

The BioInitiative Report –  
comments from an  
epidemiologist

Mark Elwood

# The BioInitiative Report (2007)



***BioInitiative Report:  
A Rationale for a Biologically-based Public Exposure  
Standard for Electromagnetic Fields (ELF and RF)***



### **Organizing Committee: (4)**

Carl Blackman, USA

Martin Blank, USA

Michael Kundi, Austria

Cindy Sage, USA

### **Participants: (9)**

David Carpenter, USA

Zoreh Davanipour, USA

David Gee, Denmark

Lennart Hardell, Sweden

Olle Johansson, Sweden

Henry Lai, USA

Kjell Hansson Mild, Sweden

Eugene Sobel, USA

Zhengping Xu and Guangdin Chen, China

### **Research Associate**

S. Amy Sage, USA



# 17 Sections

- C.Sage: 6 sole, 1 joint
- H. Lai: 2 sole
- M. Kundi: 1 sole, 1 joint
- 8 Others: 1 sole or joint



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**This report has been written by 14 (fourteen) scientists, public health and public policy experts to document the scientific evidence on electromagnetic fields. Another dozen outside reviewers have looked at and refined the Report.**

**The purpose of this report is to assess scientific evidence on health impacts from electromagnetic radiation below current public exposure limits and evaluate what changes in these limits are warranted now to reduce possible public health risks in the future.**

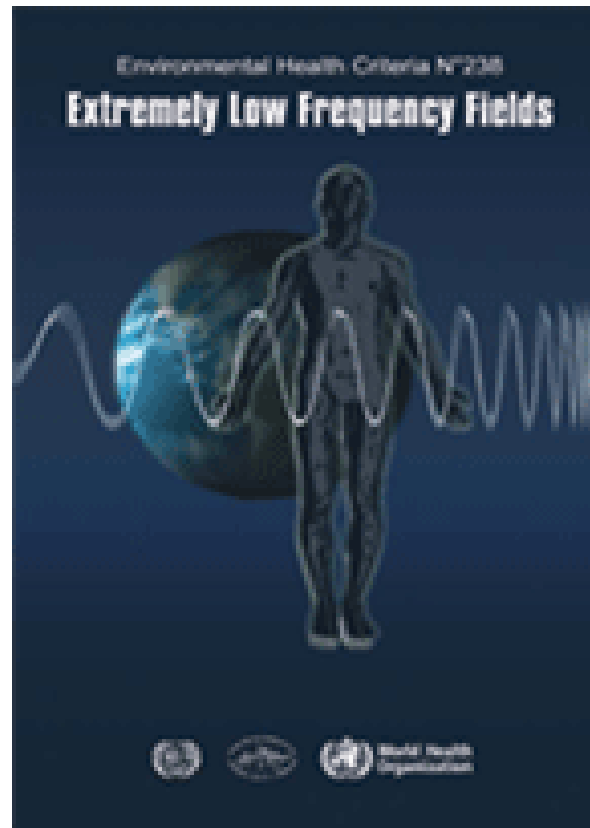
**Not everything is known yet about this subject; but what is clear is that the existing public safety standards limiting these radiation levels in nearly every country of the world look to be thousands of times too lenient. Changes are needed.**

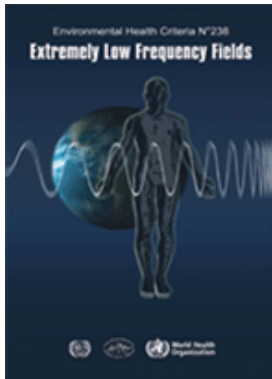
**New approaches are needed to educate decision-makers and the public about sources of exposure and to find alternatives that do not pose the same level of possible health risks, while there is still time to make changes.**



- Choice of authors – based on conclusions?
- Separate chapters or a consensus?
- Other peer review?
- Conflict of interest?

