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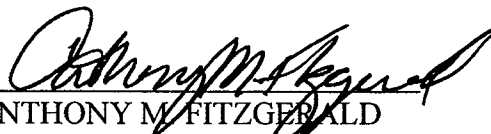
Petition 754

Re: 2006 Revision of the Electric and Magnetic Field      October 26, 2006  
Best Management Practices

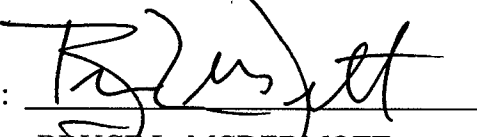
COMMENTS  
OF  
DR. MICHAEL H. REPACHOLI  
CONCERNING  
THE COUNCIL'S PROPOSED  
REVISED ELECTRIC AND MAGNETIC FIELD  
BEST MANAGEMENT PRACTICES

The Connecticut Light and Power Company and The United Illuminating  
Company hereby submit comments of Dr. Michael H. Repacholi.

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**Comments to the Connecticut Siting Council on Petition No. 754: Best Management Practices for Electric and Magnetic Fields (21 Sept 06 draft)**

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**From 1 November 2006, Visiting Professor, University of Rome "La Sapienza", Rome, Italy**

**INTRODUCTION**

I have been asked by the Connecticut Light and Power (CL&P) Company to comment on the draft Best Management Practices (BMPs) for Electric and Magnetic Fields (21 Sept 2006 draft) and on the comments to the 4 May 2006 draft of the BMPs from the Connecticut Department of Public Health (DPH). A brief CV with selected publications is attached as Annex 1.

My report will focus mainly on the recommendations of the World Health Organization (WHO) that relate to public health protection from exposure to electric and magnetic fields from power lines. Most of the information that I refer to in this report can be found on the WHO web site at: [www.who.int/emf](http://www.who.int/emf).

Until 30 June 2006 I was the Coordinator of WHO's Radiation and Health Unit.

During my 11 years at WHO I started the International EMF Project to:

1. Complete thorough reviews of the scientific literature on EMF with the aim of identifying what health effects have been established and what gaps in knowledge still exist where more research would allow better health risk assessments to be made.
2. Promote EMF health effects research world wide, particularly at levels below current internationally accepted exposure limits.
3. Conduct formal health risk assessments and risk characterization of EMF using WHO criteria for such assessments
4. Publish all results in formats suitable for the general public, government authorities and the scientific community
5. Provide recommendations for national and local authorities on how to manage the various EMF issues

My comments are based on published WHO reports and a recent review of the science on the biological and health effects of extremely low frequency (ELF) fields. ELF fields include the 50 and 60 Hz electric and magnetic fields from the generation, distribution and use of electric power.

This report is structured to provide relevant information from WHO's International EMF Project, and to use this information as a basis for my discussion on the draft BMPs and the comments by the CT DPH on a previous draft of the BMPs.

As set out in more detail in the following pages, I suggest that:

- The 100 mG edge of right of way (RoW) screening level contemplated by the BMPs is extremely conservative and very highly protective of the public, including children and that there is no scientific reason to indicate that this level should be any lower than 100 mG.

- There are no scientific or sound policy reasons that support
  - establishing a lower screening level at selected locations along the RoW or
  - making substantial investments to lower the predicted field levels below 100 mG at selected locations.

## DISCUSSION

### WHO Process for Reviewing Health Risks

WHO has been assessing health risks from biological, chemical and physical agents for over 60 years. Criteria for making these assessments to ensure valid conclusions are reached have been perfected over this time and are well accepted by all WHO Member States.

When the health outcome of concern is cancer, WHO works with its own specialized agency the International Agency for Research on Cancer (IARC). When the International EMF Project was established in 1996, agreement was reached with IARC that they would conduct their "carcinogen identification and classification" review, and that their results would be incorporated into a full risk assessment of all possible health outcomes, which would be conducted by WHO Headquarters. The criteria for conducting health risk assessments for EMF have been published (Repacholi and Cardis, 1997). This process has been followed for ELF fields and key aspects of it are briefly described below.

