The BioInitiative Report

A Rationale for A Biologically-based Public Exposure Standard for Electromagnetic Fields (ELF and RF)

Cindy Sage, MA, Co-Editor

Royal Society, London, November 2007
Important Highlights

- 14 international experts in 9 month project
- Over 2000 scientific studies
- The evidence is ignored or dismissed
- It is the information content - not heating
- May be no lower limit that is safe
- We need new biologically-based limits
- Children are at most risk+

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Participants and Topics

- Carl Blackman USA  Modulation Effects
- Martin Blank USA  Stress Proteins (hsp)
- Michael Kundi Austria  Epidemiology - Public Health

- Henry Lai USA  Neurologic Effects
- Lennart Hardell Sweden  Brain Tumors
- Kjell H. Mild Sweden  Brain Tumors
- Zhengping Xu China  Proteomics/Genomics

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Participants and Topics

• Olle Johansson  Sweden  Immune Function  Hypersensitivity
• Eugene Sobel  USA  Melatonin - Alzheimers
• Zoreh Davanipour USA  ALS - Breast Cancer
• David Carpenter  USA  Public Health
• David Gee  Denmark  Precautionary Principle
• Cindy Sage USA  Editor-EMF Policy Planning
• Amy Sage  USA  Research Associate

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Objectives

• To document key scientific studies and reviews that identify low-intensity effects for which any new human exposure standards should provide safety limits.

• To write a rationale for a biologically-based human exposure standard.

• To identify “next steps” in advancing biologically-based exposure standards that are protective of public health; that are derived in traditional public health approaches.

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Biologically-Based Exposure Standards Are Needed to Protect

- Integrity of the human genome (DNA genotoxicity)
- Immune and neurological function
- Cognitive function and memory
- Cellular communication, metabolism, DNA repair
- Cancer surveillance and protection
- Fertility and reproduction
- Sleep and sleep architecture
- Depression and fatigue
- Cardiac effects (dysregulation of ANS)
Immune Function

• Both human and animal studies report large immunological changes with exposure to environmental levels of electromagnetic radiation (EMR). Some of these exposure levels are equivalent to those of e.g. wireless technologies in daily life.

• Measurable physiological changes that are bedrock indicators of allergic response and inflammatory conditions are stimulated by EMR exposures (mast cells increase, for example).
Immune Function

- Over-reaction of immune system = inflammatory response
- Alterations of immune cells
- Profound increases in mast cells in the upper skin
- Increased degranulation of mast cells and larger size of mast cells in electrohypersensitive individuals
- Presence of biological markers for inflammation that are sensitive to EMF exposure at non-thermal levels
- Changes in lymphocyte viability
- Decreased count of NK cells and T lymphocytes
- Negative effects on pregnancy (uteroplacental circulatory disturbances and placental dysfunction with possible risks to pregnancy).
Electrical hypersensitivity is reported by individuals in the United States, Sweden, Switzerland, Germany, Denmark and many other countries of the world. Estimates range from 3% to perhaps 10% of populations, and appears to be a growing condition of ill-health leading to lost work and productivity.
Stress Proteins (hsp)

- Cells react to an EMR as potentially harmful:
  - Direct interaction of ELF and RF with DNA has been documented and both activate the synthesis of stress proteins.
  - Biochemical pathway that is activated is the same pathway in both ELF and RF and it is non-thermal.
  - Existing limits do not protect us.
ELF and RFR are Genotoxic

• There is substantial evidence that RFR may be considered genotoxic (cause DNA damage). Of 28 total studies on radiofrequency radiation (RFR) and DNA damage, 14 studies reported effects (50%) and 14 reported no significant effect (50%). Of 29 total studies on radiofrequency radiation and micronucleation, 16 studies reported effects (55%) and 13 reported no significant effect (45%). Of 21 total studies on chromosome and genome damage from radiofrequency radiation, 13 studies (62%) reported effects and 8 studies (38%) reported no significant effects.

• Extremely-low frequency (ELF-EMF) has also been shown to be genotoxic and cause DNA damage. Of 41 relevant studies of genotoxicity and ELF-EMF exposure, 27 studies (66%) report DNA damage and 14 studies (44%) report no significant effect.
Genotoxicity

• Radiofrequency radiation exposure can induce genetic damages/changes in cells and organisms at non-thermal exposure levels.

• This can lead to change in cellular functions, cancer, and cell death.

• Frequency, intensity, exposure duration, and the number of exposure episodes can affect the response, and these factors can interact with each other to produce different effects. Must know if the effect is cumulative, whether compensatory responses result, and when homeostasis will break down.
Childhood Leukemia

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

Children who have leukemia and are in recovery have poorer survival rates if their ELF exposure at home (or where they are recovering) is between 1mG and 2 mG in one study; over 3 mG in another study.