# World Health Organization Environmental Health Criteria 238 (2007)

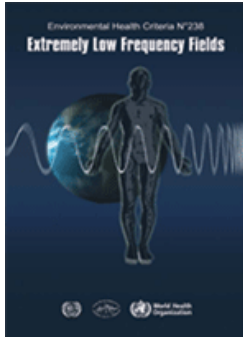




In the evaluation of human health risks, sound human data, whenever available, are generally more informative than animal data. Animal and in vitro studies provide support and are used mainly to supply evidence missing from human studies.

All studies, with either positive or negative effects, need to be evaluated and judged on their own merit, and then all together in a weight of evidence approach. It is important to determine how much a set of evidence changes the probability that exposure causes an outcome. Generally, studies must be replicated or be in agreement with similar studies. The evidence for an effect is further strengthened if the results from different types of studies (epidemiology and laboratory) point to the same conclusion.





A first draft prepared by consultants or staff from a RAD Collaborating Centre is based initially on data provided from reference databases such as Medline and PubMed and on IARC and ICNIRP reviews.

The draft document... may require an initial review by a small panel of experts to determine its scientific quality and objectivity.

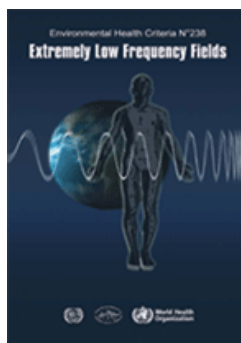
Once the document is acceptable as a first draft, it is distributed, in its unedited form, to well over 150 EHC contact points throughout the world who are asked to comment on its completeness and accuracy and, where necessary, provide additional material.

The contact points, usually designated by governments, may be Collaborating Centres, or individual scientists known for their particular expertise.

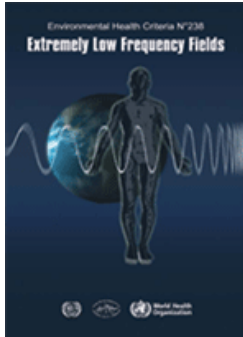
A second draft incorporating comments received and approved by the Coordinator (RAD), is then distributed to Task Group members, who carry out the peer review, at least six weeks before their meeting

The Task Group members serve as individual scientists, not as representatives of their organization.

The composition of the Task Group is dictated by the range of expertise required for the subject of the meeting (epidemiology, biological and physical sciences, medicine and public health) and by the need for a balance in the range of opinions on the science, gender and geographical distribution.



All individuals who as authors, consultants or advisers participate in the preparation of the EHC monograph must, in addition to serving in their personal capacity as scientists, inform WHO if at any time a conflict of interest, whether actual or potential, could be perceived in their work. They are required to sign a conflict of interest statement. Such a procedure ensures the transparency and probity of the process.



The World Health Organization recognizes the important role played by non-governmental organizations (NGOs).

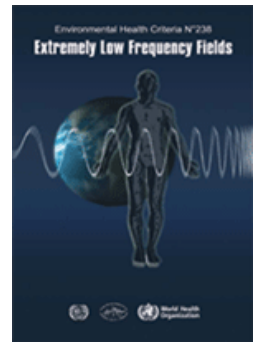
Representatives from relevant national and international associations may be invited to join the Task Group as observers.

While observers may provide a valuable contribution to the process, they can only speak at the invitation of the Chairperson.

Observers do not participate in the final evaluation; this is the sole responsibility of the Task Group members. When the Task Group considers it to be appropriate, it may meet *in camera*.

# Task Group on ELF electric and magnetic fields, Geneva, 3–7 October, 2005

*Members (20)*



Prof. Anders Ahlbom, Institute of Environmental Medicine, Karolinska  
Institute, Stockholm, Sweden

Dr Larry Anderson, Battelle Pacific Northwest National Laboratory, Richland,  
WA, **USA**

Dr Christoffer Johansen, Institute of Cancer Epidemiology, Copenhagen,  
Denmark

Dr Jukka Juutilainen, University of Kuopio, Kuopio, Finland

Dr Michinori Kabuto, National Institute for Environmental Studies, Tsukuba,  
Ibariki, Japan

