

Protecting the public from EMF: an EU perspective



*Laurent BONTOUX, PhD
DG SANCO*

*European Commission
laurent.bontoux@ec.europa.eu*

**Radiation Research Trust conference
London, 09 Septembre 2008**

Structure

- **Legal basis**
- The Precautionary Principle
- Product safety
- Safety of food
- Safety of medicines
- EMF at the European Commission
- Recommendation 1999/519/EC
- Review of exposure limits
- Research

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 basis: the EU Treaty – Public Health

- **Article 152 §1:** *“A high level of human health protection shall be ensured in the definition and implementation of all Community activities and policies”.*
- **Article 152 §4:** provides for the adoption of recommendations by the Council *“with a view to complement national policies for improving public health, preventing human illness and diseases, and obviating sources of danger to human health”.*

Structure

- Legal context
- **The Precautionary Principle**
- Product safety
- Safety of food
- Safety of medicines
- EMF at the European Commission
- Recommendation 1999/519/EC
- Review of exposure limits
- Research

The Precautionary Principle - 1

- Prescribed by the EU Treaty specifically for the environment
- Commission Communication (2000)1
- Applied in practice
 - « *Where preliminary **objective scientific** evaluation indicates that there are reasonable grounds for concern* »
 - When potential hazards may be inconsistent with the « *high level of health protection* » chosen for the Community.

The Precautionary Principle - 2

- Should be considered within a structured approach to risk analysis
- Its use must follow a **scientific evaluation** showing evidence of a plausible association between exposures and potential impacts
- It is a **risk management** measure that examines **costs and benefits**

Structure

- Legal basis
- The Precautionary Principle
- **Product safety**
- Safety of food
- Safety of medicines
- EMF at the European Commission
- Recommendation 1999/519/EC
- Review of exposure limits
- Research

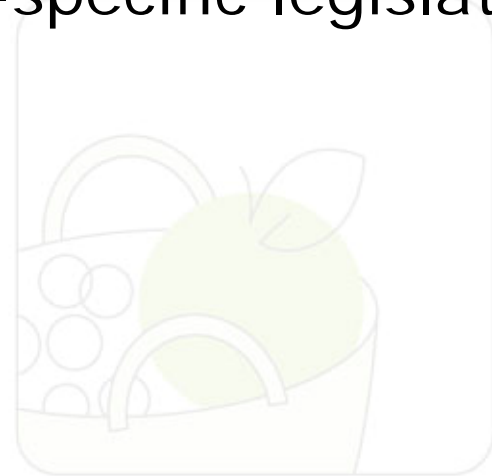
Safety of Consumer Products -1

- General Product Safety Directive (2001/95/EC)
- Generic definition of a safe product
- Obligation of producers and distributors to put **safe products on the market**
- Obligation for MS to ensure market **surveillance**
- **RAPEX** system: alert on dangerous products, info shared with all EU authorities

Safety of Consumer Products - 2

■ GPSD complemented by sector-specific legislation

- Chemicals (REACH, biocides)
- Toys
- Personal protective equipment
- Cosmetics
- Pharmaceuticals
- Machinery
- Recreational craft
- Liability for defective products



Safety of Consumer Products - 3

■ Also specific legislation for EMF emitting equipment

- Directive 1999/5/EC (telecoms equipment)

- Directive 2006/95/EC (« low voltage » Directive)

