

# **International Health Risk Assessments**

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**MTHR Research Seminar  
4 November 2003**



# WHO and RADIATION

CLUSTER

Sustainable Development and Healthy Environment (SDE)

DIVISION

Protection of the Human Environment (PHE)

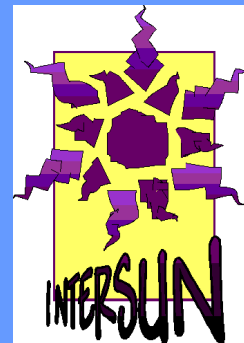
UNIT

Radiation and Environmental Health (RAD)



**Ionizing  
Radiation Safety**

*International*  
**EMF** Project



# Why so much concern about RF?



**Mobile telecommunications  
save hundreds of lives daily**

**Fear of health effects, of new  
technology or lack of  
understanding of how it works?**



# *International* **EMF** *Project*

- ⇒ **Established in 1996**
- ⇒ **To assess health and environmental effects of exposure to electromagnetic fields in the frequency range from 0 to 300 GHz**
- ⇒ **A multinational, multidisciplinary effort to create and disseminate information appropriate to human health risk assessment for EMF**
- ⇒ **Coordinated by WHO**





# Objectives



- ⇒ **Evaluate scientific evidence**
  - ⇒ **Report on current status of knowledge**
  - ⇒ **Identify gaps in knowledge needing to be filled by focused research to make better health risk assessments**
- ⇒ **Promote and facilitate research programs (with national programs such as MTHR)**
- ⇒ **Conduct health risk assessments and risk estimation, and develop policy options**
- ⇒ **Provide information on standards, management programs and advice to national authorities**



