EUROPEAN COMMISSION
HEALTH & CONSUMER PROTECTION DIRECTORATE-GENERAL
Directorate C – Public Health and Risk Assessment

SCIENTIFIC COMMITTEE ON EMERGING AND NEWLY IDENTIFIED HEALTH RISKS (SCENIHR)

Preliminary Opinion on Possible Effects of Electromagnetic Fields (EMF) on Human Health

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by

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Recommendations:

1) This Preliminary Opinion is an inadequate basis for judgment and should be sent back to the Scientific Committee on Toxicity, Ecotoxicity and the Environment (CSTEE) for revisions. It is unreliable for updating the EU opinion on "Possible Effects of Electromagnetic Fields (EMF), Radiofrequency Fields (RF) and Microwave Radiation on Human Health".

2) The CSTEE should be directed to utilize a standard of evidence more appropriately directed toward judging the adequacy of the emerging science. In order to draw conclusions about whether changes in the ICNIRP public and occupational exposure standards are warranted, the standard of evidence should be consistent with identifying "**Possible Effects**" as the title of the report suggests (and the charge to the CSTEE indicates). Further, this standard of evidence would then be consistent with the EU Constitutional Principle on Health where "sufficient evidence to compel prudent public health caution" is the measure.

3) The Committee should be directed to avoid a scientific standard of evidence that, by definition, requires causal scientific evidence or certainty of effect that is demonstrated by absolute proof of risk and demonstration of a mechanism - to guide recommendations by SCENIHR on changes in ICNIRP standards.

Findings:

1) **The document is titled " Preliminary Opinion on <u>Possible</u> Effects of Electromagnetic Fields (EMF) on Human Health". Yet the entire analysis for each chapter, in the end, dismisses "possible effects" where they are reported in the scientific literature.**

2) **The report is deficient in its clarity about definitions used by the Committee. It is inconsistent in applying those definitions in the course of its analysis of new scientific papers, and the weight they should be given.**

Is the Committee charged with identifying **possible effects**, based on new, emerging science, as the report title specifics? If so, the standard of evidence for making final recommendations should be one that does not require proof of effect before acknowledging that one or a series of mutually-reinforcing lines of scientific evidence, while not causal, indicates possible effects? It clearly does not say the charge was to **confirm health risks.** Yet, nearly every conclusion is based on a higher standard of evidence than "possible effect" (See Section 4 below).

A further difficulty is that the report has conflicting definitions, as is what 'screen' is to be used to assess the science. Is it based on the definition "below those of established biological mechanisms or is it based on science that reports health effects at levels below the ICNIRP limits?

The Executive Summary states *"health effects might occur at exposure levels below those **of established biological mechanisms**"* (paragraph 1, page 4).

The Scientific Rationale states *"the current issue is the possibility that health effects occur at exposure levels below those where the **established mechanisms** play a role and in particular as effects of long term exposure at low level."*

The Committee Opinion states, *"In conclusion, no health effect has been consistently demonstrated **at exposure levels below ICNIRP-limits** established in 1998."* (Paragraph 1, page 5).

Is the threshold for a finding that health effects are possibly occurring at levels below where we have established biological mechanisms, or below the ICNIRP standards? They are not the same.

3) The report consistently ignores or dismisses published scientific studies that report positive findings at exposure levels below ICNIRP standards (and below levels where biological mechanisms are established).

A) The Cancer Epidemiology section on RF (Section 3.3.2.1) reports on acoustic neuromas. It states *"the data suggest that there may be an increased risk when the preferred side of the head of use is considered in the analysis. For 10+ years of use of mobile phones, the relative risk for acoustic neuroma at the preferred side of use was 1.8 (1.1-3.1*)."

The Committee Opinion from 2001 (Section 4, page 41, paragraph 4) states, *"The balance of epidemiological evidence indicates that mobile phone use of less than 10 years does not pose any increased risk of brain tumor or acoustic neuroma. For longer use, data are sparse and any conclusions are therefore uncertain. From the available data, however, it does appear that there is no increased risk for brain tumors in long-term users, with the exception of acoustic neuroma, for which there are some indications of an association."*

The series of papers reporting increased risk of acoustic neuroma should be adequate to cause the CSTEE to recommend changes in ICNIRP standards. Because the basis for judging the science is supposed to be "possible effects", and because there exists a body of published, peer-reviewed science reporting increased risk of acoustic neuroma from multiple authors (Hardell et al. 2006a; Lonn et al. 2004; Schoemaker et al. 2005; Inskip et al. 2001; Muscat et al. 2002) the CSTEE authors have erred in dismissing this evidence, and not recommending changes in ICNIRP standards as a result. In fact, only one investigation (Christensen et al. 2004) reported no increased risk for the longest period of mobile phone use. However, the study was based on only 5 cases. But even including this study into the body of evidence there is overall a significantly increased risk that further increases substantially if restricted to ipsilateral exposures. Furthermore, if studies are excluded that cover latencies too short to provide a basis for risk assessment, then the combined evidence from the remaining 5 studies (Hardell et al. 2006; Schuez et al. 2006; Hepworth et al. 2006; Christensen et al. 2005; Auvinen et al. 2002) strongly indicates an increased risk of glioma associated with the longest exposure duration. They demonstrate an increased risk for longest exposure duration and the combined estimate for all 7 studies significantly exceeds unity.

