

SCENIHR Risk Analysis Approach and Overview of Recent Opinions on Electromagnetic Fields

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What is SCENIHR?

- Scientific Committee on Emerging and Newly Identified Health Risks
- One of three independent non-food scientific committees at DG SANCO
- First mandate period 2004-2008
- New mandate period 2009-2011
- Presently 17 members covering many areas of expertise

SCENIHR Mandate

Emerging or newly identified risks, broad, complex or multi-disciplinary issues requiring a comprehensive assessment of risks to consumer safety or public health

(NB! Risk management issues specifically excluded)

Examples

- new technologies (e.g. nanotechnologies)
- medical devices, tissue engineering, blood products
- physical hazards (e.g. noise and electromagnetic fields)
- antimicrobial resistance
- fertility reduction, cancer of endocrine organs
- interaction of risk factors, synergic or cumulative effects
- methodologies for assessing new risks

SCENIHR –mode of working

- Question(s) framed by one or more Commission Services
- Question discussed in a SCENIHR Plenary Meeting. Chairman of a Working Group (WG) is appointed
- External experts are identified and invited for the WG. NB! all members must declare any relevant interests at each meeting.
- WG produces a preliminary report (6-18 months)
- Report is discussed at SCENIHR and a preliminary opinion / final opinion is agreed upon
- Public consultation
- Final Opinion, belonging to EC DG SANCO and/or other DG, is published

Policy follow-up of Opinions

- EU legislation
- EC Directives directly influenced
- Community research priorities
- International collaboration on risk assessment and guidelines
- Internal work of Commission services

Risk assessment – A weight of evidence approach

- The primary objectives of health risk assessment are:
 - to identify and characterise any hazardous properties of a given agent
 - to examine the relationship between exposure and these hazards (dose response relationship)
 - to highlight uncertainties in the determination of hazards and dose response relationships
 - to evaluate the possible modes/mechanisms for each hazard of concern.
- A health risk assessment evaluates the evidence within several areas of studies (human epidemiological studies, human volunteers studies, animal studies, in vitro studies)
- The evidence from across the areas are **weighed** to produce a combined assessment.

Risk assessment –

A weight of evidence approach (cont´d)

- The combined assessment should address the question of cause and effect. The answer to this question is not necessarily a definitive yes or no, but may express the weight of the evidence for the existence of a hazard.
- If such a hazard is judged to be present, the risk assessment should also address the magnitude of the effect and the shape of the dose-response function,
- A full risk assessment also includes exposure characterisation in the population and estimates of the impact of exposure on burden of disease.

Since risk assessment is using the scientific literature, relevant publications have to be found

- Published scientific papers obtained via electronic literature searches, papers known to assessing experts
- Published governmental reports and opinions of other relevant scientific committees
- Requested from stakeholders

Criteria for weighting

High priority papers:

1. Peer reviewed
2. Well established highly rated journal
3. Full experimental details provided in the paper
4. Findings agree with other published work and/or findings compatible with known science
5. Established methodology used (e.g. OECD), valid statistical methods, valid control groups included
6. Work performed to GLP/GCP
7. Work from an organisation /scientist with a good reputation in the area of the publication
8. No obvious information gaps

Low priority papers:

1. Not peer reviewed
2. Journal not well known
3. Limited or no experimental details provided
4. Unexpected findings not supported by other high quality papers on the same topic
5. Methodology not well established or unclear. Statistical evaluation not significant. Suitable control groups not used.
6. Work not audited
7. Organisation/author not well known in area or considered to be prejudiced
8. Data provided appears to be incomplete, selective, or unreferenced

Risk assessment based on evidence from several lines of investigation

- Exposure assessment
- Animal studies
- In vitro studies
- Human epidemiological studies
- Human volunteers studies

Two recent SCENIHR Opinions on EMF

- SCENIHR Opinion on: Health Effects of Exposure to EMF. 19 Jan 2009. 83 pp.
http://ec.europa.eu/health/ph_risk/04_scenihr/docs/scenihr_o_022.pdf
- SCENIHR Opinion on: Research Needs and Methodology to Address the Remaining Knowledge Gaps on the Potential Effects of EM. 6 July 2009 28 pp.
http://ec.europa.eu/health/ph_risk/committees/04_scenihr/docs/scenihr_o_024.pdf

Health effects of exposure to EMF- Conclusions regarding RF exposure and cancer

- Three independent lines of evidence (epidemiological, animal and in vitro studies) indicate that exposure to RF fields is unlikely to lead to an increase in cancer in humans
- Since common long-term exposure of humans to RF fields from mobile phones is shorter than the induction time of some cancers, further studies are required to identify if considerably longer-term human exposure to such phones might pose some cancer risk