# Structure



**EMF Project  
Secretariat**

**International  
Advisory  
Committee**

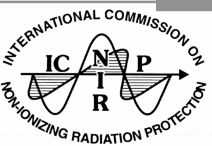
**Research  
Coordinating  
Committee**

**Standards  
Harmonization  
Committee**

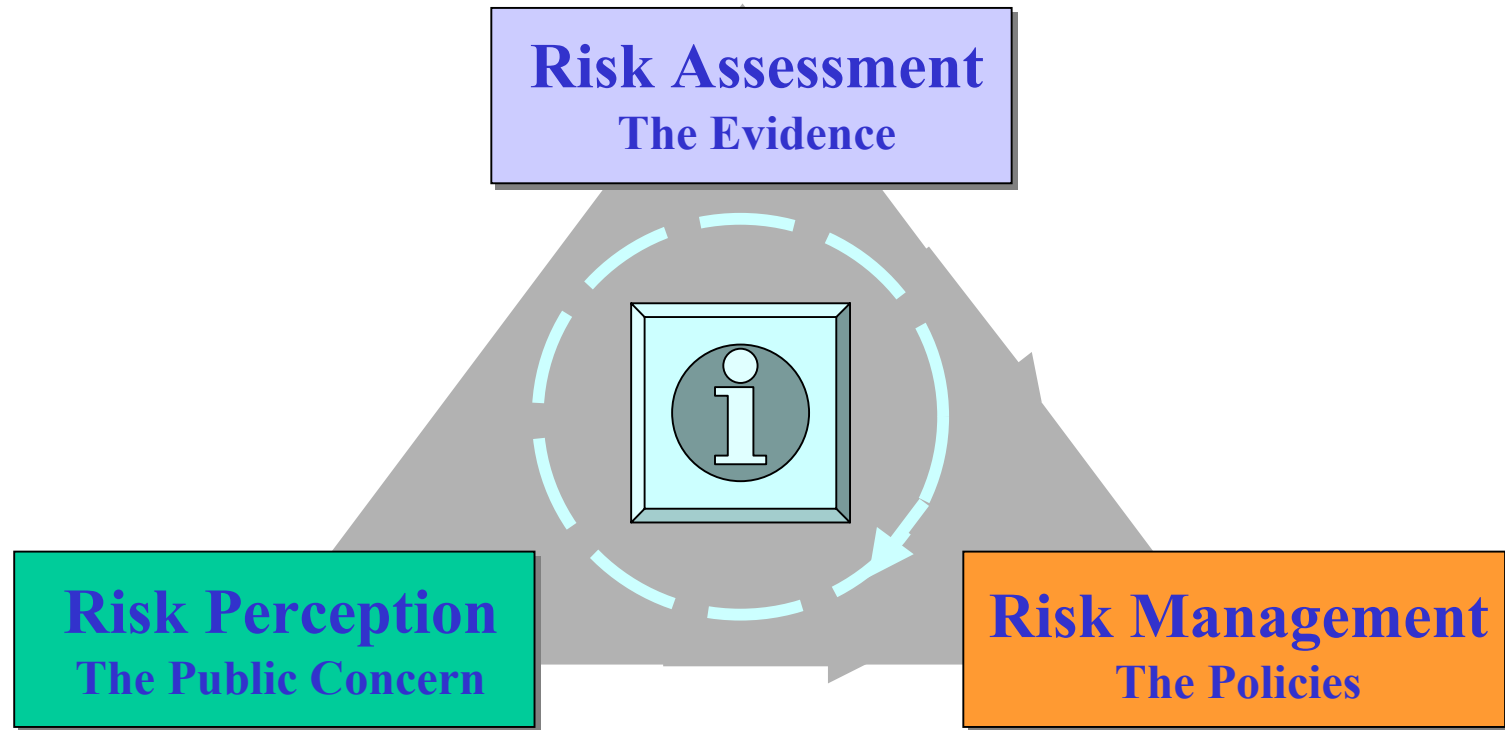
**International  
Organizations**

**Collaborating  
Institutions**

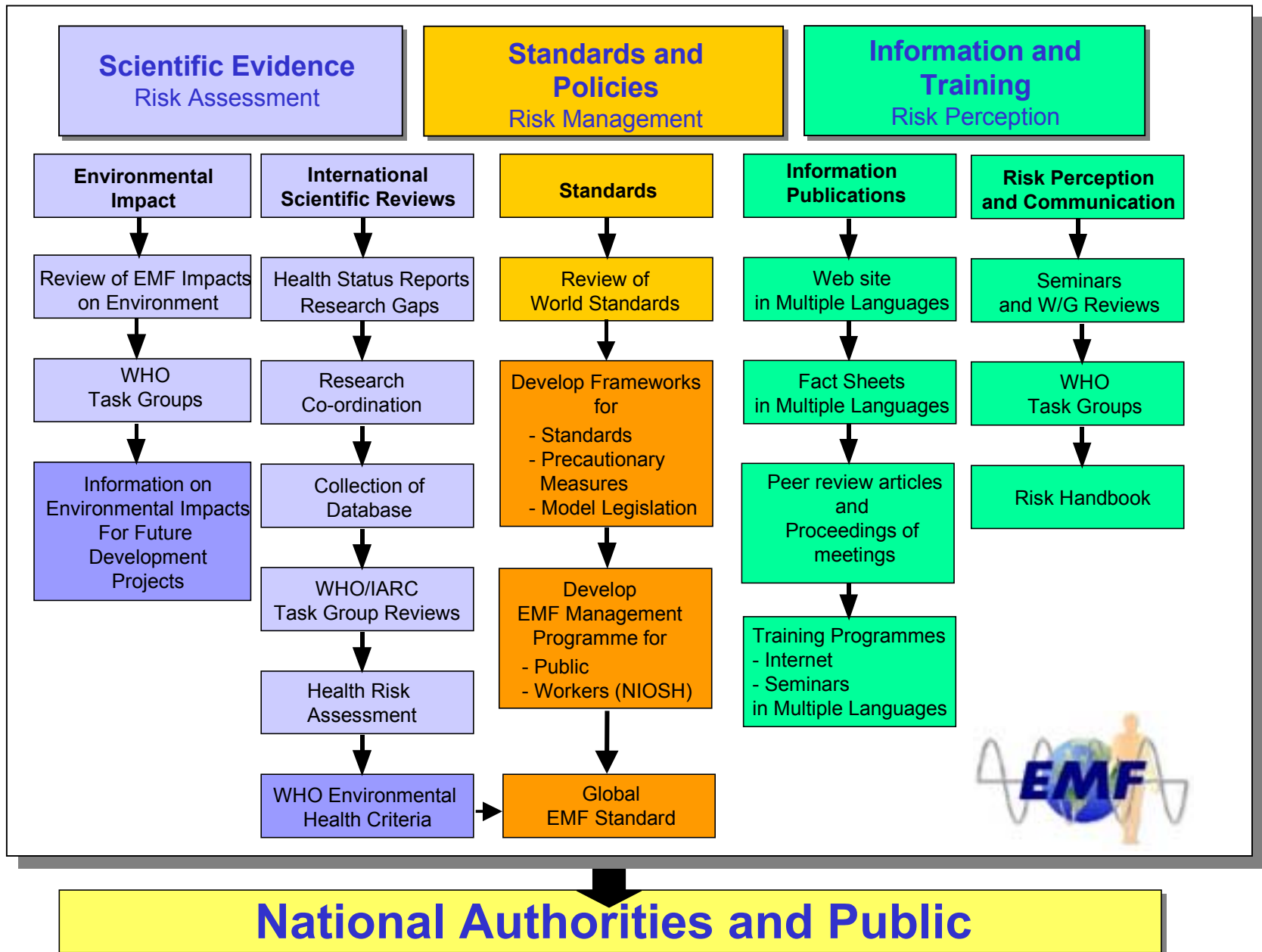
**>50 National  
Authorities**



# EMF: How to Address?



# WHO EMF Project





# Biological and Health Effects

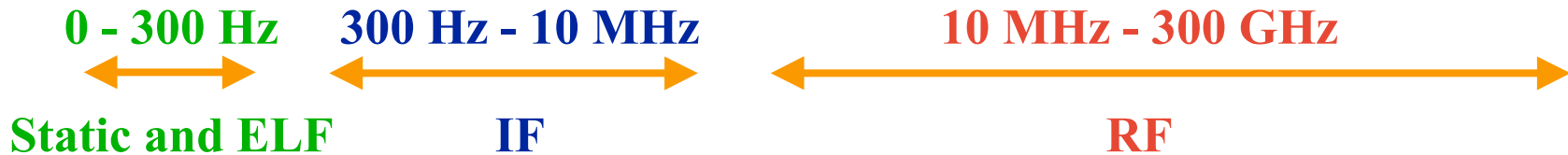
## Working definitions for health risk assessments

⇒ A **biological effect** is a measurable physiological response to EMF exposure ....not necessarily hazardous...this must be evaluated

⇒ An **adverse health effect** is a biological effect outside the body's normal range of physiological compensation that is detrimental to health or well-being



# International Scientific Reviews



➔ **Static and ELF fields, Bologna, 1997**

⇒ **Intermediate frequency fields, Maastricht, 1999**

➤ **RF fields, Munich, 1996**

➤ **RF pulse-modulated fields, Erice, 1999**

→ **Psychosocial impacts of EMF exposure, Graz, 1998**

→ **Environmental impacts of EMF, Ismaning, 1999**

→ **Adverse temperature levels in the human body, Geneva, 2002**

→ **Application of the Precautionary Principle to EMF, Feb. 2003**

→ **Child sensitivity to EMF, Istanbul, June 2004**

→ **Hypersensitivity to EMF Prague, 2004**



# International Scientific

## WHO Process

- ⇒ Working groups on specialised topics
- ⇒ Special meetings in countries having large research programs but results not translated into English, eg Russia and China
- ⇒ WHO does **NOT** issue recommendations without above process .....

