

The European Commission's non-food Scientific Committees



DG SANCO - Health Information Unit





3 SCIENTIFIC COMMITTEES SCCS - SCHER - SCENIHR



The three independent non-food Scientific Committees ensure systematic assessment of risks, based on best practice for EU policy needs on health, consumers and environment.

Other EU risk assessment bodies are European Food Safety Authority (**EFSA**); the European Medicines Agency (**EMA**); the European Centre for Disease Prevention and Control (**ECDC**); and the European Chemicals Agency (**ECHA**)



Composition of the Scientific Committees



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- Scientists from academia, research or other scientific bodies, appointed by the EC in their personal capacity, following an open call. Scientists have to provide a declaration of commitment, a declaration of interests and a declaration of confidentiality
- Selection criteria: competence and independence. As far as possible, geographical and gender balance
- External experts may be invited to WG when special expertise is needed





Mandates

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- SCHER: advice on toxicity and eco-toxicity of chemical, biochemical and biological products, chemicals in toys, waste, environmental contaminants, drinking water quality, indoor and ambient air quality, endocrine disrupters
- **SCENIHR:** advice on emerging risks, newly identified risks, complex or multidisciplinary issues requiring comprehensive assessment, biology, chemistry, biophysics, medical devices nanotechnologies, issues not covered by other bodies
- SCCS: advice on risks related to consumer products (non-food) mostly on cosmetics but also on toys, textiles, clothing, household products, non-chemical risks (mechanical, physical, biological), consumer services (for example, tattooing, tanning devices)



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the items on the agenda. CVs and declarations are publicly available on the Scientific Committees website.

Due to the complexity of the requested opinions, an ad hoc working group is organized for each topic, recruiting some members of the committee and some external experts selected on the basis of their excellence, such as internationally recognized expertise and peer reviewed publications linked to the subject, and their independence.

The mandate of SCENIHR is to give advice to the European Commission on Emerging risks, Newly Identified Risks, broad, complex or multidisciplinary issues requiring comprehensive assessment and issues not covered by other bodies. This includes for example



SCENIHR Opinion on

Potential health effects of exposure to electromagnetic fields (EMF)

Theodoros Samaras Chair^{*}, EMF WG *since April 2013





WG Members

SCENIHR members:

Prof. Dr. Norbert Leitgeb Graz University of Technology, AU Dr. Theodoros Samaras University of Thessaloniki, GR

External experts (former SCENIHR):

Prof. Anssi Auvinen University of Tampere and STUK, FI Prof. Mats-Olof Mattsson Austrian Institute of Technology, AU Dr. Hannu Norppa Institute of Occupational Health, FI Dr. Joachim Schüz IARC, FR External experts:

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Health and Consumers



Background

- SCENIHR has a *standing mandate* on EMF issues.
- Previous opinion issued in 2009 was based on material available until September 2008. Since then, a sufficient number of new scientific publications have appeared to warrant a new analysis of the scientific evidence on possible effects on human health of exposure to EMF.
- The development of new technologies using EMF in the THz range called for new assessments.
- A meeting organized by the European Commission in Brussels under the auspices of the SCENIHR in November 2011 (the International Conference on EMF and Health) provided an overview of the most recent scientific developments in this area as a first preparation for a future scientific opinion.





Terms of Reference

- 1. To update the opinions of 2009 in the light of newly available information.
- 2. To give particular attention to issues affected by important gaps in knowledge in the previous opinions, especially:
 - the potential adverse effects of EMF on the nervous system, including neuro-behavioural disorders and on the risk of neo-plastic diseases;
 - the understanding of biophysical mechanisms that could explain observed biological effects and epidemiological associations; and
 - the potential role of co-exposures with other environmental stressors in biological effects attributed to EMF.





Terms of Reference (cont'd)

- 3. To review the scientific evidence available to understand the potential adverse health effects of EMF in the THz range.
- 4. To develop a set of prioritized research recommendations updating previous efforts in this area (in particular by the SCENIHR and the WHO). These recommendations should include methodological guidance on the experimental design and minimum requirements to ensure data quality and usability for risk assessment.