Mrs Shaiela Kandel, Soreq Nuclear Research Center, Yavne, Israel

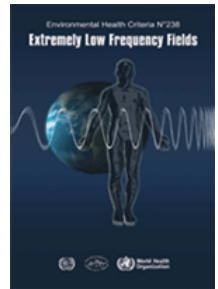
Prof. Leeka Kheifets, UCLA School of Public Health, Los Angeles, CA, **USA**

Dr Isabelle Lagroye, National Graduate School of Chemistry and Physics of  
Bordeaux (ENSCP), Pessac, France

Dipl-Ing Rüdiger Matthes, Federal Office for Radiation Protection,  
Oberschleissheim, Germany

# Task Group on ELF electric and magnetic fields, Geneva, 3–7 October, 2005

*Members (20)*



Prof. Jim Metcalfe, University of Cambridge, Cambridge, United Kingdom

Prof. Meike Mevissen, Institut für Tiergenetik, Bern, Switzerland

Prof. Junji Miyakoshi, Hirosaki University, Hirosaki, Japan

Dr Alastair McKinlay, Health Protection Agency, Chilton, United Kingdom

Dr Shengli Niu, International Labour Organization, Geneva, Switzerland

Dr Chris Portier, National Institute of Environmental Health Sciences,  
Research Triangle Park, NC, **USA**

Dr Eric van Rongen, Health Council of the Netherlands, The Hague, The  
Netherlands

Dr Nina Rubtsova, RAMS Institute of Occupational Health, Moscow, Russian  
Federation

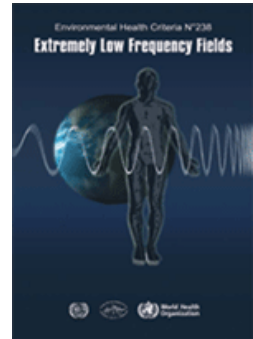
Dr Paolo Vecchia, National Institute of Health, Rome, Italy

Prof. Barney de Villiers, University of Stellenbosch, Cape Town, South  
Africa

Prof. Andrew Wood, Swinburne University of Technology, Melbourne, Australia

Prof. Zhengping Xu, Zhejiang University School of Medicine, Hangzhou,  
China

## Task Group on ELF electric and magnetic fields, Geneva, 3–7 October, 2005



### *Observers*

Mr Kazuhiko Chikamoto, Japan NUS Co., Minato-Ku, Tokyo, Japan

Dr Robert Kavet, Electric Power Research Institute, Palo Alto, CA, **USA**

Prof. Hamilton Moss de Souza, CEPEL - Electrical Energy Research Center, Adrianópolis, Brazil

Dr Michel Plante, Hydro-Québec, Montreal, **Canada**

Dr Martine Souques, EDF Gaz de France, Paris, France

Dr John Swanson, National Grid Transco, London, UK

### *WHO Secretariat*

Dr Houssain Abouzaid, WHO – Regional Office for the Eastern Mediterranean (EMRO), Nasr City, Cairo, Egypt

Dr Emilie van Deventer, WHO, Geneva, Switzerland

Dr Chiyoji Ohkubo, WHO, Geneva, Switzerland

Dr Michael Repacholi, WHO, Geneva, Switzerland

Dr Rick Saunders, c/o WHO, Health Protection Agency, Chilton, United Kingdom



# Challenges to existing guidelines

Other scientific review bodies and agencies have reached different conclusions than we have by adopting standards of evidence so unreasonably high as to exclude any conclusions likely to lead to new public safety limits.



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Why is this happening? One reason is that exposure limits for ELF and RF **are developed by bodies of scientists and engineers that belong to professional societies who have traditionally developed recommendations**; and then government agencies have adopted those recommendations.

The standard-setting processes have little, if any, input from other stakeholders **outside professional engineering and closely-related commercial interests**. Often, the industry view of allowable risk and proof of harm is most influential, rather than what public health experts would determine is acceptable.





# Challenges to existing guidelines

- Previous standards of evidence do not lead to the conclusion we favour – change the standards
- Claim of little involvement other than of engineers and industry in standards / guidelines setting processes



## **SUMMARY OF THE SCIENCE**

### **A. Evidence for Cancer**

#### *1. Childhood Leukemia*

The evidence that power lines and other sources of ELF are consistently associated with higher rates of childhood leukemia has resulted in the International Agency for Cancer Research (an arm of the World Health Organization) to classify ELF as a Possible Human Carcinogen (in the Group 2B carcinogen list). Leukemia is the most common type of cancer in children.



