

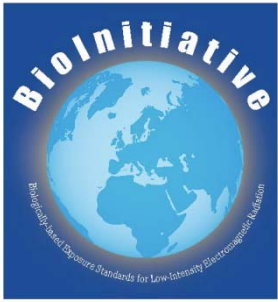


Conclusions of the BioInitiative Report

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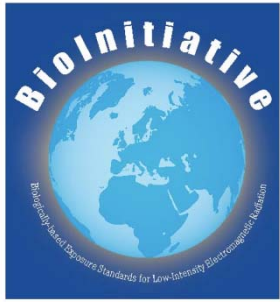
BioInitiative Organizing Committee



Preamble

“...it is impossible to derive...a proposal for a policy from a sentence stating a fact.”

K.R.Popper, *The Open Society and its Enemies*” Vol.1, Ch.5



WHO vs. WHO

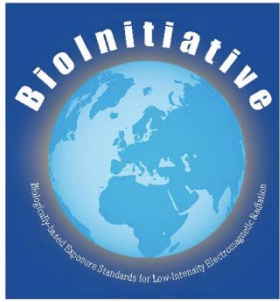
“Scientific **judgement and consensus** play an important role in establishing guidance that can be used to indicate acceptable levels of population exposure. **Value judgements are needed** and the use of **subjective terms** such as ‘adverse effects’ and ‘sufficient evidence’ is unavoidable.”

WHO Air Quality Guidelines for Europe, 2000

“However, it is **not recommended** that the limit values in **exposure guidelines be reduced** to some arbitrary level in the name of precaution. Such practice **undermines the scientific foundation** on which the **limits are based...**”
(p.12)

“If precautionary measures are considered to complement the standards, they should be applied in such a way that they do **not undermine the science-based guidelines.**” (p.367)

WHO Environmental Health Criteria 238, Extremely Low Frequency Fields, 2007



Procedure to Arrive at Policy Recommendations

Meta level 2

Recommendations for Risk Management

Level of Protection / of Proof ...

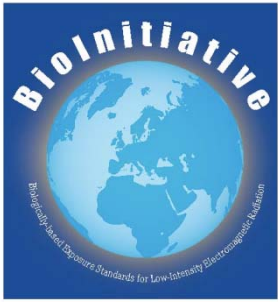
Meta level 1

Risk Assessment

**Evaluation and Interpretation of Evidence
Identification of Gaps**

Original Scientific Investigations

Epidemiologic / Animal / Provocation / In vitro Studies



Overview

- Chronic effects of extremely low frequency EMF
 - Childhood leukaemia
 - Breast cancer
- Chronic effects of radio frequency fields
 - Brain tumours



ELF & Childhood Leukaemia

- After publication of the Wertheimer & Leeper study in 1979 immediate claims of results being due to

“unlikely due to chance” IARC 2001

- Chance

“result in bias towards the null”
IARC 2001

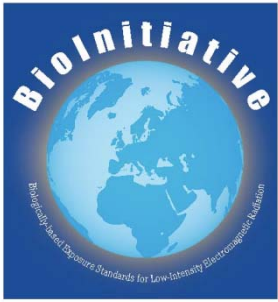
- Misclassification bias

- Other sources of bias

may account for part but not all of the
increased risk (Schüz et al. 2001)

- Confounding

“Bias due to unknown confounding factors is
very unlikely” IARC 2001

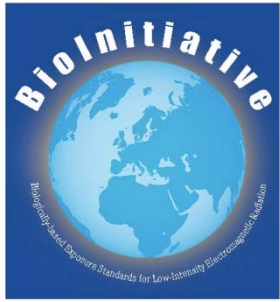


Evaluation by IARC 2001

Extremely low-frequency magnetic fields are *possibly carcinogenic to humans (Group 2B)*.

based on

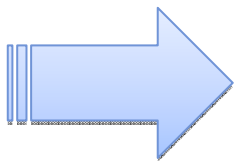
limited evidence in humans for the carcinogenicity of extremely lowfrequency magnetic fields in relation to childhood leukaemia