Considerations

- Primarily English language material published in international peerreviewed scientific journals
- Mainly publications published between 2009 and May 2013 (Extension to the publication cut-off date to 30 June 2014)
- Inclusion and evaluation criteria according to the SCENIHR Memorandum "Use of the scientific literature for risk assessment purposes – weight of evidence approach" plus criteria given in section 3.2 "Methodology"
- About 540 references cited in the preliminary opinion text (About 190 references added due to deadline extension)
- Additional papers were identified but not cited







- Extension to the publication cut-off date to 30 June 2014 ►
 About 190 new references were added to the already 540 ones
- A new section on interaction mechanisms added
- Conclusions remained almost unchanged



Weight of Evidence (1/2)

A weight of evidence approach is used to assess the scientific support for a specific outcome. This is based on data from human, animal and mechanistic studies (the primary evidence) along with exposure. For each line of evidence, the overall quality of the studies is taken into account, as well as the relevance of the studies for the issue in question. The weighting also considers if causality is shown or not in the relevant studies.



Weight of Evidence (2/2)

- Strong overall weight of evidence

Coherent evidence from human and one or more other lines of evidence (except for symptoms where only human evidence is available); no important data gaps

Moderate overall weight of evidence

Good evidence from a primary line of evidence (human experimental or epidemiological, animal and mechanistic studies together with exposure), but evidence from several other lines is missing (important data gaps)

Weak overall weight of evidence Weak evidence from primary lines of evidence, severe data gaps

- Discordant overall weight of evidence
 Conflicting information from different lines of evidence
- Weighing of evidence not possible
 No suitable evidence available





Received around 3000 comments with multiple points; they included mainly

- Criticism about procedures (e.g., members' CoI, composition of the WG, personal attacks, web form instead of in-paper comments, why an update and a not a thorough review since the stone-age, etc.)
- Criticism about literature included. It was clear that:
 - People disregarded study inclusion criteria, although they were described in Methodology.
 - The list of identified but not cited studies (because they were not useful for risk assessment) was missed by most people.
 - People did not realize this was an Opinion UPDATE.
- Literature published after the initial cut-off date, or in journals which are not peer-reviewed or was anecdotal/unpublished evidence.
- Hypothetical biophysical mechanisms of interaction.



Abstact

Executive summary

Scientific rationale

- **Exposure** to EMF
- Interaction mechanisms
- Health effects overview according to frequency bands
- Health effects overview according to special cases
- Research recommendations
- Guidance on research methods

Opinion





Scientific rationale

- **Exposure** to EMF \rightarrow
- Interaction mechani
- Health effects over
- Health effects over
- Research recomme
- Guidance on resear Trans

Opinion

Wireless communication technologies

- Industrial applications
- Medical applications
 - Security applications
- Power generation and transmission
- Transportation
 - Household appliances
 - THz technologies





Scientific rationale

- Exposure to EMF
- Interaction **mechanisms** \rightarrow
- Health el Established (per frequency range)
- Health ef Other
- Research recommendations
- Guidance on research methods

Opinion





Scientific rationale

- Exposure to EMF
- Interaction mechanisms
- Health effects overview according to frequency bands \rightarrow
- Health el THz technologies 0.3 20 THz
- Research Radiofrequency 100 kHz 300 GHz
- Guidance Intermediate frequency 300 Hz 100 kHz
 Extremely low frequency 1 300 Hz
- Opinion Static magnetic fields (0Hz)





Scientific rationale

- Exposure to EMF
- Interaction mechanisms
- Health effects overview according to frequency bands
- Health effects overview according to special cases
- Research Combined exposure to different EMF
- Guidance Co-exposure to other stressors
 - EMF effects on implanted medical devices

Opinion





For each section on health effects:

- All lines of evidence discussed (human, in vivo, in vitro)
- Primary conclusions on line of evidence and outcome level
- Where appropriate, special consideration (due to mandate) of
 - neoplastic diseases,
 - nervous system effects,
 - neurobehavioural disorders,
 - symptoms and other effects





Scientific rationale

- Exposure to EMF
- Interaction mechanisms
- Health effects overview according to frequency bands
- Health effects overview according to special cases
- Research recommendations
- Guidance on research methods

Opinion





Scientific rationale

- Exposure to EMF
- Interaction mechanisms
- Health effects overview according to frequency bands
- Health effects overview according to special cases
- Research recommendations
- Guidance on research methods

Opinion \rightarrow response to the terms of reference





1. To update its opinions of 2009 in the light of newly available information

In most of the sections of the Scientific Rationale in the current opinion, reports appearing in the literature after 2009, i.e., after the publication of the previous opinions, have been considered.

Therefore, the final opinion covered studies that were published between 2009 and June 30,2014.

However, certain sections of the "Scientific Rationale" were not covered in the previous opinions. In such cases, reports published before 2009 have also been taken into account for the risk assessment.