BioInitiative Report, Section 1 Summary
Brain Tumors + Acoustic Neuromas

• Studies on brain tumors and use of mobile phones for ≥ 10 years gave a consistent pattern of an increased risk for acoustic neuroma and brain tumors (gliomas).

• The risk is most pronounced for high-grade glioma. The risk is highest for ipsilateral exposure.

• Existing standards do not protect us.
Brain Tumor - RF Epidemiology

- Only few studies of long-term exposure but evidence is consistent with a moderately elevated risk. Occupational studies indicate that long term exposure at workplaces may be associated with an elevated brain tumor risk at levels below existing limits.

- Epidemiological studies as reviewed in the IEEE C95.1 revision (2006) are deficient to the extent that the entire analysis is professionally unsupportable. IEEE's dismissal of epidemiological studies that link RF exposure to cancer endpoints should be disregarded, as well as any IEEE conclusions drawn from this flawed analysis of epidemiological studies (Kundi, 2007).
Melatonin and Alzheimer’s Disease (AD)

- There is **strong epidemiologic evidence** that long-term exposure to ELF MF is a risk factor for AD.
- There is **considerable in-vitro and animal** evidence that melatonin protects against AD.
- Human studies indicate that MF exposure can decrease melatonin production.
- New exposure limits are warranted, and preventative action is needed now.
Melatonin and Breast Cancer

• Human studies have found that low melatonin production is a likely risk factor for breast cancer.

• Human studies indicate that ELF exposure can decrease melatonin production.

• ELF blocks melatonin and tamoxifen
  Laboratory studies of MCF-7 human breast cancer cells show more malignant cell proliferation with 6 - 12 mG ELF by blocking melatonin’s protective action (also true for tamoxifen).
Melatonin and Breast Cancer

- Occupational studies indicate that high (10 mG and greater) ELF exposure increases the risk of breast cancer.

- There are no epidemiologic studies of RF radiofrequency exposure and breast cancer which do not include ELF magnetic fields.
Neurological Effects

• Effects on neurophysiological and cognitive functions are quite well established.

• Pulsed high-frequency electromagnetic fields can affect normal brain functioning.

• CNS effects occur at very low intensities (cell phone, base station, WI-FI levels).
Neurological Effects

• There is some evidence for effects on sleep, performance, judgment, reaction time, immune function, and behavior.

• There is good evidence for effects on learning and memory; synchronization of brainwave activity and cognition (electrical activity $\leq 0.1$ W/kg). 2 W/kG is limit now.

• There is substantial evidence that low-level RF activates endogenous opioids (addictive center) in the brain.

• There is substantial evidence that RF is a stressor: chronic stress could have serious effects on general health and wellbeing.
Therapeutic Uses of EMF

- Electromagnetic fields are widely used in therapeutic medical applications.

- **Proof of effectiveness has been demonstrated** in numerous clinical applications of low-intensity ELF and RF (FDA approved).

- EMFs have been shown to be effective in treating conditions of disease at energy levels far below current public exposure standards.
Therapeutic Uses of EMF

- EMF (both ELF and RF) are both a cause of disease, and also used for treatment of disease (at levels far below existing public exposure standards).

- Multiple sources of EMF exposure in daily life = indiscriminate EMF exposure. Ill-advised at even at common environmental levels.

- EMF exposure may need to be regulated as drugs are regulated.
Information Content of EMR

It appears it is the INFORMATION conveyed by electromagnetic radiation (rather than heat) that causes biological changes - some of these biological changes may lead to loss of wellbeing, disease and even death.

BioInitiative Report, Section 1- Summary

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Conclusions

• Bioeffects are indisputable and chronic exposures may lead to harm.

• ICNIRP and FCC limits are inadequate.

• Biologically-based public exposure standards are warranted for ELF and RF.

• It is not in the public interest to wait.

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Conclusions

• Biological effects may include both potential adverse health effects and loss of homeostasis and well-being.

• A biologically-based exposure limit needs to be protective against ELF and RF intensity and modulation factors, which, with chronic exposure, can reasonably be presumed to result in impacts to health and well-being.
Conclusions

• The standard for taking action should be precautionary.
• There is substantial public concern.
• There is widespread distrust of government.
• There is inadequate warning to the public and there is no “informed consent”.
• No positive assertion of safety can be made.
Plausible biological mechanisms that can account for genotoxicity (DNA damage) already well known - oxidative damage via free-radical action. Although there is not yet absolute proof….. proof of mechanism is not required to set prudent public health policy, nor is it mandatory to set new guidelines or limits if adverse health effects are established at lower-than-existing IEEE and ICNIRP limits.
Standards of Evidence for Action

• Conclusive scientific evidence (a causal link) between ELF-EMF and RF-EMF is not required to take reasonable, interim prudent public health action.