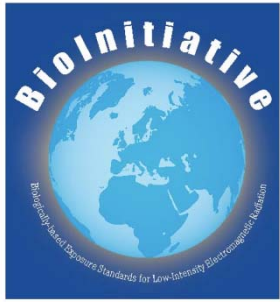
Response by the WHO EMF Program

However, two recent pooled analyses of epidemiological studies provide insight into the epidemiological evidence that played a pivotal role in the IARC evaluation. These studies suggest that, in a population exposed to **average** magnetic fields in excess of 0.3 to 0.4 μT , twice as many children might develop leukaemia compared to a population with lower exposures. **In spite of the large number data base, some uncertainty remains as to whether magnetic field exposure or some other factor(s) might have accounted for the increased leukaemia incidence.**

This statement is scientifically flawed! It is nothing else than an **immunisation strategy**.



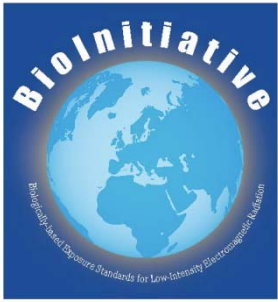
There is no finite series of empirical tests to falsify such a statement!



The WHO EHC 238

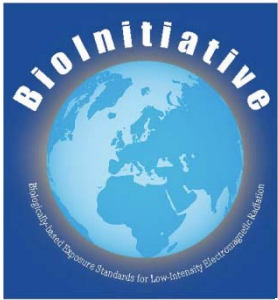
Scientific evidence suggesting that everyday, chronic low-intensity (above 0.3–0.4 μT) power-frequency magnetic field exposure poses a health risk is based on epidemiological studies demonstrating a consistent pattern of increased risk for childhood leukaemia. Uncertainties in the hazard assessment include the role that control **selection bias** and **exposure misclassification** might have on the observed relationship between magnetic fields and childhood leukaemia. In addition, **virtually all of the laboratory evidence and the mechanistic evidence fail to support a relationship between low-level ELF magnetic fields and changes in biological function or disease status**. Thus, on balance, the evidence is not strong enough to be considered causal, but sufficiently strong to remain a concern.

Selection and misclassification bias have been studied and the evidence suggests that these biases cannot fully account for the increased risk!