Instead, the authors say they "*must await results of the whole Interphone dataset before drawing conclusions"* (page 15, paragraph 4). This creates an arbitrary limit, which is inconsistent with the Committee's requirement to report back on "possible effects". This is particularly egregious since the CSTEE authors then go on to indicate doubts that the Interphone Study will resolve anything at all (Page 16, paragraph 2). The section indicates confusion on the part of the authors as to their charge, vacillation on the basis for judging the need for changes in the current ICNIRP standards, and obvious bias in ignoring and/or dismissing scientific evidence which they were required to assess.

B) Section 3.3.2.3 on heat-shock proteins is grossly incomplete. The report makes no mention of a body of scientific evidence that is vital for inclusion (Blank et al, 1994; Goodman et al, 1994; Goodman and Blank, 1998, 2002; Blank and Goodman, 2000, dePomerai et al, 2000; Kwee et al, 2001; Leszczynski, 2002; Shallom et al, 2002; Weisbrot et al, 2003; Blank and Goodman, 2004). The latest laboratory research points to serious inadequacies in the safety standards recommended by ICNIRP and IEEE committees. In particular, stimulation of the stress response by ELF and RF frequencies indicate the following:

- EM fields probably cause molecular (e.g., DNA) damage in both frequency ranges.

- protective biological processes are activated in cells by non-thermal mechanisms.

- the same cellular processes are evoked by many parts of the EM spectrum. The measured ELF thresholds to EM fields are low, both in terms of field strength and exposure duration, and there is great variability in the sensitivity of biological systems. Physiological systems have many protective mechanisms that tend to mitigate the potentially harmful effects of the EM fields, but cannot always cope. Because of the wide range of biological systems affected, the wide range of frequencies that are biologically active, the low response thresholds and the possibility of cumulative effects by repetitive stimulation, the exposure standards should be revised to take into account: a) the importance of non-thermal mechanisms in assessing risk, b) total cumulative exposure across the different divisions of the EM spectrum, c) the increasing EM field background due to proliferation of electronic devices and d) the most sensitive populations.

The treatment of genotoxicity papers is inconsistent and unnecessarily exclusionary (page 21). The section was particularly dismissive of the REFLEX Project findings (Diem et al, 2005; Nicolova et al, 2005). The accumulated evidence for both ELF and RF genotoxicity is substantial, but not provided here. This report is supposed to highlight major new research initiatives that confirm findings of previous investigators related to genotoxicity. Instead, there is a weak and ambiguous discussion, which excludes any real overview of the accumulated literature. The positive effects reported from the REFLEX Program are merely "handled" in the report by saying *"recent results suggesting genotoxic effects need to be better understood."*

4) Criteria for Judging Scientific Evidence is Flawed

This report is not useful for the purpose intended due to the ambiguous basis for judging the sufficiency of the scientific evidence, which forms the basis for concluding whether changes in the ICNIRP standards are warranted, The lack of a clear statement about the basis for judging what constitutes sufficient evidence of "Possible Effects", and the up-shifting language used by the authors as a basis for their conclusions, renders this report in need of major revision.

The evaluative language quoted below indicates the disparity between what was asked of the authors (to identify Possible Effects of EMF) and what they eventually chose to use as a basis for their recommendation that no change in the ICNIRP standards is warranted at this time.

"failed to provide consistent support for" (page 4)

"For long-term use, data are sparse, and the following conclusions are therefore uncertain and tentative" (page 4).

"no consistent indication" (page 4)

"no health effect has been consistently demonstrated" (page 5)

"but the data base for this evaluation is limited, especially for long-term low-level exposure" (page 5

"the link remains uncertain" (page 5)

> "has not provided any consistent proof" (page 23)
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> " a relationship has not been proven" (page 24)
>
> "do not show any clear neurotoxic effect" (page 25)
>
> "although some positive findings have been reported, no specific type of malformation or other adverse outcome has been consistently reported" (page 26)
>
> "no health effect has consistently been demonstrated" (page 27)
>
> " no consistent indication from in vitro research that RF fields affect cells at the nonthermal exposure level" (page 42)
>
> "no health effect has been consistently demonstrated at exposure levels below the ICNIRP-limits established in 1998" (page 42)
>
> "there is no convincing suggestion of any other carcinogenic effect of ELF" (page 42)
>
> "reports require confirmation" (page 42)
>
> "a relationship has not been demonstrated" (page 43)

All the terms used for the evaluation of evidence are subjective. There is no definition of what constitutes 'sufficient', 'convincing' evidence or what is considered as 'consistent indication' or 'consistent proof'. With such ambiguous and subjective terms any result can be dismissed and any conclusion justified.

These are all statements that ignore positive evidence in an effort to justify recommending no action be taken. These statements are inconsistent with a review that reports on "Possible Effects". Some statements acknowledge important new evidence of effect; yet then shift the burden of proof to a higher level requiring that adverse health effect or physical evidence of harm be demonstrated. There is nothing in the report that says the authors were directed to provide proof of effect (or consistent indications, or consistent demonstration of effect; or consistent support for, or certainty of effects) at levels below ICNIRP limits. With the same attitude as demonstrated by the SCENIHR hardly any environmental or occupational condition would be qualified as a health hazard.