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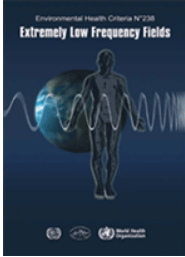
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**There is little doubt that exposure to ELF causes childhood leukemia.**

‘possible carcinogen” and

“little doubt that exposure to ELF causes”

are not equivalent



### *Chronic effects*

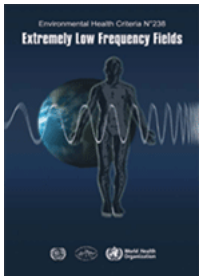
Scientific evidence suggesting that everyday, chronic low-intensity (above 0.3–0.4  $\mu\text{T}$ ) power-frequency magnetic field exposure poses a health risk is based on epidemiological studies demonstrating a consistent pattern of increased risk for childhood leukaemia.

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.



**There is little doubt that exposure to ELF causes childhood leukemia.**



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Other childhood cancers have been studied, including brain tumors, but not enough work has been done to know if there are risks, how high these risks might be or what exposure levels might be associated with increased risks. The lack of certainty about other childhood cancers should not be taken to signal the “all clear”; rather it is a lack of study.

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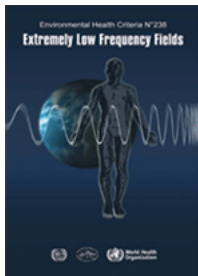
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**There is some evidence that other childhood cancers may be related to ELF exposure but not enough studies have been done.**

The assumption is that more studies will give stronger evidence.....



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the evidence for other childhood cancers remains inadequate.



## **ELF Magnetic Field EXPOSURE and MELATONIN PRODUCTION**

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1. Are there only 13 studies?
2. Do 11 of them provide positive evidence?



## **ELF Magnetic Field EXPOSURE and MELATONIN PRODUCTION**

*Conclusion: Eleven (11) of the 13 published epidemiologic residential and occupational studies are considered to provide (positive) evidence that high MF exposure can result in decreased melatonin production.*

*One positive study showing that high MF exposure reduces melatonin is this one:*

### **Effects of Electric and Magnetic Fields from High-power Lines on Female Urinary Excretion of 6-Sulfatoxymelatonin**

Patrick Levallois,<sup>1,2</sup> Marie Dumont,<sup>3</sup> Yvan Touitou,<sup>4</sup> Suzanne Gingras,<sup>1</sup> Benoît Masse,<sup>5</sup> Denis Gauvin,<sup>1</sup> Edeltraut Kröger,<sup>1</sup> Michel Bourdages,<sup>6</sup> and Pierre Douville<sup>7</sup>

***Am J Epidemiol* 2001;154:601–9.**



*From the published summary:*

In 1998, the authors studied the effect of residential exposure to electric and magnetic fields from high-power lines on female urinary excretion of 6-sulfatoxymelatonin (6-OHMS) in the Quebec city, Canada, metropolitan area.

A sample of 221 women living near a 735-kV line was compared with 195 women the same age living away from any power lines.

Participants provided morning urine samples on 2 consecutive days and wore a magnetic dosimeter for 36 consecutive hours to measure personal magnetic exposure. The indoor electric field was assessed by spot measurements.