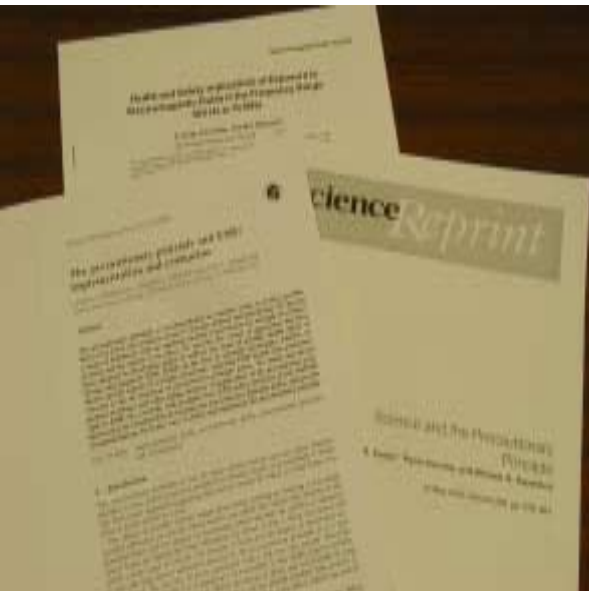


# International Scientific Reviews

## Outputs

- Peer-reviewed journal reports on health effects
- Proceedings of meetings

- Fact Sheets



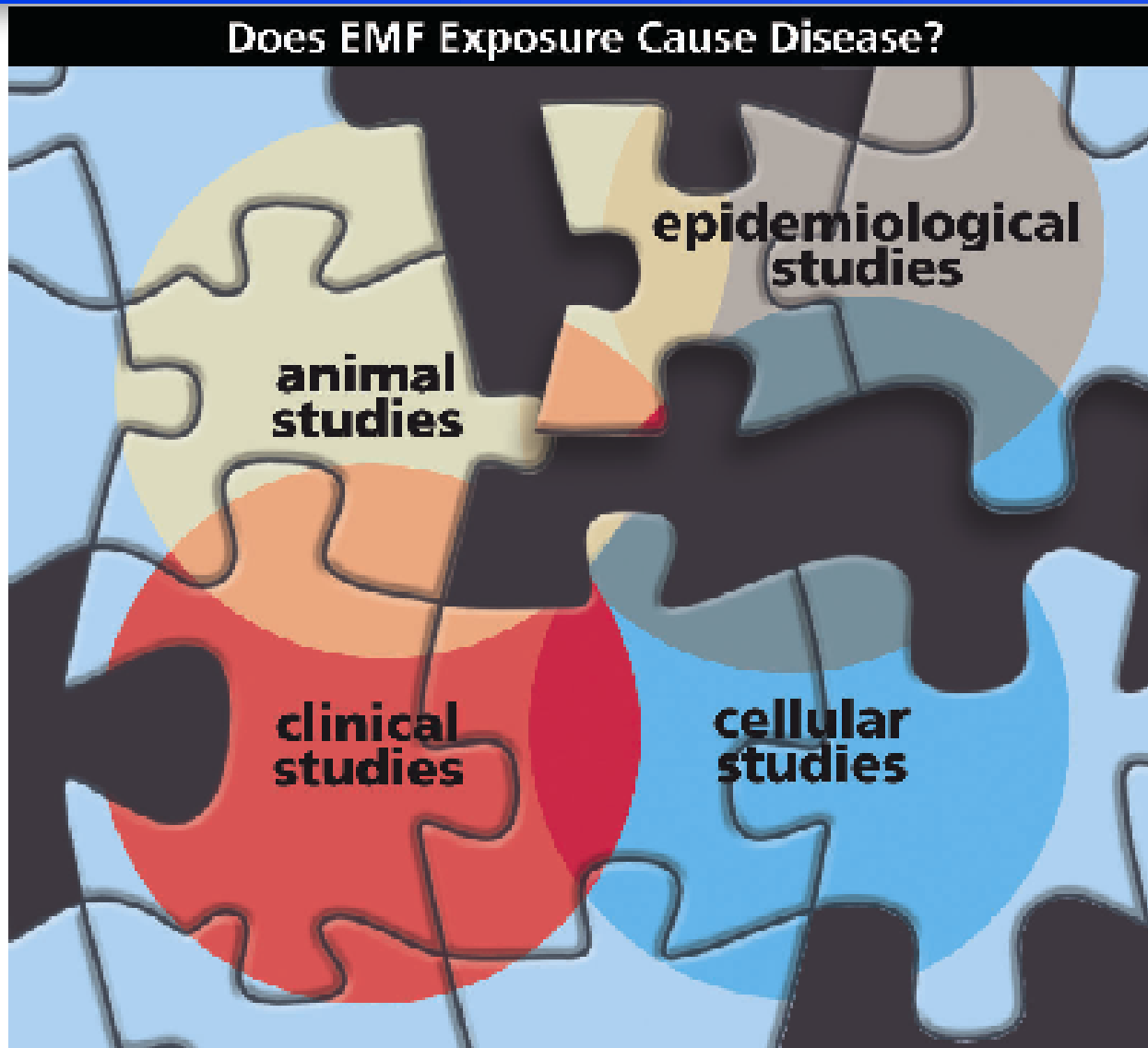
# WHO risk assessment criteria

- ⇒ In-depth, weight-of-evidence, critical review and evaluation of **ALL** EMF research world wide
- ⇒ Study reports **MUST** have descriptions of methods used, all data, and analyses of results and conclusions
- ⇒ All studies **MUST** be replicated or be in agreement with similar studies
- ⇒ All studies, with either positive or negative effects, **MUST** be assessed equally



