

EMF-NET Coordination Action 2004-2008





The EMF-NET Methodology and Interpretation of Evidence

Gugliemo d'Inzeo

dinzeo@die.uniroma1.it



ICEmB@Department of Electronic Engineering University "Sapienza" of Rome - Italy



Workshop on EMF and Health: Science and Policy to address public concerns Bruxelles, February 11-12, 2009

The EMF-NET Structure

Coordinator

Dr. Paolo Ravazzani -

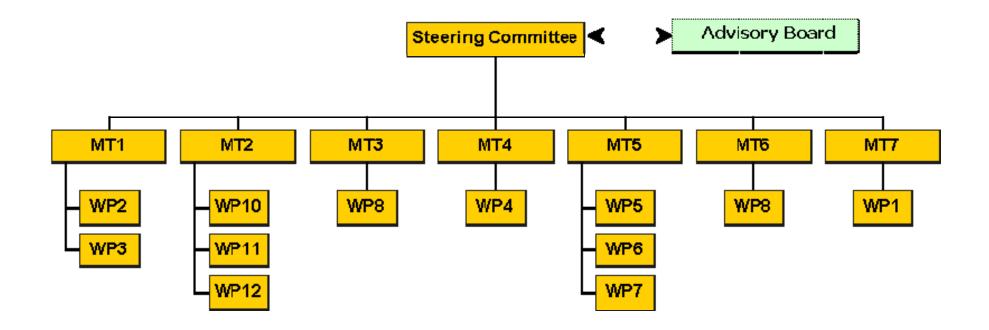
Istituto di Ingegneria Biomedica CNR, Milan, Italy

Scientific officer Dr. Tuomo Karjalainen

Steering Committee

Paolo Ravazzani (Coordinator), Joschen Buschmann, Elisabeth Cardis, Lawrence Challis, Guglielmo D'Inzeo, Maria Feychting, Gerd Friedrich, Kjell Hansson Mild, Jukka Juutilainen, Jolanta Karpowicz, Norbert Leitgeb, Demosthenes Papamelethiou, Theodoros Samaras, Gyorgy Thuroczy, and Bernard Veyret.

The EMF-NET Structure



The EMF-NET Structure Steering Committee Activities

- The SC, chaired by the Coordinator, was in charge of overall direction of the Project.
- The SC was responsible for:
 - Agreeing all documents and reports delivered or published by the Project.
 - Assisting the Coordinator to prepare reports on the whole Project.
 - Providing approval to Project activities, the related use of the Project funds and the dissemination and exploitation plan and activities
- SC meetings were organized approximately every 6 months

The EMF-NET Stucture

Main Task Managers

• MT1: Scientific evaluation of the results of the studies on EMF health effects:

J. Juutilainen - J. Buschmann (laboratory Studies)

- E. Cardis, M. Feychting (Epidemiological Studies)
- MT2: EMF exposure related risk in the working environment:

J. Karpowicz

• MT3: Improvement of specific common aspects of the research on EMF and health:

T. Samaras

• MT4: Risk communication and risk perception:

D. Papamelethiou

The EMF-NET Stucture

Main Task Managers II

• MT5: Observatory function and monitoring

N. Leitgeb (Emerging Technologies)

B. Veyret (Monitoring Research Plan in EU and outside Europe)

G. Thuroczy (Coordination with EU acceding Countries and other European Countries)

• MT6: Dissemination:

P. Ravazzani

- MT7: Management:
 - P. Ravazzani

The EMF-NET Structure

Advisory Board

Franz Adlkofer, Paolo Bernardi, Jürgen H. Bernhardt, Ferdinando Bersani, Bruno Bianco, Gilbert Decat, René De Seze, J. Leo Debecker, Peter Gajšek, Gian Piero Gallerano, Maila Hietanen, Kari Jokela, Alastair McKinlay, Michael Milligan, Lluis Mir, Alain Le Calvè, Michael Repacholi, Paolo Rossi, Jack Rowley, Marc Sapir, John Scowcroft, Paolo Vecchia, Joe Wiart, Eirini Zafeiratou

The EMF-NET Structure

Advisory Board activities

- The AB was composed by members of the scientific community and stakeholders
- AB was involved in the Consultation Processes related to reports delivered by EMF-NET
- AB has been consulted by the SC during the lifetime of the project on particular questions, seeking for advice

Methodological Approach

- Identification and definition of *Scientific Key Issues* and *Interpretation Key Issues* on EMF and health
- Production, systematic update, and validation of

Interpretation Reports

to be communicated at several levels:

- Level 3: scientific reviews
- Level 2: interpretation for policy making
- Level 1: other documents addressed to differently interested persons, prepared on a case by case basis (European Fast Response Team)

