (to the extent possible) technology neutral
- Delegation to private bodies of such standards requires full transparent procedures:
  - ➔ *A Decision on a work item is taken (in ETSI 4 Members is sufficient)*
  - ➔ *Technical Committee drafts standard*
  - ➔ *Draft standard goes for public enquiry*
  - ➔ *Standard is formally voted upon (weighted national vote)*
- The Directive provides for safeguards against faulty standards
- List of Harmonised Standards always available on Commission Website



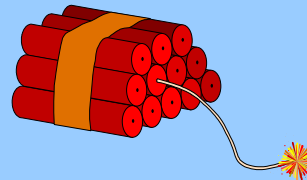
- Main principle:
  - ➔ *Manufacturer takes full responsibility and should test to reinsure himself*
  - ➔ *Technical file to be kept at the disposal of surveillance authorities for 10 years after last product has been marketed!*
- Exception (R&TTE): for radio transmitters, there are obligations to contact a notified body:
  - ➔ *When harmonised standards don't prescribe essential radio tests a NB prescribes (Annex III)*
  - ➔ *Where a product doesn't follow harmonised standards: NB to give an opinion on these aspects in the technical file (Annex IV)*
- Exception (EMC): obligation to contact a competent body (This will disappear with the updated Directive)
  - ➔ *When product doesn't comply with a harmonised standard*



- Alternative to obligations to consult a Notified Body: Full Quality Assurance (Annex V)
- Possibility to use LVD and EMC procedures
- Manufacturers may **VOLUNTARILY** seek the opinion of a Notified Body on any aspect of their technical file



- Only for R&TTE:
- No administrative approval by the authorities is necessary anymore but certain radio products need to be notified to national spectrum authorities before being marketed (article 6.4) at least 4 weeks before marketing
- Difference of opinion between MS on which products need to be notified
- MS may go and test product in 4 week period as part of market surveillance





- How should a product be marked?

- *Article 4.1: Equivalence between interfaces and definition of equipment classes.*  
*Current application: 2 main classes subdivided in subclasses.*

- ✓ **Class 1: equipment, which can freely move and be switched on in the Community (wired equipment, GSM, Receive-only equipment, etc.)**

- ✓ **Class 2: equipment, for which this is not the case (transmitters, which are to be licensed)**

- *Marking: simple marking scheme agreed between Member States:*

- ✓ **CE mark only for class 1 equipment (+ NB Numbers)**

- ✓ **CE mark +  for class 2 equipment (+ NB Numbers)**

- *Most radio products are still class 2 (unfortunately)!*

- *Improvement of situation through spectrum Decision*

- *For EMC: CE mark only*



### • User information (R&TTE only)

- *Marking should go on the packaging*
- *Marking should go in the user manual*
- *Copy of the Declaration of Conformity to go in the manual*
  - ✓ **Too strict interpretation of article 6.3 would have led to unworkable situation: original DoC in 11 languages and signed**
  - ✓ **Compromise: Original DoC on web or otherwise available and generic statement on compliance in the manual**
- *Manufacturer obliged to extensively inform the user of:*
  - ✓ **the intended use of equipment (notably to which network types it can be connected)**
  - ✓ **the geographic limitations (in which spectrum can it function)**







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- Europe has a lighter market access regime than its main trading partners and hence CABs are not involved in main stream standard products;
- A main problem in Europe remains the lack of spectrum harmonisation. Manufacturers should carefully inform themselves about that;
- Less ex ante more ex post: We are setting up an efficient surveillance infrastructure;
- Public authorities will leave more to the market: markets should not fail to take their responsibility
- We need to address the global picture however as well, notably in the interest of smaller companies



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