• There is a large difference between what constitutes causal evidence, what constitutes sufficient evidence for purposes of interim public health policy, and what constitutes "a more likely than not" case.
Preventative Action (Precautionary Principle)

- Precautionary preventative actions are specifically justified at a point in time before scientific proof is established but where a reasonable suspicion of risk exists.

- Preventative policies that are protective of public health, safety and welfare are warranted now, given the evidence we have.
Precautionary Action (PP)

- The lessons from the histories of most well known hazards show that precautionary-based yet proportionate measures taken in response to robust early warnings can avoid the kinds of costs incurred by asbestos, smoking, PCBs, X rays etc. Such lessons are relevant to the EMF issue (David Gee, EEA, 2007)
Clarification of Key Terms  
(Amended from EEA, 2001)

<table>
<thead>
<tr>
<th>Situation</th>
<th>State and dates of knowledge</th>
<th>“Nature of the justification for Action”</th>
</tr>
</thead>
<tbody>
<tr>
<td>Risk</td>
<td>‘Known’ impacts; ‘known’ probabilities e.g. asbestos</td>
<td>Prevention: action taken to reduce known hazards e.g. eliminate exposure to asbestos dust</td>
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<tr>
<td>Uncertainty</td>
<td>‘Known’ impacts; ‘unknown’ probabilities e.g. antibiotics in animal feed and associated human resistance to those antibiotics</td>
<td>Precautionary prevention: action taken to reduce exposure to potential hazards</td>
</tr>
<tr>
<td>Ignorance</td>
<td>‘Unknown’ impacts and therefore ‘unknown’ probabilities eg the ‘surprises’ of chlorofluorocarbons (CFCs) in 1974</td>
<td>Precaution: action taken to anticipate, identify and reduce the impact of ‘surprises’</td>
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Why SAGE and SCENIHR Differ from BioInitiative

- Embedded assumptions differ.
- From the outset, if assumption is that we must have conclusive (clear and convincing) evidence of health effects, SAGE and SCENIHR inevitable
- They require a showing of scientific certainty - proof before acting. Industry sets “proof”.
- That is a high bar - unrealistic and counter to EC Treaties 152 and 174 and WHO policy.
- BioInitiative acts on principle that precautionary action based on reasonable suspicion of risk is adequate for preventative actions.
<table>
<thead>
<tr>
<th>REPORT</th>
<th>CHANGE ICNIRP?</th>
<th>KEEP ELF IARC 2B?</th>
<th>ACTION NOW?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bio-Initiative</td>
<td>YES</td>
<td>YES</td>
<td>Preventative = &lt; 1 mG ELF and &lt; 0.1 µW/cm² (Prolonged)</td>
</tr>
<tr>
<td>SCENIHR (EC)</td>
<td>NO</td>
<td>YES</td>
<td>None-Research</td>
</tr>
<tr>
<td>SAGE (UK)</td>
<td>No Position</td>
<td>No Position</td>
<td>No-Low Cost</td>
</tr>
</tbody>
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Standards of Evidence

- Why do people argue over *when* to take action?
- What definitions and criteria are different?
- EU/EEA = Bigger the risk, smaller the evidence needed (the ultimate sliding scale)
- Can act on thin evidence if risk is large
- US = Action proportionate to risk
- US = Industry uses heavy hand in delaying
The highest standard of evidence = conclusive evidence based on:

95% - 99%
- Epidemiology (Hill Criteria)
- Cell Studies
- Whole Animal Studies
- Replication
- Scientific Consensus (Science/Industry)

51%

10-30%

“Preponderance of the evidence”

“More likely than not”

“Potential for significant impact”

STANDARDS OF EVIDENCE

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STANDARDS OF EVIDENCE FOR ACTION

Public health requires actions proportionate to potential risks.
WHERE ARE WE?

PRECAUTIONARY PRINCIPLE

PREVENTATIVE ACTION

ELF Regulation And RF Prevention

INCREASING EVIDENCE

c. 1997 Sage Associates
2007
With the Precautionary Principle: THE RIGHT ACTION VARIES WITH RISK OF HARM

INCREASING HARM IF RISK EXISTS
JUSTIFIES EARLIER ACTION ON LESS EVIDENCE

INCREASING EVIDENCE

Low Risk of Harm if No Action

Moderate Risk Of Harm Exists

GREAT HARM If NO EARLY ACTION

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