2. To give particular attention to issues affected by important gaps in knowledge in the previous opinions, especially:

2a. the potential adverse effects of EMF on the nervous system, including neurobehavioural disorders and on the risk of neo-plastic diseases

RF fields

Conclusions regarding:

- changes in the EEG
- symptoms
- neurological diseases and symptoms (incl. child development and behavioural problems)
- epidemiological studies and brain tumours
- in vivo studies and carcinogenesis
- in vitro studies pertaining both to genotoxic as well as non-genotoxic endpoints

IF fields

No definitive conclusions can be drawn

ELF fields

Conclusions regarding:

- waking EEG
- behavioural outcomes and cortical excitability
- neurodegenerative diseases
- symptoms
- childhood leukaemia



2a. the potential adverse effects of EMF on the nervous system, including neuro-behavioural disorders and on the risk of neo-plastic diseases;

RF fields

Previous studies suggesting that RF exposure may affect brain activities as reflected by changes in the EEG during wake and sleep are confirmed by results of more recent studies. However, given the variety of applied fields, duration of exposure, number of considered leads, and statistical methods it is difficult to derive firm conclusions. For event-related potentials and slow brain oscillations results are inconsistent. Likewise, studies on cognitive functions in humans lack consistency. The biological relevance of reported small physiological EEG changes remains unclear, and mechanistic explanation is still lacking.



EHS or

(officially)

IEI-EMF

2a. the potential adverse effects of EMF on the nervous synapping neuro-behavioural disorders and on the risk of neo-planeters and o

RF fields (cont'd)

A reasonable body of experimental evidence now suggests that exposure to RF does not trigger symptoms, at least in the short-term. While additional observational studies are required to assess whether longer-term exposure could be associated with symptoms, the evidence to date weighs against a causal effect.

Human studies on neurological diseases and symptoms show no clear effect, but the evidence is limited. Human studies on child development and behavioural problems suffer from conflicting results and methodological limitations. Therefore, the evidence of an effect is weak. Effects of exposure on foetuses from mother's mobile phone use during pregnancy are not plausible owing to extremely low foetal exposure.



2a. the potential adverse effects of EMF on the nervous symplectic neuro-behavioural disorders and on the risk of neo-planet

Mobile phones and cancer

RF fields (cont'd)

Overall, the epidemiological studies on RF EMF exposure do not show an increased risk of brain tumours. Furthermore, they do not indicate an increased risk for other cancers of the head and neck region. Some studies raised questions regarding an increased risk of glioma and acoustic neuroma in heavy users of mobile phones. The results of cohort and incidence time trend studies do not support an increased risk for glioma while the possibility of an association with acoustic neuroma remains open. Epidemiological studies do not indicate increased risk for other malignant diseases including childhood cancer.



2a. the potential adverse effects of EMF on the nervous system, including neuro-behavioural disorders and on the risk of neo-plastic diseases;

RF fields (cont'd)

A considerable number of well-performed in vivo studies using a wide variety of animal models have been mostly negative in outcome. These studies are considered to provide evidence for the absence of a carcinogenic effect.

A large number of in vitro studies pertaining to genotoxic as well as nongenotoxic end-points have been published since the last Opinion. In most of the studies, no effects of exposure at levels below exposure limits were recorded, although in some cases DNA strand breaks and spindle disturbances were observed.



2a. the potential adverse effects of EMF on the nervous system, including neuro-behavioural disorders and on the risk of neo-plastic diseases;

IF fields

This part of the frequency spectrum remains poorly investigated with respect to potential health effects resulting from exposure to EMF.



2a. the potential adverse effects of EMF on the nervous system, including neuro-behavioural disorders and on the risk of neo-plastic diseases;

ELF fields

Studies investigating possible effects of ELF MF exposure on the power spectra of the waking EEG of volunteers are too heterogeneous with regard to applied fields, duration of exposure, number of considered leads, and statistical methods to draw any sound conclusion. The same applies for the results concerning behavioural outcomes and cortical excitability.

Only a few new epidemiological studies on neurodegenerative diseases have been published since the previous Opinion. They do not provide support for the previous conclusion that ELF magnetic field exposure could increase the risk for Alzheimer's disease or any other neurodegenerative diseases or dementia. Animal studies that have suggested beneficial effects of streng magnetic fields require confirmation.

Powerlines and neurodegenerative diseases



EHS or

(officially)

IEI-EMF

and

childhood)

2a. the potential adverse effects of EMF on the nervous synapping neuro-behavioural disorders and on the risk of neo-place

ELF fields (cont'd)

The evidence with respect to self-reported symptoms is discordant. While most studies have not found an effect of exposure, two experimental studies have identified individual participants who may reliably react to magnetic fields. However, replication of these findings is essential before weight is given to these results.