# RESEARCH

Balance of studies needed



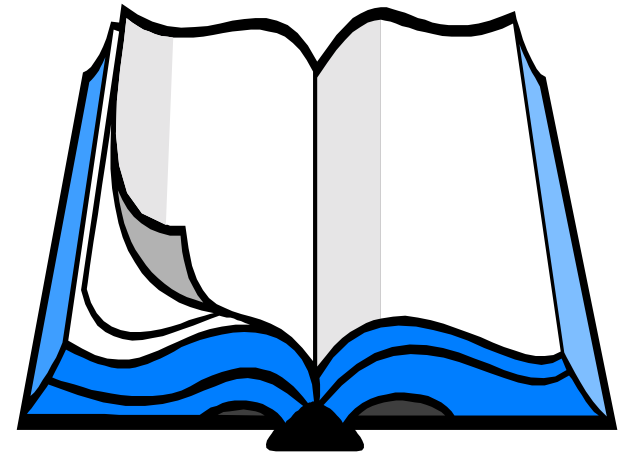
# WHO Environmental Health Criteria

<b>Static and ELF</b>	<b>RF</b>
<b>IARC 2001-2002</b> <b>EHC 2002-2004</b>	<b>IARC 2005-6</b> <b>EHC 2006-7</b>
	



# EHC Contents

- ⇒ Executive summary
- ⇒ Introduction
- ⇒ Sources of exposure and measurement
- ⇒ Environmental levels and human exposure
- ⇒ Internal dosimetry and biophysical mechanisms
- ⇒ Effects on laboratory test systems
- ⇒ Effects on humans
  - ⇒ Cancer
  - ⇒ Reproduction
  - ⇒ Cardiovascular
  - ⇒ Neurodegenerative
  - ⇒ Behavioural
  - ⇒ Hypersensitivity
- ⇒ Methodological issues health risk assessment
- ⇒ Evaluation of dose-response
- ⇒ Evaluation of human health risks and risk estimation
- ⇒ Protective measures and policy options (including precautionary approach)
- ⇒ Conclusions & recommendations
- ⇒ Further research
- ⇒ References





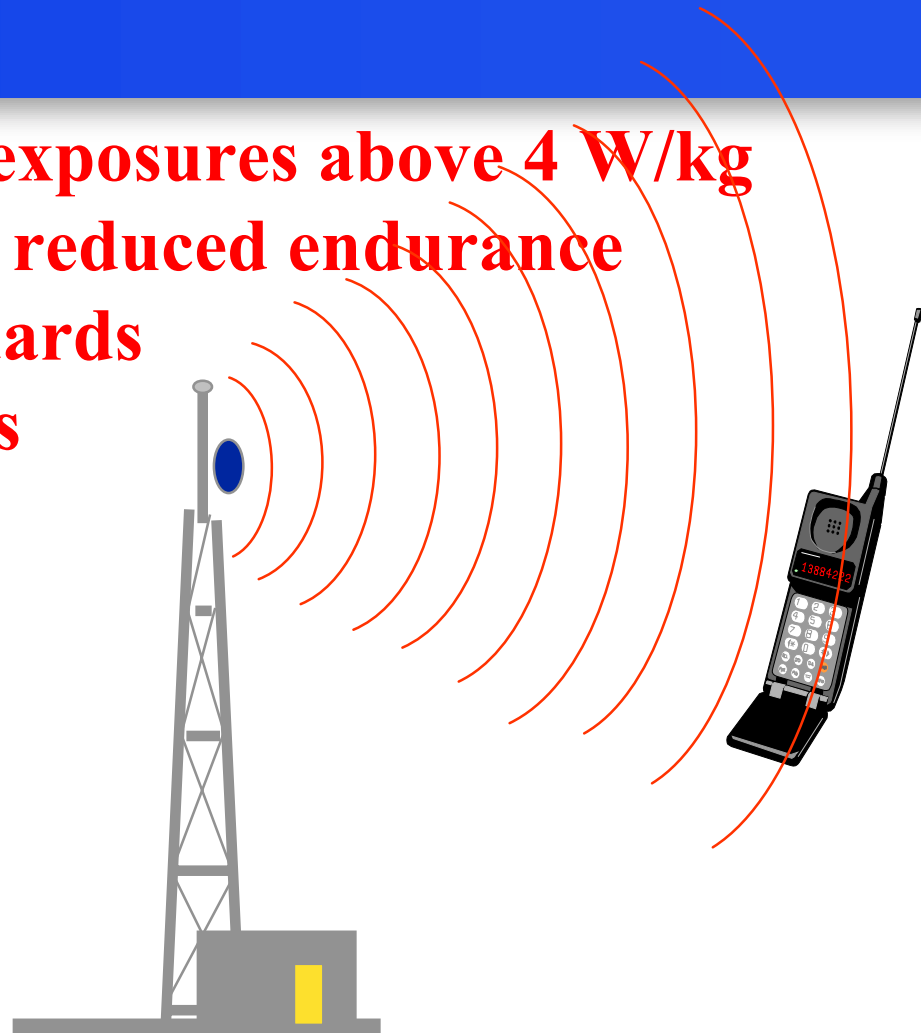
## See new WHO RF Research Agenda

# RF Fields

- RF health effects are due to exposures above 4 W/kg causing behavioural changes, reduced endurance
- Basis for International standards
- No health effects below limits