Conclusions regarding RF exposure and non-cancer outcomes

- No support for an effect of RF fields on self-reported symptoms. A placebo effect (an adverse non-specific effect that is caused by expectation or belief that something is harmful) may play a role in symptom formation.
- There is some evidence that RF fields can influence EEG patterns and sleep in humans. The health relevance is uncertain.
- Other studies on functions/aspects of the nervous system, show no or no consistent effects.
- Recent studies have not shown effects from RF fields on human or animal reproduction and development. No new data has appeared that indicate any other effects on human health.
- Information on possible effects caused by RF fields in children is limited. Furthermore, there is a lack of information on diseases other than those discussed in this report.

Conclusions regarding IF exposure

- Very little research on IF and health risks in occupational settings or for the general public have been presented since the previous opinion and no epidemiologic study has appeared.
- Consequently, the data are still too limited for an appropriate risk assessment.

Conclusions regarding ELF exposure

- The few new epidemiological and animal studies that have addressed ELF exposure and cancer do not change the previous assessment that ELF magnetic fields are a possible carcinogen and might contribute to an increase in childhood leukaemia
- No new studies support a causal relationship between ELF fields and self-reported symptoms
- New epidemiological studies indicate a possible increase in Alzheimer's disease arising from exposure to ELF fields
- Recent animal studies provided an indication for effects on the nervous system at flux densities from 0.10-1.0 mT. However, there are still inconsistencies in the data, and no definite conclusions can be drawn concerning human health effects
- Very few recent in vitro studies have investigated effects from ELF fields on diseases other than cancer and those available have very little relevance
- In vivo and in vitro studies show effects at exposure levels to ELF fields that are considerably higher than the levels encountered in the epidemiological studies which showed an association between exposure and diseases

Conclusions regarding exposure to static MF

- Many mixed and contradictory results in studies
- A lack of adequate data for a proper risk assessment
- Short term effects have been observed primarily on sensory functions for acute exposure. However, there is no consistent evidence for sustained adverse health effects from short term exposure up to several Tesla

Specific occupational considerations

- Increase in use of MRI-equipment (static MF, gradient fields, RF fields)
- Other medical devices and welding machines using RF fields
- Large knowledge gaps regarding IF fields
- ELF field exposure and neurodegenerative diseases
- NB! Knowledge gaps do not equal health risks

Research recommendations - RF

Health effects from RF from wireless communication in adults
(prospective cohort study)

Health effects from RF from wireless communication in children
(interdisciplinary study including dosimetry, epidemiology and animal experimental work)

RF mechanisms and verification of important but preliminary findings
(experiments testing the existence of modulation-specific effects or demodulation of RF signals in biological structures; experimental studies on EEG patterns and sleep parameters)

Research recommendations - IF

- *Investigation of possible health effects*
(an interdisciplinary project on health effects in specific occupational settings that should examine pregnancy outcome and selected biomarkers in personnel working close to anti-theft devices. This would include dosimetry, biomarker studies, epidemiology, as well as experimental in vivo and in vitro studies)

Research recommendations - ELF

Experimental studies relevant to possible carcinogenicity of ELF fields

(laboratory studies using *in vitro* and/or animal models)

Studies on the association between ELF magnetic fields and neurodegenerative diseases

(epidemiological study (cohort study or register-based case-control study) on Alzheimer's Disease. Residential exposure or clearly defined occupational groups are preferable. Data on other neurodegenerative diseases (such as Parkinson's Disease or ALS) can be included, although the evidence is weaker than for Alzheimer's disease; laboratory study using animal models (and possibly additional *in vitro* models) of Alzheimer's disease.)

Research recommendations – Static fields

Epidemiological studies on patients and workers

(feasibility study of pediatric MRI patients; cohort studies on personnel dealing with equipment that generates strong static magnetic fields including biomarker studies of possible cancer risk)

Experimental studies on possible health effects

(experimental animal and in-vitro studies on end-points relevant for human health, including genotoxicity; experimental human and animal studies on possible cognitive effects of exposure to magnetic gradient fields; experimental human studies on the functioning of the cardiovascular system at flux densities > 3 T)

Research recommendations – Environmental considerations

Environmental effects

(comparison of selected ecosystem(s) before and after the installation of a new facility and/or located at varying field strengths from specific ELF EMF source(s))