*From the published summary:*

After adjustment for other factors associated with low melatonin secretion, such as medication use or light exposure,

**nighttime concentration of 6-OHMS [*melatonin*] was similar in the two groups** [*those living near a 735 kV powerline and those living far away*]

When either 24-hour or sleep-time exposure to magnetic field or electric field measurements was used, **no exposure-effect relation was evident.**



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But, unanticipated subgroup effect: if closer to lines, greater decrease with age, and lower levels in more obese women

## ***So: is this a 'positive' study ?***

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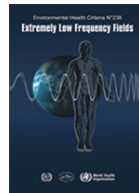
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But, unanticipated subgroup effect: if closer to lines, greater decrease with age, and lower levels in more obese women



There is strong evidence from epidemiologic studies that high ( $\geq 10$  milligauss or mG)\*, longterm exposure to extremely low frequency (ELF,  $\leq 60$  Hz) magnetic fields (MF) is associated with a decrease in melatonin production



The results of volunteer studies as well as residential and occupational studies suggests that the neuroendocrine system is not adversely affected by exposure to power-frequency electric and/or magnetic fields. This applies particularly to the circulating levels of specific hormones of the neuroendocrine system, including melatonin,



# Childhood leukemia

- Chapter by Martin Kundi, Institute of Environmental Health, Univ Vienna



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*On confounding:*

It is virtually impossible that such a risk factor has not yet been detected.

Therefore, confounding alone as an explanation for the relationship with leukemia can practically be ruled out.



# Childhood leukemia

*On measurement error:*

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.



# Childhood leukemia

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**Up to 80% of childhood leukemia may be caused by exposure to power frequency EMF.**