The new epidemiological studies are consistent with earlier findings of an increased risk of childhood leukaemia with estimated daily average exposures above 0.3 to 0.4 μ T. As stated in the previous Opinions, no mechanisms have been identified and no support is existing from experimental studies that could explain these findings, which, together with shortcomings of the epidemiological studies prevent a causal interpretation.

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2. To give particular attention to issues affected by important gaps in knowledge in the previous opinions, especially:

2b. the understanding of biophysical mechanisms that could explain observed biological effects and epidemiological associations

Despite a number of studies continuing to report candidate mechanisms, particularly regarding effects on reactive oxygen species, lipid peroxidation and antioxidant defense, no mechanism that operates at levels of exposure found in the everyday environment has been firmly identified and experimentally validated. It is important to stress here the difficulties of demonstrating small changes in gene expression that may occur following in vivo exposure to EMF which are due to inherent variability of biological responses and the technical limitations in the sensitivity of existing technologies.





2. To give particular attention to issues affected by important gaps in knowledge in the previous opinions, especially:

2c. the potential role of co-exposures with other environmental stressors in biological effects attributed to EMF

The opinion of 2009 concluded that there was some evidence from in vivo studies to suggest that co-exposure with ELF fields may act as a cocarcinogen, while there was no evidence that RF fields could act in a similar way. The results reported since then indicate that exposure to ELF or RF can interact with several chemical or physical agents resulting in either an increase or a decrease in their effect. Nevertheless, due to the small number of available investigations and the large variety of protocols adopted (different chemical or physical treatments and different EMF exposure conditions), it is not possible to draw definitive conclusions. The effects lack consistency and are not linked to specific experimental conditions. Therefore, their relevance to human health under real life exposure conditions remains unclear.





3. To review the scientific evidence available to understand the potential adverse health effects of EMF in the THz range.

A risk assessment on health effects from THz exposures is difficult to perform since no suitable evidence is available. The number of studies investigating potential biological , non-thermal effects of THz fields is small, but has been increasing over the recent years, due to availability of reliable sources and detectors.

In vivo studies indicate mainly beneficial effects on disorders of intravascular components of microcirculation in rats under immobilization stress, but do not address acute and chronic toxicity or carcinogenesis. In vitro studies on mammalian cells differ greatly with respect to irradiation conditions and endpoints under investigation. Studies suggesting effects of exposure have not been replicated in independent laboratories. Some theoretical mechanisms have been proposed, but no conclusive experimental support is available.





4. To develop a set of prioritized research recommendations taking updating previous efforts in this area (in particular by the SCENIHR and the WHO). These recommendations should include methodological guidance on the experimental design and minimum requirements to ensure data quality and usability for risk assessment.

A set of prioritized research recommendations and methodological guidance on the experimental design and minimum requirements to ensure data quality and usability for risk assessment are provided in sections 3.13 and 3.14 of the opinion.





Research recommendations

- There is a research need for (preferably multicentre) neurophysiological studies in volunteers with pre-defined effect sizes, based on a priori considerations of power and sample size (type I and type II errors and adequate sample size for the statistical test(s) to be used) for data analysis according to a predefined analysis protocol.
- There are a few studies indicating that women are more affected than men, exposure effects vary with age, and that patient populations could be more affected than healthy subjects. Hence, proposed studies should cover a wide range of ages, look at data for females and males separately and, if possible, include patient populations, e.g. insomniacs in sleep studies or patients with neurological disorders including neurodegenerative diseases.





A BIG thank you to

the WG members, and Giulio, Silvia, Donata and all the Secretariat people for helping with this little cute 'monster' called 'EMF Opinion'...



Health and Consumers



Thank you for your attention!





- The Danish cohort study rules out risks that would affect large segments of the population. Evidence against an association also arises from the large-scale UK Million Women study with prospective exposure information.
- Case-control studies show associations for moderate mobile phone use, with decreased risk estimates in Interphone and increased risk estimates in the Hardell studies.
- The results of case-control studies are incompatible with the observed incidence rate time trends (ecological studies) demonstrating the vulnerability of case-control studies with self-reported mobile phone use to bias.
- However, the incidence time trends do not contradict a modest risk increase in heavy users because numbers of excess cases would remain too small to be detectable in the time period analysed.