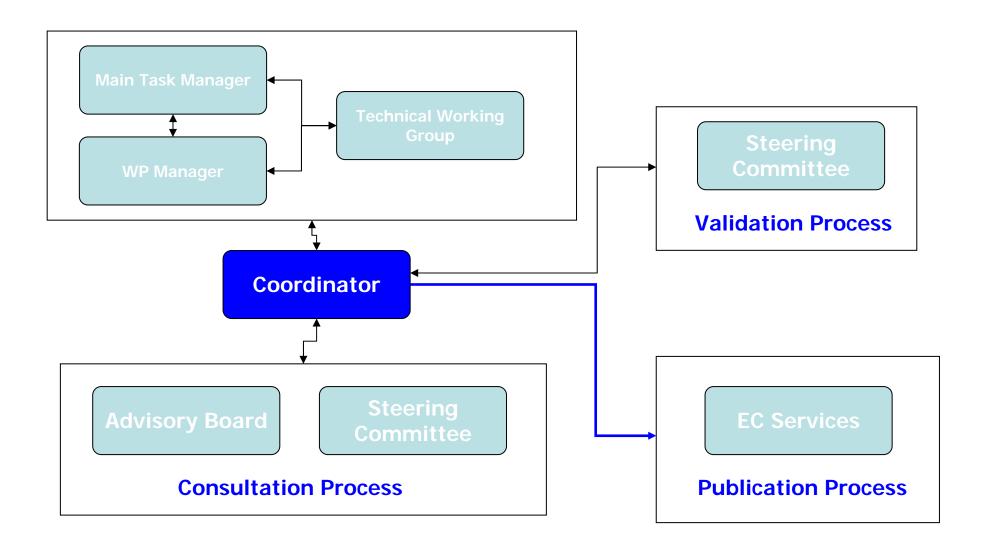
Methodological Approach

- Technical Working Groups of experts
 - Involving more than 85 European and international experts
 - Main Task: preparation of the Interpretation Reports
- Advisory Board Consultation Process
- Steering Committe Validation Process
- Delivery to EC Services and publication (if permitted)

Technical Working Groups of experts

- Data Base publication
- Subgroup Evaluation
- WG specific meeting and workshop
- Round Tables
- Scientific evidence
- Deliverables

Elaboration Process



Deliverables and Interpretation Reports

EMF-NET Consultation Process -	-June 30, 2006	
	6	
Consultation Process on		
Deliverable D30-1 Report on European EMF plans		
Consultation Process	RD/EMF-NET/04/06	
Comments prepared by		*
Date of Preparation		(
Due Date	July 10, 2006 – Midnight	
RIVENETOLICS		Consultation Form

Process

RD/EN

Scientific evidence?

IARC-like Approach

sufficient evidence

Imited evidence

inadequate evidence

evidence suggesting lack of effects

Definition obtained by consensus among the scientists involved in the research and rewieved by SC



Sufficient evidence

- when a positive relationship is observed between the exposure and the effect investigated.
- when the effect is replicated in several studies by independent investigators or under different protocols, and when there is a consistent exposureresponse relationship.
- when confounding factors could be ruled out with reasonable confidence.



Limited evidence

- when the evidence of the effect is restricted to a few studies, or when there are unsolved questions regarding the adequacy of the design, conducting or interpretation of the study.
- when in the studies confounding factors could not be ruled out with reasonable confidence.



Inadequate evidence

- when the studies are of insufficient quality, consistency or statistical power to permit a conclusion.



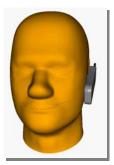
Evidence suggesting lack of effects

- when no effects are reported in several studies by independent investigators under different protocols involving at least two species or two cell types and a sufficient range of field intensities.

EMF-NET Cancer

Type of biological effect and/or potentially affected biological system	Evidence for effects (<i>Classification based on studies</i> <i>published by the year 2000; The impact of newer studies</i>)			
CARCINOGENICITY STUDIES				
Exposure to RF fields alone	Evidence suggesting lack of effect: Later studies further strengthens the previous conclusion			
Combined exposure to RF fields with a known genotoxic agents	Inadequate evidence: Later studies do not give support to the suggested association			
Studies exposing genetically especially tumour-prone animals to RF fields	Inadequate evidence: Later studies do not give support to the suggested association			
Development of transplanted tumours	Evidence suggesting lack of effect: No relevant recent studies			
Mortality	Evidence suggesting lack of effect: Later studies further strengthens the previous conclusion			
IN VIVO STUDIES ON GENOTOXIC EFFECTS				
Gene mutations	Evidence suggesting lack of effect: Later studies further strengthens the previous conclusion			
Structural changes at the level of chromosomes:Micronucleus	Limited evidence: The later studies do not give further support to the suggested association			
DNA Damage/effect assessment	Inadequate/Limited evidence: The later studies do not give further support to the suggested association			
SOME OTHER POSSIBLY CANCER-RELATED IN VIVO STUDIES				
Ornithine Decarboxylase (ODC)	No relevant studies available: Inadequate evidence			
Gene expression (Heat Shock Proteins)	Limited evidence: The later studies have given some support to the suggested association			

Human studies



- Melatonin
- Evoked or event-related potentials (ERPs)
- Cognitive functions
- EHS
- Cardio vascular system
- Sleep EEG



Animal studies (RF)



- DNA damage
- Memory
- Tumour promotion
- Skin
- Hearing
- Blood-brain barrier (BBB)



Cell studies (RF)



- Melatonin
- Apoptosis
- DNA damage
- Free radicals
- Heat shock proteins
- Immune cells
- Cell growth
- Gene expression

By courtesy of B. Veyret

Outputs

- Interpretation reports (several releases)
- Short reports
- EFRT Documents
- Newsletters
- Proceedings of conferences/workshops
- Books
- Information on/for the activities of European Projects
- EMF-NET website: http://emf-net.isib.cnr.it

This paper was produced for a meeting organized by Health & Consumer Protection DG and represents the views of its author on the subject. These views have not been adopted or in any way approved by the Commission and should not be relied upon as a statement of the Commission's or Health & Consumer Protection DG's views. The European Commission does not guarantee the accuracy of the data included in this paper, nor does it accept responsibility for any use made thereof.