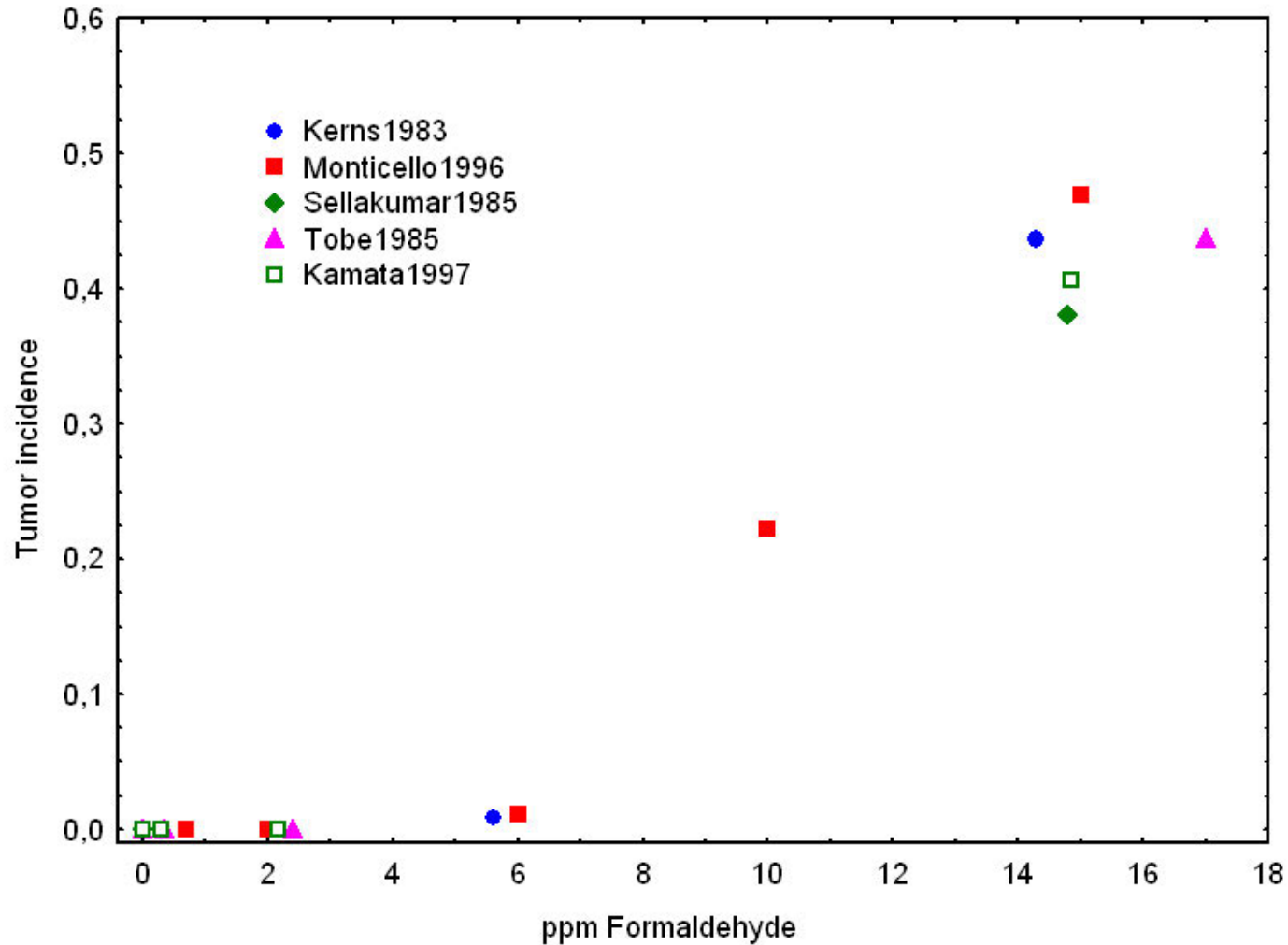


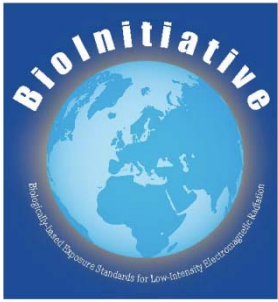
Why is there only weak support from animal studies

- There is no animal model for ALL, the most frequent childhood leukaemia
- Long-term animal carcinogenicity studies are typically done close to the acute toxicity level at exposures 100 to 1000 times higher than occurring in occupational or environmental settings
- Such high exposures would result in nerve and muscle excitations making it impossible to compare results to human exposures



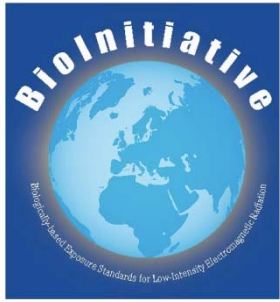
Example: Formaldehyde





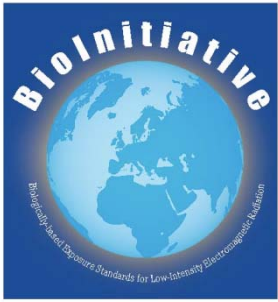
WHO EHC 238 conclusions about ELF & childhood leukaemia

- Scientific evidence suggesting that everyday, chronic low-intensity (above 0.3–0.4 μT) power-frequency magnetic field exposure poses a health risk is based on **epidemiological studies demonstrating a consistent pattern of increased risk for childhood leukaemia.**
- ...virtually all of the laboratory evidence and the mechanistic evidence **fail to support a relationship between low-level ELF magnetic fields** and changes in biological function or disease status.
- Thus, on balance, the **evidence is not strong enough to be considered causal**, but sufficiently strong to remain a concern.
- **Assuming that the association is causal**, the number of cases of childhood leukaemia worldwide that might be attributable to exposure can be estimated to range from **100 to 2400 cases per year.**
- Provided that the health, social and economic benefits of electric power are not compromised, implementing **very low-cost precautionary procedures** to reduce exposure is reasonable and warranted.



