



European Commission

Enterprise and industry

Directorate General

From scientific advice to safety in the EU product legislation



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Workshop on EMF and Health:
Science and Policy to address public concerns Brussels 11-12 February 2008

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Legal basis: the EU Treaty – Internal Market

Article 95 §3

 *“The Commission, in its proposals... concerning health, safety, environmental protection and consumer protection, will take as a base a high level of protection”.*



- Legal context
- Product safety
 - ✚ The legal basis
 - ✚ Standards
 - ✚ Enforcement
- Responsibility of Member States



- Primary product legislation on EMF:
 - ✚ The Radio and Telecommunications Terminal Equipment Directive (1999/5/EC)
 - ✚ The Low Voltage Directive (2006/95/EC)
- Obligation of producers and distributors to put safe products on the market and into service
- Obligation for MS to ensure market surveillance
- Main tool to demonstrate compliance is through Harmonised Standards



- So-called New Approach Directives
- Harmonised Standards: comprehensive list has now been developed
- They ensure that the public is **NOT** exposed beyond agreed safety levels (as in Rec. 1999/519/EEC)

- ✚ EN 50360:2001 Product standard to demonstrate the compliance of mobile phones with the basic restrictions related to human exposure to electromagnetic fields (300 MHz - 3 GHz)
- ✚ EN 50364:2001 Limitation of human exposure to electromagnetic fields from devices operating in the frequency range 0 Hz to 10 GHz, used in Electronic Article Surveillance (EAS), Radio Frequency Identification (RFID) and similar applications
- ✚ EN 50366:2003 Household and similar electrical appliances — Electromagnetic fields— Methods for evaluation and measurement
- ✚ EN 50371:2002 Generic standard to demonstrate the compliance of low power electronic and electrical apparatus with the basic restrictions related to human exposure to electromagnetic fields (10 MHz - 300 GHz) - General public
- ✚ EN 50385:2002 Product standard to demonstrate the compliance of radio base stations and fixed terminal stations for wireless telecommunication systems with the basic restrictions or the reference levels related to human exposure to radio frequency electromagnetic fields (110 MHz - 40 GHz) - General public
- ✚ EN 50401:2006 Product standard to demonstrate the compliance of fixed equipment for radio transmission (110 MHz - 40 GHz) intended for use in wireless telecommunication networks with the basic restrictions or the reference levels related to general public exposure to radio frequency electromagnetic fields, when put into service
- ✚ EN 62311:2008 Assessment of electronic and electrical equipment related to human exposure restrictions for electromagnetic fields (0 Hz - 300 GHz) (IEC 62311:2007 (Modified))



Product safety – Enforcement

- Standards cover both handsets, appliances and masts, including the installation of masts in an existing EMF environment
- EMF has not given rise to safeguards or immediate withdrawals of products from the market except 1 recent case
- For aspects that would not be covered by these Directives: General Product Safety Directive (2001/95/EC)
- RAPEX system: alert on products that pose an serious danger to consumers
- No alerts had been issued until recently



Product safety – Handsets

- Handsets are operating well below the limits (0,4-1 W/kg)
- 2 W/kg regulatory limit is only reached in worst-case scenario (handset at >10 km distance from base station)
- Automatic power control to save battery energy
- Exposure from other than cellular phones not above limits, exposure situation differs:
 - ✚ RFID readers: short time whole body exposure
 - ✚ DECT phones: local exposure, lower power level than GSM
 - ✚ WiFi: source remote from consumer whole body exposure
- Member States to enforce



The recent case:

-  A handset was found in the Netherlands which showed Specific Absorption Rate limits of 2,7-2,9 W/kg
-  EN 50360 only allows for 2 W/kg
-  The Netherlands telecommunications agency addressed the matter with the manufacturer (SAMSUNG)
-  Apparently a production error
-  Result: voluntary withdrawal and replacement of 140.000 hand sets already on the NL market!

This case is unprecedented in the world



Product safety – Electrical appliances

- Standards have been set
- Little discussion on compliance levels
- No safeguards from MS on non-compliance
- Issue may be relatively unexplored
- Are we paying too much attention to mobile phones and to little to cooking ranges?



- The R&TTE Directive leaves discretion to Member States to handle licensing of masts
- The regulatory framework for telecommunications allows Member States to attach specific requirements to licenses
- In general:
 - ✚ Exposure levels factor 100-1000 below limits (except in a circle of 1-4 meters around masts),
 - ✚ Perception of exposure in the public at odds with factual exposure levels or known risks
 - ✚ Public concern reduces where there is legal clarity
 - ✚ Trust in public authorities low in certain parts of the EU
 - ✚ Public policy incoherent and sometimes risk avoiding (leave it to the courts)



- They are responsible for the protection of the population against potential risks from EMF
- They may apply more stringent limits than those set in the Recommendation.
- The Council Recommendation asks the MS
 - ✚ to implement a framework of Basic Restrictions and Reference Levels
 - ✚ to ensure that adequate health protection measures are taken
 - ✚ To ensure that the general public is adequately informed.