### Effects not established:

- ⇒ Memory loss
- ⇒ Cancer
- ⇒ Blood pressure changes
- ⇒ Blood brain barrier
- ⇒ Altered reaction times
- ⇒ Subjective effects (Hypersensitivity)



# Major risk related to mobile phone use



# RF fields

## What is the way forward?

- ⇒ **Coordinated and focused research program: see WHO's new RF research agenda ([www.who.int/emf](http://www.who.int/emf))**
- ⇒ **Risk assessment program**
- ⇒ **Advise national authorities**
- ⇒ **Process and information must be transparent and disseminated in a way that is user-friendly to the public, workers, government and industry**



# WHO RF Research Agenda

WHO meeting June 2003



## Exposure Assessment

- ⇒ Develop personal dosimeters (for epi studies and exposure assessment of populations...for risk estimation)
- ⇒ Exposure assessment specific for children



# WHO RF Research Agenda

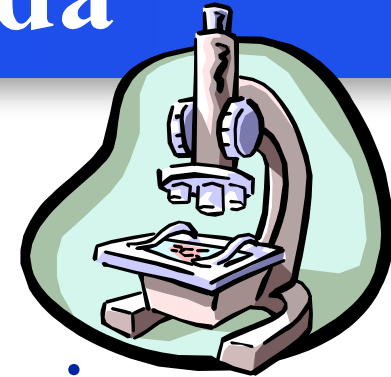
## Interaction mechanisms

- ⇒ There are no novel hypotheses to test relevant to health risk assessment
- ⇒ More work on micro-dosimetry at the cellular or sub-cellular levels might give new information about the targets of RF



# WHO RF Research Agenda

## Animal, Cell Studies



- ⇒ **Effects on immune system – follow-up on Russian studies suggesting RF-induced disruption of antigenic structures in brain tissue**
- ⇒ **Blood brain barrier and neural damage**
- ⇒ **Test new signals in large scale chronic studies**
- ⇒ **Soon to be implemented: NTP study**
- ⇒ **Stress and heat shock proteins (e.g. HSP-27) induction and phosphorylation**



# WHO RF Research Agenda

## Epidemiology

- ⇒ **Ongoing:** IARC study of brain and parotid tumours
- ⇒ **New:** Prospective cohort study of mobile phone users
- ⇒ **New:** Base station epidemiological studies – tie in with feasibility (UK research program)



# WHO RF Research Agenda

## Human studies

**Ongoing:** Reaction times, memory, performance

**New:** Sleep, headaches, hypersensitivity





# WHO RF Research Agenda

## Overarching Principles

- ⇒ Use commercially relevant RF signals
- ⇒ Test interactions with other agents
- ⇒ Study impact of age of animal,
- ⇒ Dose patterns (regimen, duration, intermittency)

## In Human Studies

- ⇒ Include children in study designs
- ⇒ Use populations with well-defined exposures



# Key issues

## Exposure from Base Stations



- ⇒ Is it possible to do a valid study of exposure to RF sources, and distinguish the effect of base station exposures from other RF sources?
- ⇒ Are there any low-level long term effects?

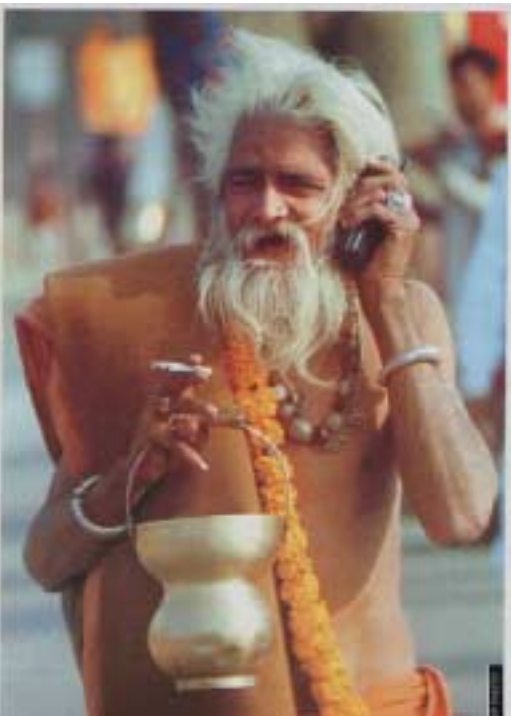


# Key issues

## International Cohort Study of Mobile Phone Users



- ⇒ **Follow-up to IARC Interphone case-control study**
- ⇒ **WHO EMF Project currently assisting in formation for long-term follow-up**



# International Cohort Study of Mobile Phone Users

## Need

- ⇒ **Epidemiological studies provide most relevant evidence for Risk Assessment and highest weight in weight-of-evidence approach**
- ⇒ **With huge number of mobile phone users worldwide any health effect could be an important public health issue**
- ⇒ **Current IARC Interphone studies focus on head and neck tumors and not other cancers or diseases**
- ⇒ **Cohort Study of Mobile Phone Users highest priority on WHO research agenda**
- ⇒ **Not being addressed by any ongoing research**



# International Cohort Study of Mobile Phone Users

## Unique opportunity

- ⇒ Provide long term surveillance
- ⇒ Address diseases of concern not in current research
- ⇒ Document prevalent, but rapidly changing exposure
- ⇒ Unique resource to address future, unanticipated issues
- ⇒ Timely given widespread use of technology and disease latency
- ⇒ Most powerful epidemiological design
- ⇒ Data which toxicology can't provide
- ⇒ Top priority on the WHO research agenda