### IARC Reviews

IARC has conducted "carcinogen identification and classification" reviews on over 800 potentially carcinogenic agents. Details on the review process and the classification reached for various agents can be obtained from their web site at: [www.iarc.fr](http://www.iarc.fr).

The EMF review process involves selection of a committee of world recognized experts who are specialists in the range of scientific specialities needed to properly assess the literature and conduct the review. Selected specialists are asked to draft chapters on each of the areas of science relevant to cancer. The compiled text is sent for extensive review and comment world wide, and the revised manuscript subjected to an IARC Working Group (WG) review that normally lasts for some 10 days.

One of the key outcomes of the review is the consensus of the WG on which category or carcinogen group the agent falls into. This is described here because there has been a lot of misunderstanding about what these categories mean. *IARC assigns categories related to degrees of evidence for carcinogenicity in humans and experimental animals. These categories refer only to the strength of evidence that exposure is carcinogenic and not to the extent of its carcinogenic activity (potency) nor to the mechanisms involved.*

As a general rule, IARC considers that if an agent causes cancer in 2 different animal species, it almost certainly will produce cancer in humans. So far there have not been any exceptions found to this rule. *Thus the importance of carefully conducted animal studies in the assessment of the carcinogenic potential of ELF magnetic*

*fields cannot be underestimated.* More details on the IARC reviews and criteria are given in IARC (1995) and Repacholi and Cardis (1997).

### ***Carcinogenicity in Humans***

The applicability of an evaluation of carcinogenicity of exposure in given situations, occupations or industries on the basis of evidence from epidemiological studies depends on the variability over time and place of exposure. The Working Group identifies the specific exposure or activity which is considered most likely to be responsible for any excess health risk. The evidence relevant to carcinogenicity from studies in humans is classified into one of the categories given below. In some instances, these categories may be used to classify the degree of evidence related to carcinogenicity in specific organs or tissues.

**Sufficient evidence of carcinogenicity.** The Working Group considers that a causal relationship has been established between exposure and human cancer. That is, a positive relationship has been observed between the exposure and cancer in studies in which chance, bias and confounding could be ruled out with reasonable confidence.

**Limited evidence of carcinogenicity.** A positive association has been observed between exposure and cancer for which a causal interpretation is considered by the Working Group to be credible, but chance, bias or confounding could not be ruled out with reasonable confidence.

**Inadequate evidence of carcinogenicity.** The available studies are of insufficient quality, consistency or statistical power to permit a conclusion regarding the presence or absence of a causal association, or no data on cancer in humans are available.

**Evidence suggesting lack of carcinogenicity.** There are several adequate studies covering the full range of levels of exposure that human beings are known to encounter, which are mutually consistent in not showing a positive association between exposure to EMF and any studied cancer at any observed level of exposure. A conclusion of "evidence suggesting lack of carcinogenicity" is inevitably limited to the cancer sites, conditions and levels of exposure and length of observation covered by the available studies. In addition, the possibility of a very small risk at the levels of exposure studied can never be excluded.

### ***Carcinogenicity in Experimental Animals***

Evidence relevant to carcinogenicity in experimental animals is classified into one of the following categories:

**Sufficient evidence of carcinogenicity.** The Working Group considers that a causal relationship has been established between exposure and an increased incidence of malignant neoplasm or of an appropriate combination of benign and malignant neoplasm in (a) two or more species of animals or (b) in two or more independent studies of one species carried out at different times or in different laboratories or under different protocols. Exceptionally, a single study of one species might be considered to provide sufficient evidence of carcinogenicity when malignant neoplasm occur to an unusual degree with regard to incidence, site, type of tumour or age at onset.

**Limited evidence of carcinogenicity.** The data suggest a carcinogenic effect but are limited for making a definitive evaluation because, e.g. (a) the evidence of carcinogenicity is restricted to a single experiment; or (b) there are unresolved questions regarding the adequacy of the design, conduct or interpretation of the study; or (c) exposure increases the incidence only of benign neoplasm or lesions of uncertain neoplastic potential, or of certain neoplasm which may occur spontaneously in high incidence in certain strains.

**Inadequate evidence of carcinogenicity.** The studies cannot be interpreted as showing either the presence or absence of a carcinogenic effect because of major qualitative or quantitative limitations, or no data on cancer in experimental animals are available.