■ So-called 'New approach' directives

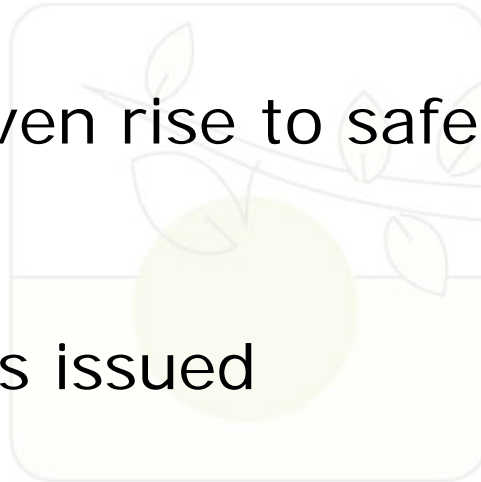
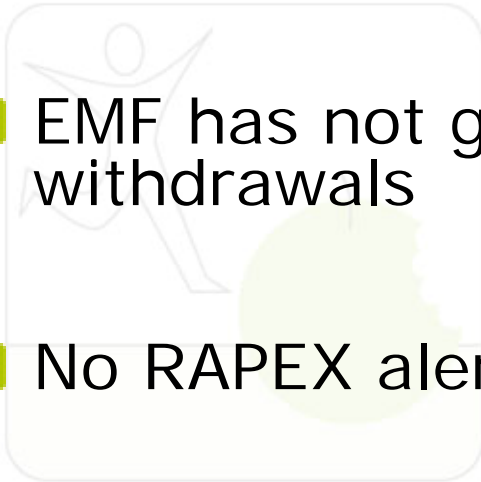
- Rely on harmonised standards ensuring that public exposure remains within agreed safety levels

Safety of Consumer Products - 4

- Handsets and masts covered

- EMF has not given rise to safeguards nor product withdrawals

- No RAPEX alerts issued



Structure

- Legal basis
- The Precautionary Principle
- Product safety
- **Safety of food**
- Safety of medicines
- EMF at the European Commission
- Recommendation 1999/519/EC
- Review of exposure limits
- Research

Safety of Food - 1

- **Integrated approach to food safety**
- Regulation EC/178/2002: **EU food law**
- To assure a high level of **food safety**
- Right of consumers to safe food and accurate information - confidence
- Coherent **farm-to-table measures** and adequate **monitoring**
- Risk analysis
- Food law underpinned by **strong science**

Safety of Food - 2

- **Effective control systems**
- **Traceability**
- Evaluation of **compliance with EU standards**, also in third countries for their exports to the EU;
- Risk assessment performed by the European Food Safety Authority (**EFSA**)
- **Science-based risk management**
- Precautionary principle (Art. 7 of Regulation)

Structure

- Legal basis
- The Precautionary Principle
- Product safety
- Safety of food
- **Safety of medicines**
- EMF at the European Commission
- Recommendation 1999/519/EC
- Review of exposure limits
- Research

Safety of Medicines - 1

- Directive 2001/83/EC
- Regulatory controls on **quality, safety and efficacy** of medicines
- System of standards
- **Pharmacovigilance** remains a high priority
 - Significance of clinical trials limited
 - In practice, safety can only be assessed after marketing

Safety of Medicines - 2

- Closer integration of EU regulatory system: creation of **EMA** in 1995
 - Centralised authorisation procedure and
 - Decentralised authorisation procedure/mutual recognition
- Pharmacovigilance based on national systems
- **Co-ordination** through EMA and CHMP

Safety of Medicines - 3

- **Rapid Alert** – Non Urgent Information System between EU regulators
- **Risk management**
- Most common source of identification of safety concerns is **spontaneous reporting** of adverse effects

Structure

- Legal basis
- The Precautionary Principle
- Product safety
- Safety of food
- Safety of medicines
- **EMF at the European Commission**
- Recommendation 1999/519/EC
- Review of exposure limits
- Research

Commission services dealing with EMF

Policy making

- *Health and Consumers DG (SANCO)*
 - *Employment DG (EMPL)*
 - *Enterprise DG (ENTR)*
 - *Environment DG (ENV)*
- public health**
- occupational health

Funding of research

- *Research DG (RTD)*
 - ✓ *Environment Directorate*
 - *Information Society and Media DG (INFSO)*
 - ✓ *Components and Systems Directorate*
- health issues**