BioInitiative conclusions about ELF & childhood leukaemia

- The balance of evidence suggests that **childhood leukemia is associated with exposure to power frequency EMFs** either during early life or pregnancy.
- Considering only average MF flux densities the population attributable risk is low to moderate, however, there is a possibility that other exposure metrics are much stronger related to childhood leukemia and may account for a substantial proportion of cases. ...**Up to 80% of childhood leukemia cases may be caused by exposure to power frequency EMF.**
- Other childhood cancers except leukemia have not been studied in sufficient detail to allow conclusions about the existence and magnitude of the risk.
- International guidelines (ICNIRP, IEEE) are designed to protect from short-term immediate effects, **long-term effects such as cancer are evoked by levels several orders of magnitudes below current guideline levels.**
- **Precautionary measures are warranted that should reduce all aspects of exposure,** because at present we have no clear understanding of the etiologically relevant aspect of the exposure.



Conclusions about ELF and breast cancer

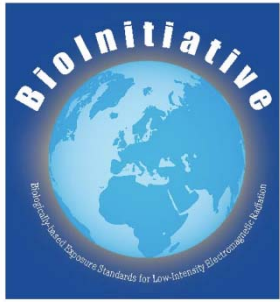
WHO EHC 238:

Subsequent to the IARC monograph a number of reports have been published concerning the risk of female breast cancer in adults associated with ELF magnetic field exposure. These studies are larger than the previous ones and less susceptible to bias, and overall are negative. With these studies, the evidence for an association between ELF magnetic field exposure and the risk of female breast cancer is weakened considerably and does not support an association of this kind.

BioInitiative 2007:

Studies of human breast cancer cells and some animal studies show that **ELF is likely to be a risk factor for breast cancer**. There is supporting evidence for a link between breast cancer and exposure to ELF that comes from cell and animal studies, as well as studies of human breast cancers.

Given the very high lifetime risks for developing breast cancer, and the critical importance of prevention; ELF exposures should be reduced for all people who are in high ELF environments for prolonged periods of time.



Mobile phone use & brain tumours

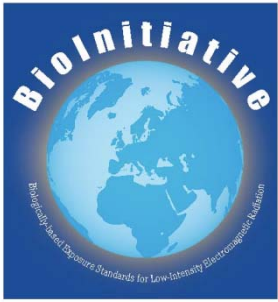
SCENIHR 2008:

Radio frequency fields (RF fields)

It is concluded from three independent lines of evidence (epidemiological, animal and in vitro studies) that exposure to RF fields is unlikely to lead to an increase in cancer in humans. However, as the widespread duration of exposure of humans to RF fields from mobile phones is shorter than the induction time of some cancers, further studies are required to identify whether considerably longer-term (well beyond ten years) human exposure to such phones might pose some cancer risk.

BioInitiative 2007:

In summary we conclude that **there is a consistent pattern of an increased risk for acoustic neuroma and glioma** after > 10 years mobile phone use. We conclude that current standards for exposure to microwaves during mobile phone use are not safe for long-term brain tumor risk and need to be revised.



Closing Remarks

- The BioInitiative conclusions are at odds with the conclusions of most other reviewing groups
- The reasons for this divergence are differences in the risk evaluation process and the approach to arrive at recommendations for risk management
- Whether to follow the recommendations of the BioInitiative or some other is a matter of
 - rationality of argumentation
 - and trust!

This paper was produced for a meeting organized by Health & Consumer Protection DG and represents the views of its author on the subject. These views have not been adopted or in any way approved by the Commission and should not be relied upon as a statement of the Commission's or Health & Consumer Protection DG's views. The European Commission does not guarantee the accuracy of the data included in this paper, nor does it accept responsibility for any use made thereof.