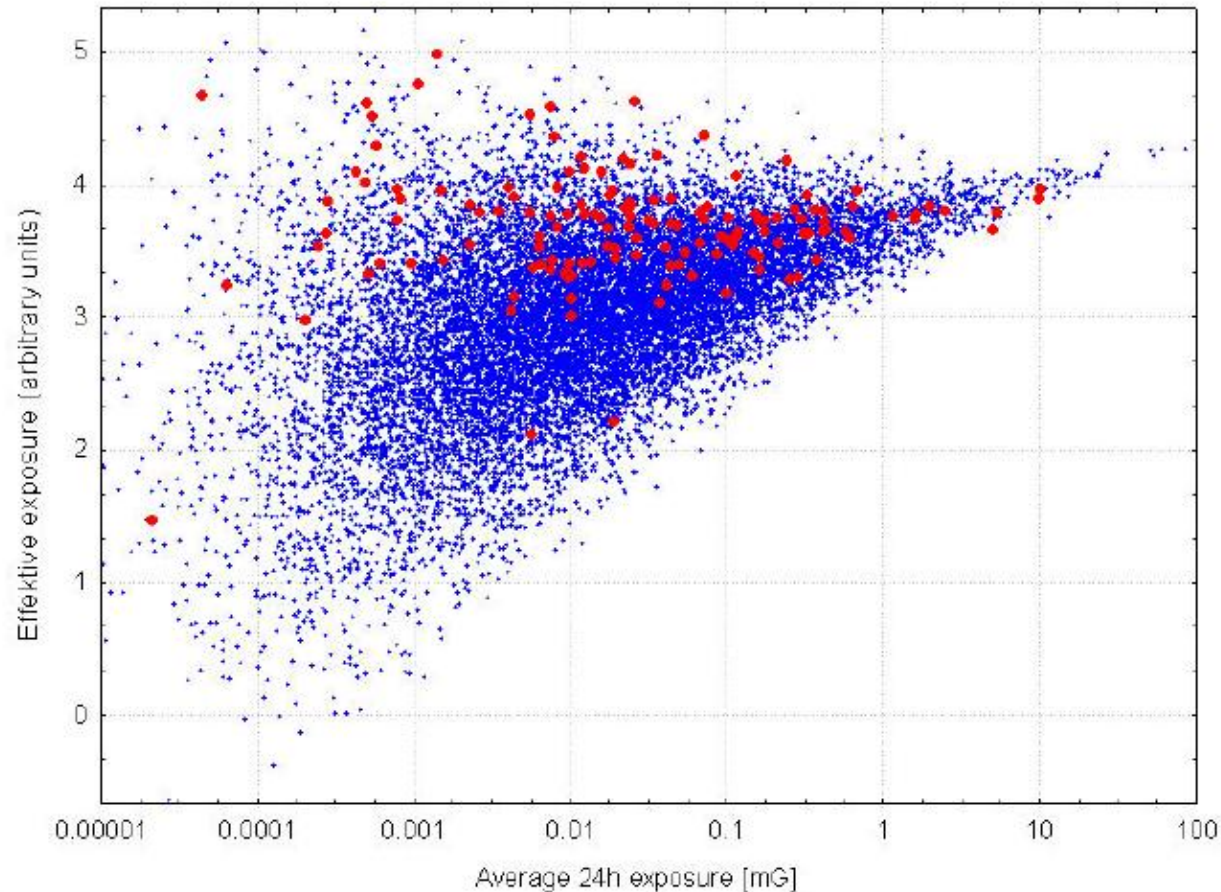


Fig. 1: Results of Monte Carlo simulation under the assumption of a log-normal distribution of average magnetic flux densities in the homes of children that are related to an assumed 'effective' exposure metric that follows the conditions a. and b. mentioned in the text. Blue are controls and red children with leukemia. The purported 'effective' exposure metric is associated with an attributable fraction of 80% and the odds-ratio for the highest quartile is around 50.





# childhood leukemia

- the association with childhood leukaemia is causal (not confounding)
- If we assume that the biologically relevant 'true' exposure is only weakly related to measured average magnetic fields, and risk increases much more steeply with this 'true' exposure, the relative risk is not about 2, but may be about 50
- and if we assume there is no lower limit of hazard
- and if we use 'worst-case' assumptions
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## **Residential Case-Control Studies of MF Exposure as a Risk Factor for Breast Cancer**

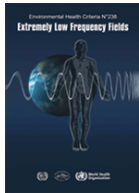
For these reasons, these studies are not relevant to the purposes of this review.



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The few studies investigating the association between ELF exposure and Alzheimer disease are inconsistent. However, the higher quality studies that focused on Alzheimer morbidity rather than mortality do not indicate an association. Altogether, the evidence for an association between ELF exposure and Alzheimer disease is inadequate.