Structure

- Legal basis
- The Precautionary Principle
- Product safety
- Safety of food
- Safety of medicines
- EMF at the European Commission
- **Recommendation 1999/519/EC**
- Review of exposure limits
- Research

Recommendation 1999/519/EC

- Based on Article 152 § 4 of the Treaty
- Establishes a **Community framework** for the exposure of the general public
- Defines **restrictions** to ensure a high-level of protection for all population groups and to provide the **basis for monitoring** the situation in various conditions of exposure
- Provides a **reference framework for EU legislation** on electric and electronic products and devices emitting EMF
- Provides a basis for national policies to limit citizen's exposure

Recommendation 1999/519/EC

- The Recommendation requires that Basic Restrictions and Reference Levels be based on the **best scientific evidence** of the health effects of EMF
- The current BR and RL derive from the 1998 ICNIRP guidelines
- These guidelines use a **safety factor of 50**
 - a factor 5 (reduction of public exposure vs occupational exposure)
 - a factor of 10 to cover variations of sensitivity and exposure conditions

The role of Member States - 1

- 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.

The role of Member States - 2


- Some MS introduced more stringent limits for masts
- 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 far from masts
 - Exposure from handsets can be reduced by increasing the number of masts

Structure

- Legal basis
- The Precautionary Principle
- Product safety
- Safety of food
- Safety of medicines
- EMF at the European Commission
- Recommendation 1999/519/EC
- **Review of exposure limits**
- Research

Review of exposure limits

- The Recommendation requires that Basic Restrictions and Reference Levels be based on the best scientific evidence

 Therefore, **independent scientific reviews**

- CSTE – 2001
- SCENIHR - 2007
- SCENIHR – 2008 (ongoing)

2007 Outcome

The independent reviews concluded that, so far, scientific evidence does not justify a modification of the current exposure limits.

Structure

- Legal basis
- The Precautionary Principle
- Safety of consumer products
- Safety of food
- Safety of medicines
- EMF at the European Commission
- Recommendation 1999/519/EC
- Review of exposure limits
- **Research**

Research needs

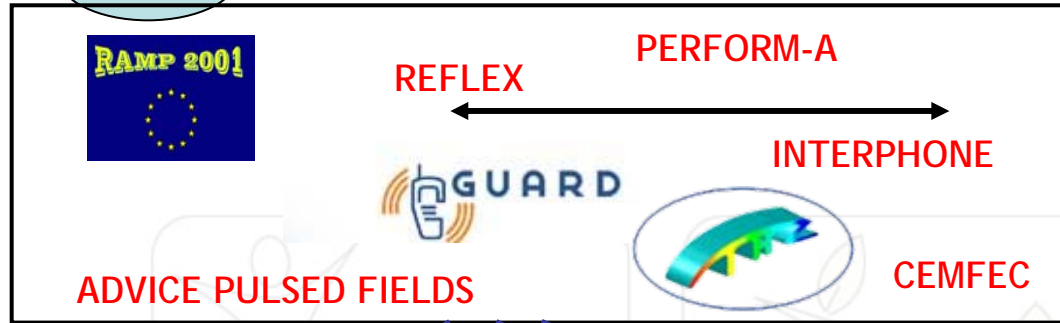
- The reviews were all based on the latest scientific evidence available
- Over the last decade, regular publication of new results
- Some results are inconsistent
- The 2007 review identifies research needs