# Key issues

## Effects of EMF on Children



- ⇒ **Stewart Report (UK: IEGMP 2000)**
- ⇒ **Health Council of the Netherlands (2002)**
- ⇒ **EC: COST 281 (2002)**
- ⇒ **WHO EMF Project workshop (Istanbul, June 2004)**



# Key issues

## Hypersensitivity to EMF



- ⇒ **COST 244 (Graz, 1998)**
- ⇒ **WHO EMF Project workshop (Prague, 2004)**



# Electromagnetic Hypersensitivity

## Symptoms

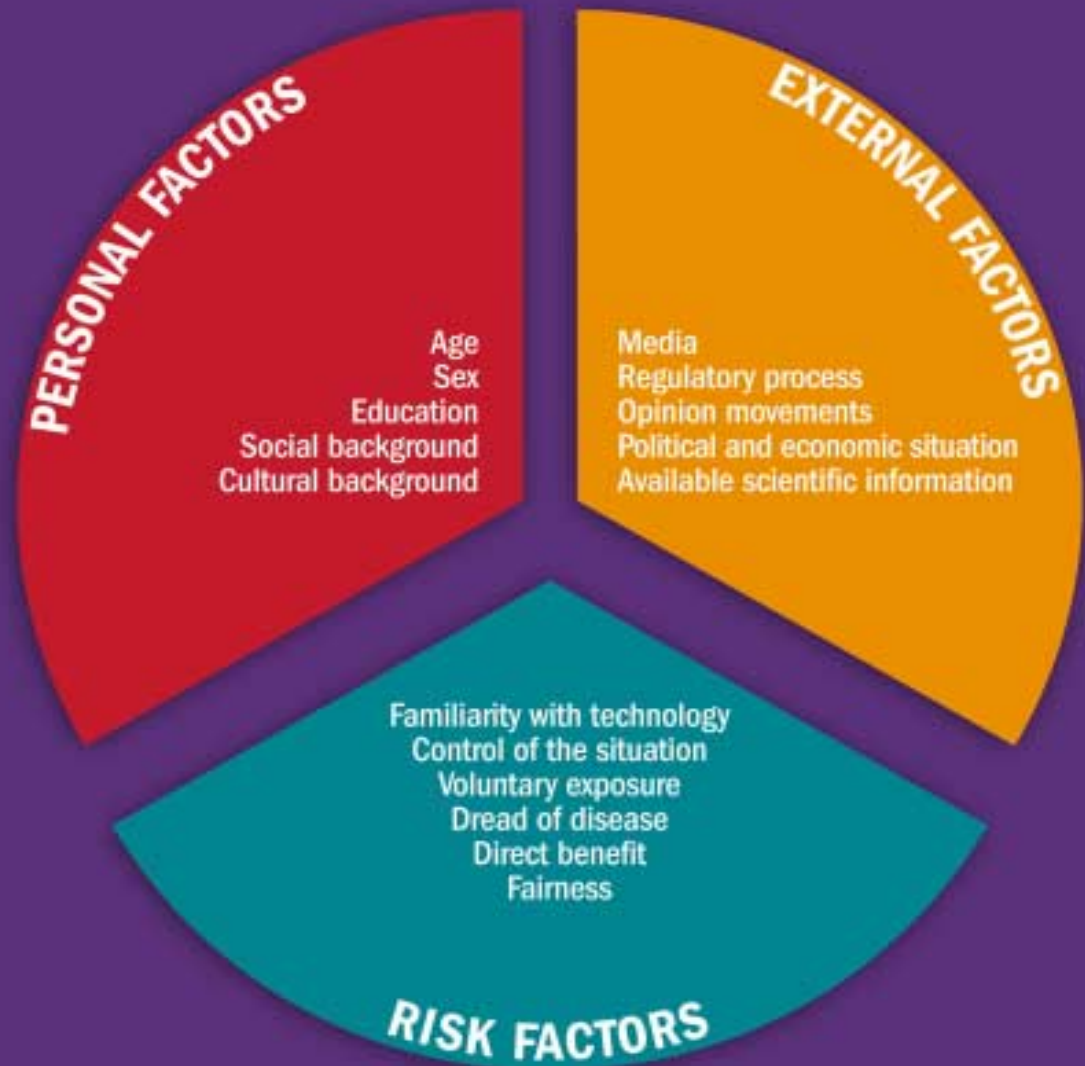
- ⇒ Nervous system symptoms (e.g. sleep disturbances, fatigue, stress)
- ⇒ Skin symptoms (e.g. facial prickling, burning sensations, rashes)
- ⇒ Various body symptoms (e.g. pain and ache in muscles)
- ⇒ Eye symptoms (e.g. burning sensations)
- ⇒ Various less common symptoms that include ear, nose, and throat problems, as well as digestive disorders
- ⇒ Symptoms faced by EHS individuals are certainly real





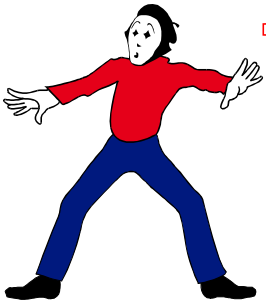
# Elements of Risk Perception

- **Extent of health risk**
- **Probability of occurrence**
- **Uncertainty**
- **Ubiquity**
- **Pattern of exposure**
- **Delayed effect**
- **Inequity and injustice**
- **Voluntary vs. involuntary exposure**