# Alzheimer's disease studies, study and relative risk

## *Biolnitiative and WHO*

- 3 case-control (S85, S86, F98), 1 cohort (Q04)  
3.0, 3.9, 0.9 2.3M, 1.0F

## *Biolnitiative only:*

- 3 c-c (G99, H03, D07)  
0.7, 4.0, 2.1

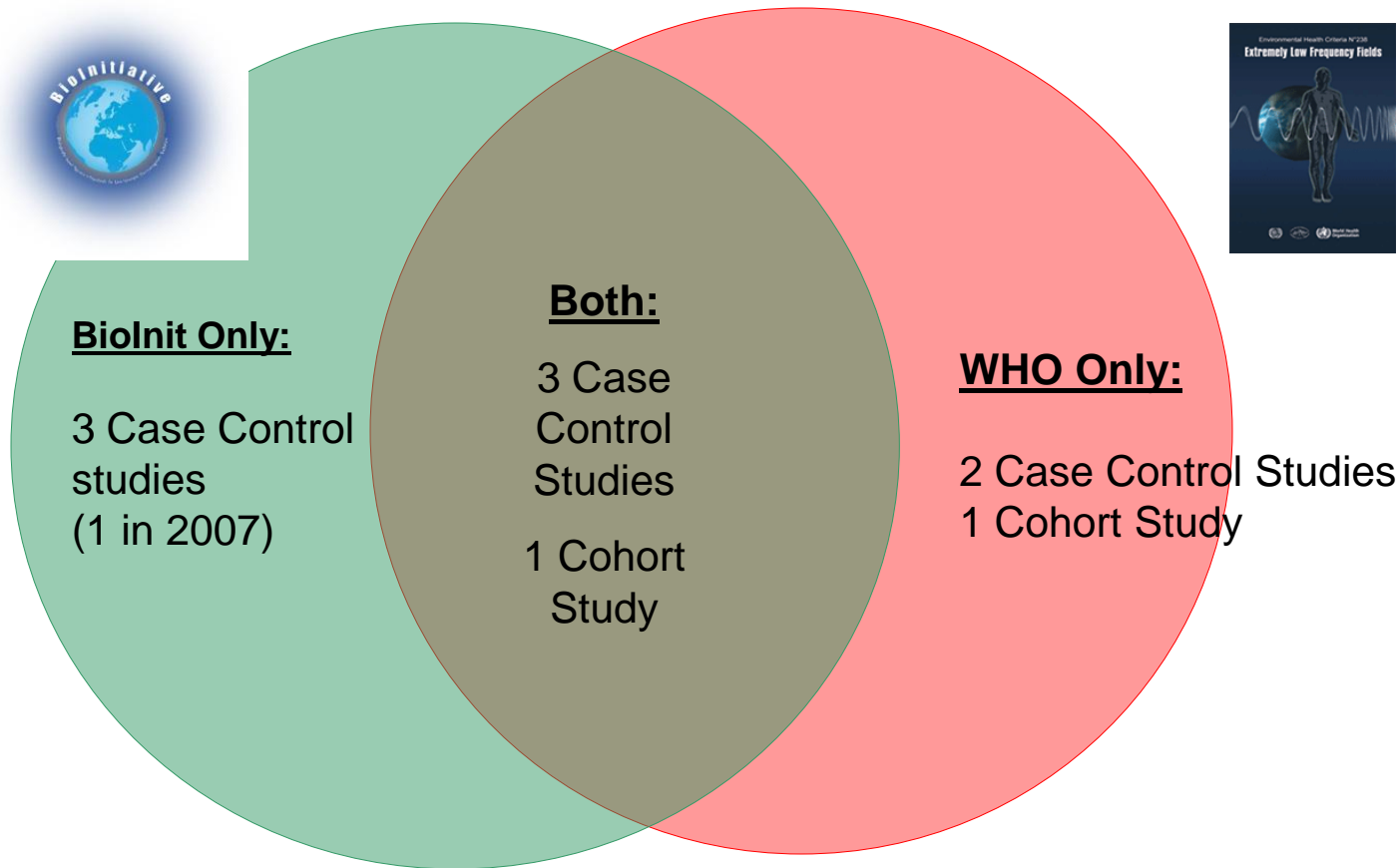
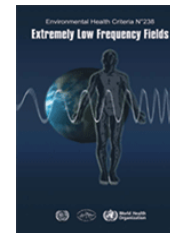
## *WHO only:*

- 2 c-c (S98, L02), 3 cohort (F03, H03, S98)  
1.2 1.3 2.3, 4.0, 1.0

## *Neither*

- 1 c-c (N02), 2 cohort (J98, R07)  
1.0 1.2, 3.2

# Alzheimer's disease: is either review good enough?



**Neither:**  
1 Case Control Study  
2 Cohort Studies  
(1 in 2007)

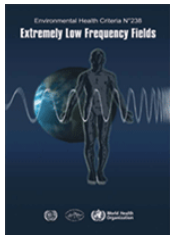


**Both ELF and RF exposures can be considered genotoxic (will damage DNA) under certain conditions of exposure, including exposure levels that are lower than existing safety limits.**





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Two groups have reported increased levels of DNA strand breaks in brain tissue following in vivo exposure to ELF magnetic fields.

However, other groups, using a variety of different rodent genotoxicity models, found no evidence of genotoxic effects. The results of studies investigating nongenotoxic effects relevant to cancer are inconclusive.

Overall there is no evidence that exposure to ELF magnetic fields alone causes tumours.

The evidence that ELF magnetic field exposure can enhance tumour development in combination with carcinogens is inadequate.



BioInitiative Report section 17 Key scientific evidence, p.14

**D. “There is no animal evidence”.**

It is correct that there is no adequate animal model system that reproducibly demonstrates the development of cancer in response to exposure to EMFs at the various frequencies of concern.

One positive animal study is that by Rapacholi et al. (1997), who demonstrated that lymphoma-prone transgenic mice developed significantly more lymphoma after exposure to 900 MHz fields (lymphoma being the animal equivalent of human leukemia) than did unexposed animals.