- Case-case analysis of the highest exposed parts of the brain have not shown increased risk when exposure indices independent of self-reported use have been employed.
- The only study of mobile phone use and brain tumours in children did not show an increased risk, but more studies are needed especially for those starting to use mobile phones as children and their cancer risk later in life.
- IARC evaluated the epidemiological evidence for glioma and acoustic neuroma as limited and classified RF fields from mobile phones as a possible human carcinogen. However, based on studies published since that assessment, the evidence for glioma has become weaker.





- For meningioma, the evidence for increased risks of long-term heavy users is weaker than for glioma, but some case-control studies do show increased risks.
- For uveal melanoma, there is no evidence for any association, including heavy users.
- For salivary gland tumours and melanoma of the cheek or ear the evidence is somewhat controversial as for glioma but based on much fewer studies.





In vitro and mechanistic studies for neoplastic disease induction

- Most of the investigations reporting effects on the DNA refer to DNA migration, spindle disturbances and foci formation, which are indicators of non-fixed DNA damage, i.e., transient and repairable damage.
- Most of the studies reporting a lack of effects refer to chromosome aberration and micronuclei, which are indicators of fixed DNA damage, i.e., unrepairable damage.
- No new mechanism has been proposed. The radical pair mechanism has again been proposed but the constraints imposed by free radical lifetimes, spatial localization, relaxation processes, and hyperfine coupling constants (Sheppard et al. 2008) still remain valid.





Mobile phone and neurodevelopment

- The large Danish National Birth Cohort study has reported results that suggest higher prevalence of some behavioural and health disorders in children, but these have not been confirmed in other studies.
- The published studies have methodological weaknesses including information on mobile phone use during pregnancy obtained only years after the birth of the child. It is not even known whether frequency of mother's mobile phone use is at all relevant for foetal RF exposure in utero.
- Attention deficit disorders have a clear hereditary component and hence it is possible that the findings could be due to reverse causality, i.e., mother's mobile phone use reflecting her hyperactive features rather than phone use causing child's behavioural problems.





RF radiation and brain function

- Several endpoints are included under these brain function studies: macrostructure of sleep, power of the sleep EEG, resting state waking EEG, event-related potentials, slow brain potentials, cognition, as well as regional blood flow and oxygenation changes.
- Variable results have been reported because of different exposure conditions and set-ups, great number of investigated outcome measures, missing replication studies in a strict sense, different levels of control of the vigilance state, and varying statistical properties. Effects sizes are usually not reported.
- It is rarely stated that measures were taken to avoid interference between the recording system and the exposure when assessments are made during exposure. RF interference can lead to artefacts (Fouquet et al. 2013). Electrodes and cables of an EEG recording system change the RF field distribution (Murbach et al. 2014).





RF radiation and brain function

- Most of the recent studies have reported an effect of RF exposure on the spectral power of sleep and the waking resting state EEG. The relevance of the small physiological changes remains unclear and mechanistic explanation is still lacking.
- With regard to event-related potentials and slow brain oscillations, results are inconsistent.
- Overall there is a lack of evidence that RF affects cognitive function in humans. Studies looking at possible effects of RF fields on cognitive functions have often included multiple outcome measures. Where effects have been found by individual studies, these have typically only been observed in a small number of these outcomes, with little consistency between studies as to which exact outcomes are affected.





In vitro and in vivo studies of effects on the nervous system

- The few available in vitro studies are not providing data useful for assessment of possible effects on the nervous system function or on disease processes in the nervous system.
- A number of different end-points have been studied at various SAR levels in both mice and rats. Although some positive findings were noted, they are inconsistent and appear mostly at levels well above guideline values. There is however a need to replicate certain of the studies, and also to perform studies at more stringent conditions (exposure and dosimetry, blinding, controls).





RF radiation and health symptoms

- The provocation studies performed were of reasonably good quality, with double-blinding, randomisation and counterbalancing. These studies have not found convincing evidence of IEI-EMF. While it cannot be ruled out that some people experience symptoms as a result of exposure to RF, if this phenomenon exists at all, it appears to affect only a small minority of all those who *believe* that they are affected.
- Early observational studies that were suggestive of a link between RF and health symptoms suffered from substantial methodological weaknesses due to their reliance on self-reported measures of exposure and their often poor control of confounding variables. Studies which have used objective measures of exposure have typically found no association between exposure and symptoms. At present these studies suggest there is no causal link between exposure and symptoms.





RF radiation and reproduction

 The previous SCENIHR Opinion concluded that there were no adverse effects on reproduction and development from RF fields at non-thermal exposure levels. The inclusion of more recent human and animal data does not change that assessment. Therefore, it is concluded that there is strong overall weight of evidence against an effect of low level RF fields on reproduction or development.