- Some MS introduced more stringent limits for masts
- Reality is that exposure from masts are a factor 100-1000 below recommendation. More stringent limits only affect the immediate safety zone around a transmitter
- More stringent rules for handsets have not been argued by MS:
 - ✚ They would fragment the market
 - ✚ Therefore would need to be agreed at EU level
- Exposure from handsets factors lower than safety levels as safety tests assume a worst case scenario:
 - ✚ Maximum power level only used when at large distance from masts
 - ✚ Exposure from handsets can be reduced by increasing the number of masts



Conclusions

- Product regulation and enforcement well developed
- It is based on the Council Recommendation
- Gives a high safety and health protection of our citizens
- Compliance with the Directives is high
- Public concern is fed by incoherent public policies, lack of information and lack of involvement of the public in decisions

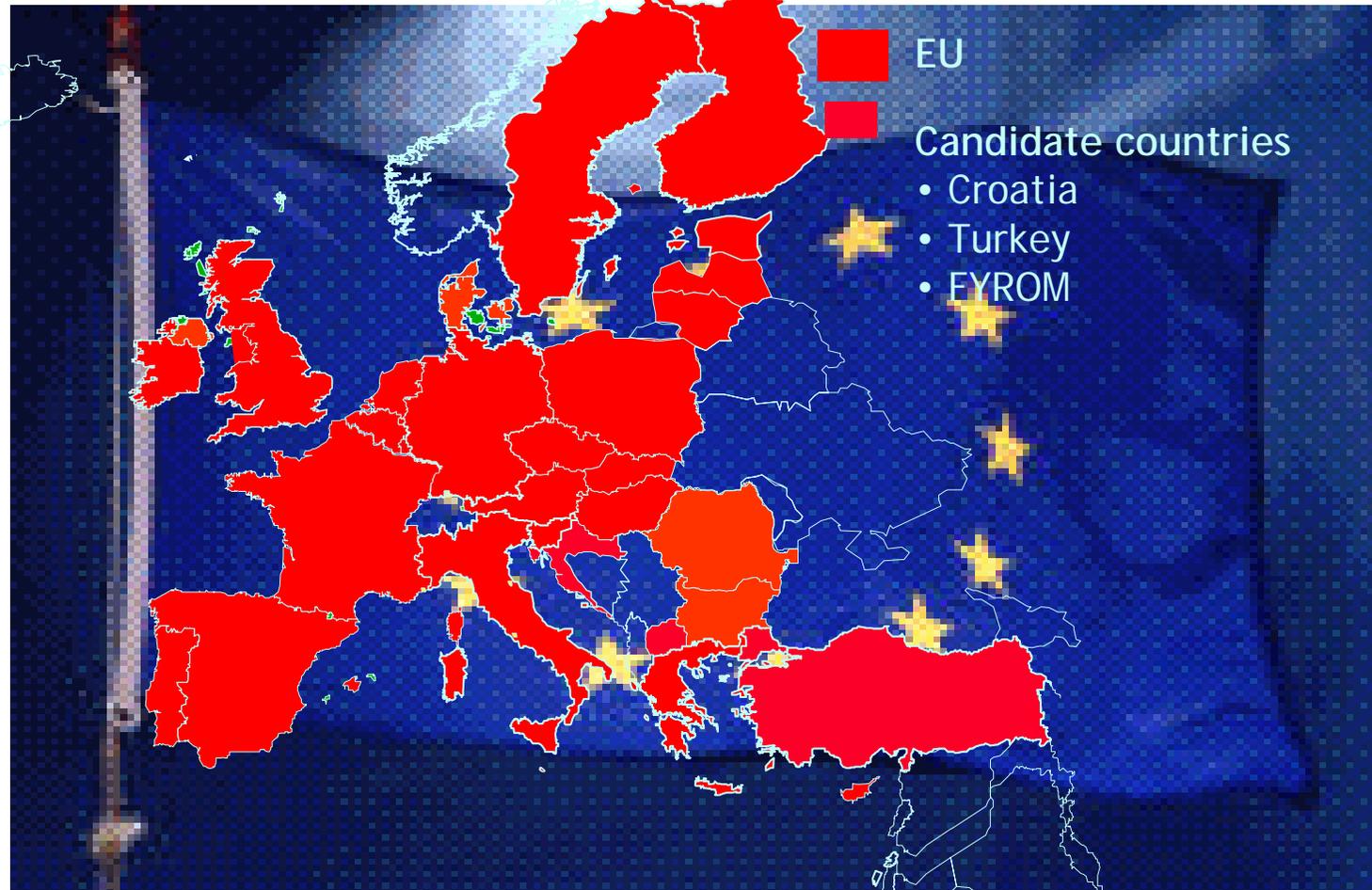


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Thank you for your attention!



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