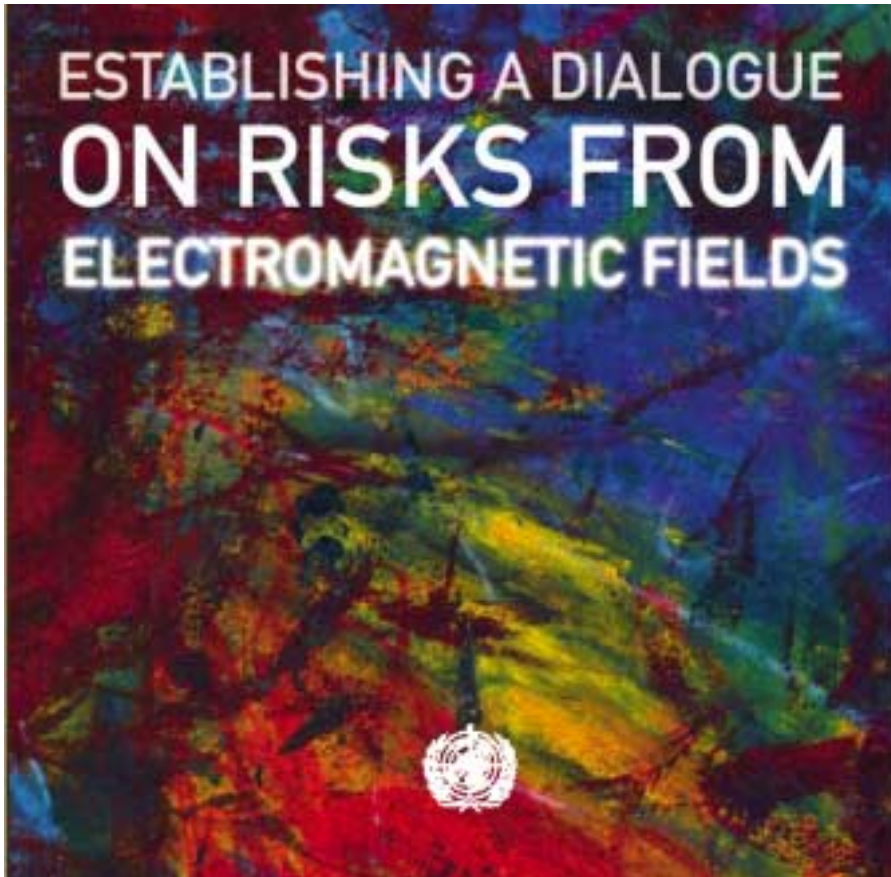


# Risk Perception and Communication

- **Crucial to establish a dialogue between all individuals and groups impacted by EMF facilities**
- **Effective dialogue includes**
  - **consultation with stakeholders**
  - **acknowledgement of scientific uncertainty**
  - **consideration of alternatives**
  - **fair and transparent decision-making process**



# Risk Perception and Communication



- ⇒ For program managers needing information on EMF risk perception, communication and management
- ⇒ Based on international seminars and working groups