EMF & Health projects in past Framework Programmes

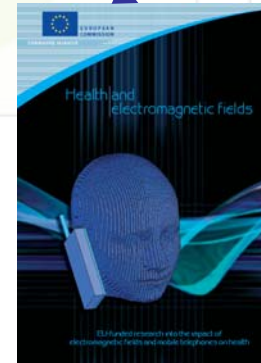
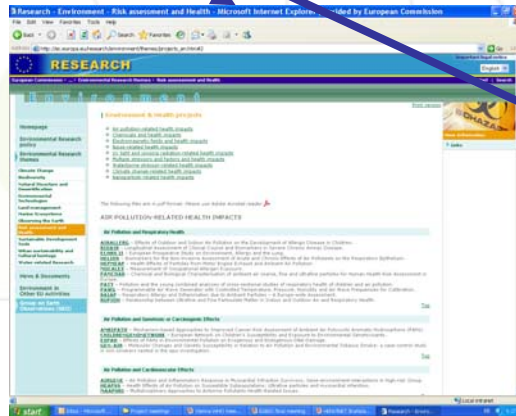
12 M€

FP5 (1998-2002)



FP6 (2002-2006)

4 M€



http://ec.europa.eu/research/environment/pdf/env_health_projects/env_health_brochure.pdf

http://ec.europa.eu/research/environment/themes/projects_en.htm

http://europa.eu.int/comm/research/quality-of-life/pdf/emf_brochure_and_sheets_en.pdf

In press



Environment
(including Climate change)

Environment and Health
sub-activity



FP7
(2006-2013)

PROPOSED TOPIC

ERA-NET for
environment
& health

Health impacts
of exposure to
radiofrequency fields
in childhood and
adolescence

Databases
based on European
cohort studies
and their exploitation for
advancement of
knowledge
of environment-
health relationships

Improved exposure
assessment
to wireless
communication
devices

ERA-ENVHEALTH
Coordination of
national
E&H
research
programmes
€2M

1 project
selected

1 project
selected

Call
currently
open

Other relevant activities





Emerging EMF Technologies and Health Risk Management

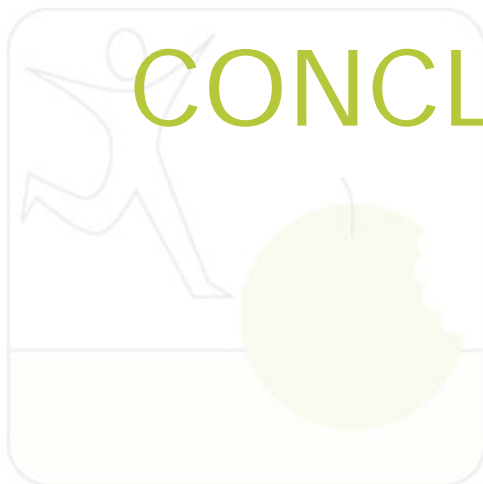
- ✓ Just starting
- ✓ Structure to help researchers in the field of EMF & Health **share knowledge and information**
- ✓ Encourage multi-laboratory **collaboration**
- ✓ **Training** of early-stage researchers in EMF & health
- ✓ Facilitate identification of technological change
- ✓ Identify **impact of new applications** on levels and spectral nature of EMF exposure of people and possible health effects



European Health Risk Assessment Network on EMF Exposure

- ✓ **Selected under the European Public Health Programme**
- ✓ **Starting soon**
- ✓ **Follow-up to EMF - NET**
- ✓ **Support to risk assessment**
- ✓ **Fast response function**

CONCLUSIONS





- ✓ The Commission is dedicated to ensuring a **high level of health protection** in the EU
- ✓ This is enshrined in the EU Treaty and is relevant **for all EU policies**, including food, consumer products and medicines
- ✓ The Commission is ready to use the **Precautionary Principle** according to Communication 2000/1 within its areas of competence
- ✓ This is equally applicable to food and consumer products.
- ✓ For medicines, the risk/benefit equation is specific



- ✓ For EMF, a framework is already in place to protect the public
- ✓ The EU EMF limit values are under periodic scientific review, latest one ongoing
- ✓ The Commission recognises that **more research** on the potential health impacts of EMF is needed to improve **science-based policy making**
- ✓ A wave of research is now coming to an end; a new wave must be prepared
- ✓ The EU Framework Programme for research will be the main source of research funding at the EU level.

Thank you for your attention!