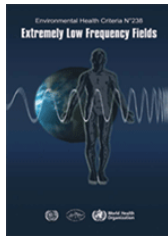
# Study not mentioned in BioInitiative Report: *Utteridge et al., Radiat Res 158: 357, 2002*

- We report here the results of the NHMRC-endorsed Australian study which tested whether exposure to 0.25, 1.0, 2.0 and 4.0 W/kg of global system for mobile communication (GSM)-modulated radiofrequency fields increased tumor incidence in E,I-Pim1 transgenic heterozygous mice.
- **While this Australian study set out to test the same central hypothesis as that of the study of Repacholi et al. (1997), refinements were included to overcome perceived shortcomings in that study, which had always been conceived as a pilot study.**
- There was no significant difference in the incidence of lymphomas between exposed and sham-exposed groups at any of the exposure levels. A dose-response effect was not detected.
- The findings showed that long-term exposures of lymphoma-prone mice to 898.4 MHz GSM radiofrequency (RF) radiation at SARs of 0.25, 1.0, 2.0 and 4.0 W/kg had no significant effects when compared to sham-irradiated animals.



# BioInitiative Report conclusions

- **We cannot afford ‘business as usual’ any longer.**
- **New regulatory limits for ELF are warranted....** It is no longer acceptable to build new power lines and electrical facilities that place people in ELF environments that have been determined to be risky (at levels generally at 2 mG and above).
- While new ELF limits are being developed and implemented, **a reasonable approach would be a 1 mG planning limit** for habitable space adjacent to all new or upgraded power lines and a 2 mG limit for all other new construction.
- It is also recommended for that a 1 mG limit be established for existing habitable space for children and/or women who are pregnant.



# WHO Report conclusions

- **Only the acute effects have been established** and there are two international exposure limit guidelines (ICNIRP, 1998a; IEEE, 2002) designed to protect against these effects.
- As well as these established acute effects, **there are uncertainties about the existence of chronic effects**, because of the limited evidence for a link between exposure to ELF magnetic fields and childhood leukaemia.
- **Therefore the use of precautionary approaches is warranted.**
- 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 and is likely to be an expensive and not necessarily effective way of providing protection.

# Comments on the BioInitiative Report

**Health Council of the Netherlands:**



In view of the way the BioInitiative report was compiled, the selective use of scientific data and the other shortcomings mentioned above, the Committee concludes that the BioInitiative report is not an objective and balanced reflection of the current state of scientific knowledge.

Therefore, the report does not provide any grounds for revising the current views as to the risks of exposure to electromagnetic fields.

**Australian Centre for Radiofrequency Bioeffects Research:**  
*agrees with HCN*



# Comments on the BioInitiative Report



**Electric Power Research Institute:**

the 1-milligauss limit the working group calls for would produce a dose in the body between 200 and 2,000 times less than the lowest dose levels expert panels believe could cause biological effects.



# Comments on the BioInitiative Report



There is a lack of balance in the report; no mention is made in fact of reports that do not concur with authors' statements and conclusions.

If this report were to be believed, EMF would be the cause of a variety of diseases and subjective effects, including:

sleeplessness, headache, fatigue, skin disorders and changes in skin sensitivity, loss of appetite, tinnitus, impairment of memory and concentration, Alzheimer's and Parkinson's disease, cardiac problems, changes in brain and nervous systems activity, stress reactions, inflammatory and allergic reactions, genotoxic effects, changes in immune system function, and many types of cancers.

None of these health effects has been classified as established in any national or international reviews that assessed biological and health effects from exposures below internationally accepted EMF limits



# Conclusions: limitations of the BioInitiative Report

- Selection of sources: omits many good scientific studies, including several major studies that do not support their conclusions
- Selection of results: for some studies, emphasizes particular results that support their conclusions
- Reliance on extremes: in some instances, presents results based on extreme assumptions
- Lack of balance: fails to assess implications of their recommendations

# Conclusions: limitations of the BioInitiative Report

- Selection of sources, selection of results, reliance on extremes, and lack of balance
- are not random but appear as deliberate methods designed to emphasise putative hazards of ELF magnetic fields
- and thus make this an advocacy document, not a balanced scientific review;
- hence the conclusions given should be read as opinions or propositions;
- but many of the results quoted (such as the childhood leukemia – magnetic fields association) do raise important questions that need to be addressed more fully.