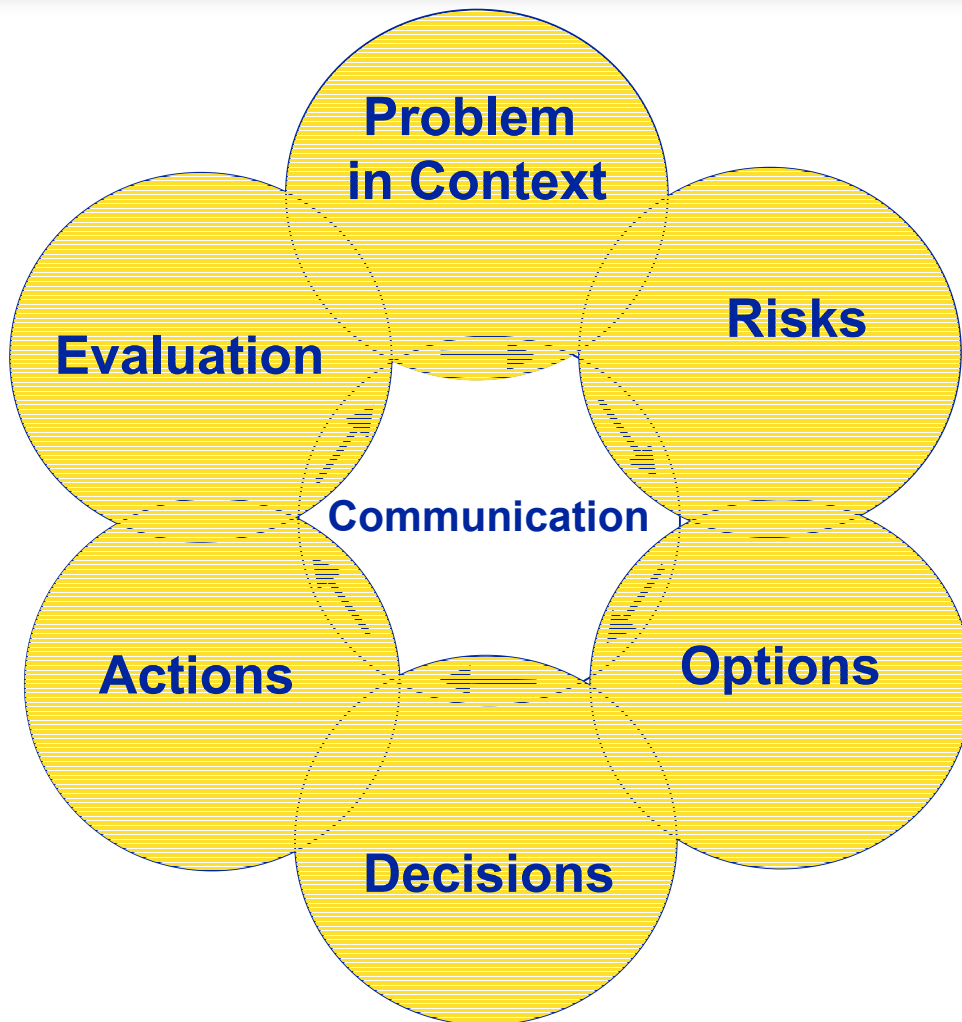


# WHO's Precautionary Framework

## Objectives

- to **anticipate** and respond to possible threats before introduction of an agent or technology
- to **address public concerns** that an uncertain health risk is minimised after introduction of an agent
- to **develop and select options** proportional to the degree of scientific uncertainty, the severity of harm, the size and nature of the affected population and the cost

# WHO Precautionary Framework

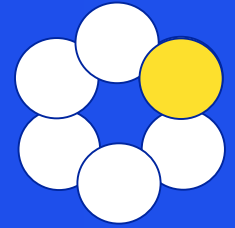


⇒ An **OVERARCHING approach** that involves precautionary measures at each step of the risk management process

⇒ A **general and practical framework** for any potential health risk



# Risk Evaluation



## Conventional: for known risks

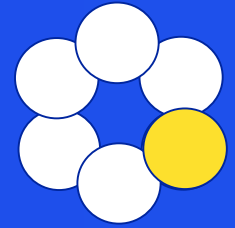
- Focus on known
- Risk assessment information adequate
- Weight of evidence evaluation
- Uncertainties and assumptions identified

## Precautionary

- Focus on key uncertainties and limitations of knowledge
- Prevention prior to accumulation of complete evidence



# Option Generation



## Conventional

- Designed to meet a limit or guideline
- Driven by technological feasibility

## Precautionary

- From “do nothing” to “ban”
- Can include individual choice and behavioural modification

**N.B. All options should be evaluated with rigour**



# Limits and Precautionary Measures

## Conventional

- Based on evidence from established science
- Incorporates reduction factors from known adverse health effects

## Precautionary

- Reduce exposure while maintaining benefits
- Code of practice: ways of keeping exposures low
- Can incorporate cost-benefit consideration

**N.B.** The WHO framework does **NOT** provide a basis for replacing science-based guidelines





## RANGE OF RISK MANAGEMENT OPTIONS

**DECISION TO TAKE NO FORMAL ACTION** is an appropriate response in cases where the risk is considered very small, or the evidence is insufficient to support formal actions. This response is often combined with watchful waiting, i.e. monitoring the results of research and measurements and the decisions being made by standard-setters, regulators, and others.

**COMMUNICATION PROGRAMMES** can be used to help people understand the issues, become involved in the process and make their own choices about what to do.

**RESEARCH** fills gaps in our knowledge, helps to identify problems, and allows for a better assessment of risk in the future.

**CAUTIONARY APPROACHES** are policies and actions that individuals, organizations or governments take to minimize or avoid future potential health or environmental impacts. These may include voluntary self-regulation to avoid or reduce exposure, if easily achievable.

**REGULATIONS** are formal steps taken by government to limit both the occurrence and consequences of potentially risky events. Standards with limits may be imposed with methods to show compliance or they may state objectives to be achieved without being prescriptive.

**LIMITING EXPOSURE** or banning the source of exposure altogether are options to be used when the degree of certainty of harm is high. The degree of certainty and the severity of harm are two important factors in deciding the type of actions to be taken.

**TECHNICAL OPTIONS** should be used to reduce risk (or perceived risk). These may include the consideration of burying power lines, or site sharing for mobile phone base stations.

**MITIGATION** involves making physical changes in the system to reduce exposure and, ultimately, risk. Mitigation may mean redesigning the system, installing shielding or introducing protective equipment.

**COMPENSATION** is sometimes offered in response to higher exposures in a workplace or environment. People may be willing to accept something of value in exchange for accepting increased exposure.



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## The International EMF Project (EMF)

[About Us](#) | [Contact Us](#) | [Publications](#)

Location: [WHO](#) > [WHO sites](#) > EMF Home

# International EMF Project

"...through its [International EMF Project](#), the World Health Organization is pooling resources and knowledge concerning health effects of exposure to EMF."



ON THIS SITE, YOU WILL BE ABLE TO FIND DETAILS ON THE FOLLOWING QUESTIONS:

- [What is the International EMF Project?](#)
- [What research on the health effects of EMF is being done?](#)
- [What are the standards and guidelines on exposure to EMF?](#)
- [What are electromagnetic fields?](#)
- [What WHO publications are available on this topic?](#)
- [What meetings are of interest?](#)

### WHAT'S NEW!

**New RF research agenda - July 2003**  
[More information](#)

**WHO response to inquiries about Epidemiological Studies Around Base Stations**  
[More information](#)

**Precautionary Framework: Update on WHO's Activities**  
[More information \[PDF 7KB\]](#)

**Precautionary Framework for Public Health Protection**  
We invite public comment on the draft. Please address comments to [emfproject@who.int](mailto:emfproject@who.int)  
[Full report \[PDF 117KB\]](#)



# NEXT STEPS

- Present framework to highest levels in WHO
- Include generic case studies

## Anticipated outcome

- Better public health protection
- Broad stakeholder participation
- Better public acceptance of health policies



# Further Information

**Home page: [www.who.int/emf/](http://www.who.int/emf/)**

