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# Risk assessment approach and overview of SCENIHR work on health effects of EMF

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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

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# 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, energy saving light bulbs and **electromagnetic fields**)
- antimicrobial resistance
- fertility reduction, cancer of endocrine organs
- interaction of risk factors, synergic or cumulative effects
- methodologies for assessing new risks

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# 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 meetings.
- WG produces a preliminary report (6-18 months)
- Report is discussed at SCENIHR and a preliminary/final Opinion is agreed upon
- Public consultation (optional)
- Final Opinion, belonging to EC DG SANCO and/or other DG, is published

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# 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

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# Opinions on Electromagnetic Fields

- (SCENIHR). Opinion on: **Possible effects of electromagnetic fields (EMF) on human health**. 21 March 2007. 64 pp. http://ec.europa.eu/health/ph_risk/committees/04_scenihr/docs/scenihr_o_007.pdf

- (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 health effects of EMF**. 6 July 2009. 28 pp. http://ec.europa.eu/health/ph_risk/committees/04_scenihr/docs/scenihr_o_024.pdf

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# Risk assessment – A weight of evidence approach

- The primary **objectives of health risk assessment** are:
  - hazard identification and characterisation
  - to examine dose response relationships
  - to highlight uncertainties in the determination of hazards and dose response relationships
  - to evaluate the possible modes of action 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, in silico studies)

- The evidence from across the areas are **weighed** for their quality and importance in regard to the response to the Commissions question(s).

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# The SCENIHR RA process – Identification of data

- Published scientific papers obtained via electronic literature searches, papers known to assessing experts
- Published governmental reports and opinions of other relevant scientific committees
- Information requested from stakeholders (NB! Confidentiality)

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# The SCENIHR RA process – Initial screening of available data

- The usefulness of a single study depends on its:
  - relevance for answering the question
  - validity/quality/reliability
  - adequacy/scope

- A requirement for a risk assessment is to evaluate the evidence across all relevant domains/lines of evidence. **Expert judgement** is needed in applying these criteria.

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# Criteria for quality/reliability

**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 prejudicial
8. Data provided appears to be incomplete, selective, or unreferenced

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# The SCENIHR RA process – General considerations in assessment of selected publications

- Epidemiological and experimental studies treated similarly in the evaluation process
- Equal importance is given to positive and negative findings in studies
- Statistical significance
- Formal scoring of publications/data sources (not adopted yet)

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# Evaluation criteria

- Stressor identification and characterisation

- Exposure to the stressor (external, internal (toxicokinetics))

- Hazard assessment based on several lines of evidence
  - animal studies (extrapolation, validity)
  - in vitro studies (genotoxic, non-genotoxic)
  - in silico data
  - epidemiological studies (bias and confounding)
  - volunteers studies (provocation studies)
  - other human data resources (e.g. clinical cases, reported experiences)

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# Risk assessment based on all the available publications

- Integration of the results from all relevant individual studies into an overall assessment, subsequent to evaluation of the individual studies
  - evaluation of exposure
  - evaluation of hazard data
  - mode(s) of action
  - estimating the risks using exposure and hazard data

- Scoring for the overall weight of evidence (not adopted yet)
  Scores from 1 (low confidence) to 4 (high confidence) for specific criteria at each of the above steps
  - overall quality
  - relevance of the papers that met threshold of acceptability
  - degree to which there are significant data gaps

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# Risk assessment based on all the available publications - considerations

- Evaluation of the combined exposure (measured data > modelled data > use estimates)
- Evaluation of combined hazard data (human data > animal data > in vitro data > in silico data)
- Evaluation based on Modes of Action
- Combining the exposure, hazard and MoA evaluations
- Expression of uncertainty

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# Structure

- Radiofrequency Fields 100 kHz–300 GHz
- Intermediate Frequency Fields 300 Hz–100 kHz
- Extremely Low Frequency Fields 1-300 Hz
- Static Magnetic Fields
- Environmental aspects

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# Results: **Possible effects of electromagnetic fields (EMF) on human health (RF)**. 2007

- Numerous studies since 2001 Opinion (Human studies, animal studies, in vitro studies)
- Mobile telephone use < 10 years, no increased risk for brain tumors, acoustic neuroma
- Few data on effects after longer term exposure
- For non-tumor diseases, few epidemiological studies
- Children´s sensitivity?

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# Results: **Possible effects of electromagnetic fields (EMF) on human health (RF)**. 2007

- RF exposure does not cause “Electrical hypersensitivity” (EHS)
- No evidence for effects on nervous system or reproduction
- Animal studies do not suggest effects on cancer development
- Cellular studies without relevance for risk assessment for human health
- Long-term studies are missing
- New technologies? Personal exposure?

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# Results: **Health Effects of Exposure to EMF (RF)**. 2009.

- 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**

- **No support for an effect of RF fields on self-reported symptoms**. A **nocebo effect** (an adverse non-specific effect that is caused by expectation or belief that something is harmful) may play a role in symptom formation.

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# Results: **Health Effects of Exposure to EMF (RF)**. 2009.

- 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.

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# Research recommendations (RF) 2009

- *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)

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Thank you for your attention

and

**Good Luck** to the FGF-group!!!