**Evidence suggesting lack of carcinogenicity.** Adequate studies involving at least two species are available which show that, within the limits of the tests used, exposure is not carcinogenic. A conclusion of evidence suggesting lack of carcinogenicity is inevitably limited to the species, tumour sites and levels of exposure studied.

#### ***Other Data Relevant to the Evaluation of Carcinogenicity***

Other evidence judged to be relevant to an evaluation of carcinogenicity and of sufficient importance to affect the overall evaluation is also considered. This may include data on preneoplastic lesions, tumour pathology, genetic and related effects, structure-activity relationships, metabolism, physicochemical parameters and analogous biological agents.

Data relevant to mechanisms of the carcinogenic action are also evaluated. The strength of evidence that any carcinogenic effect observed is due to a particular mechanism is assessed, using terms such as weak, moderate or strong. The Working Group then assesses if the particular mechanism is likely to be operative in humans. The strongest indications that a particular mechanism operates in humans come from data on human or biological specimens obtained from exposed humans. Data may be considered to be especially relevant if they show that exposure in humans has caused changes that are on the causal pathway to carcinogenesis.

#### ***Overall Evaluation***

Finally, the body of evidence is considered as a whole, in order to reach an overall evaluation of the carcinogenicity to humans. A common approach for determining this is by weight of evidence. There is no way to prove something does not cause cancer since no foolproof test exists for carcinogens or hazard identification. Thus it is necessary to estimate how much of a given set of evidence (established scientific database) changes the probability that exposure is carcinogenic.

The carcinogenicity of exposure is described according to the wording of one of the following categories. The categorization of exposure is a matter of scientific judgement, reflecting the strength of the evidence derived from studies in humans, animals and from other relevant data.

- **Group 1 - Exposure is carcinogenic to humans.**

This category is used when there is sufficient evidence of carcinogenicity in humans. Exceptionally, exposure may be placed in this category when evidence in humans is less than sufficient but there is sufficient evidence of carcinogenicity in experimental animals and strong evidence in humans that exposures act through a relevant mechanism of carcinogenicity.

- **Group 2 (divided into 2 separate categories shown below)**

This category includes exposure for which, at one extreme, the degree of evidence of carcinogenicity in humans is almost sufficient, as well as those for which, at the other extreme, there are no human data but for which there is evidence of carcinogenicity in experimental animals. Exposure is assigned to either group 2A (probably carcinogenic to humans) or group 2B (possible carcinogenic to humans) on the basis of epidemiological and experimental evidence of carcinogenicity and other relevant data.

- **Group 2A - Exposure is probably carcinogenic to humans.**

This category is used when there is limited evidence of carcinogenicity in humans and sufficient evidence of carcinogenicity in experimental animals. In some cases, exposure may be classified in this category when there is inadequate evidence of carcinogenicity in humans and sufficient evidence of carcinogenicity in experimental animals and strong evidence that the carcinogenesis is mediated by a mechanism that also operates in humans. Exceptionally, exposure may be classified in this category solely on the basis of limited evidence of carcinogenicity in humans.

- **Group 2B - Exposure is possibly carcinogenic to humans.**

This category is used when there is limited evidence of carcinogenicity in humans and less than sufficient evidence of carcinogenicity in experimental animals. It may also be used when there is inadequate evidence of carcinogenicity in humans but there is sufficient evidence of carcinogenicity in experimental animals. In some instances, if there is inadequate evidence of carcinogenicity in humans but limited evidence of carcinogenicity in experimental animals, together with supporting evidence from other relevant data, exposure may be placed in this group.

- **Group 3 - Exposure is not classifiable as to its carcinogenicity to humans.**

This category is used most commonly when the evidence of carcinogenicity is inadequate in humans and inadequate or limited in experimental animals. Exceptionally, if there is inadequate evidence of carcinogenicity in humans but sufficient in experimental animals, exposure may be placed in this category when there is strong evidence that the mechanism of carcinogenicity in animals does not operate in humans.

- **Group 4 - Exposure is probably not carcinogenic to humans**

This category is used when there is evidence suggesting lack of carcinogenicity in humans and in experimental animals. In some instances, if there is inadequate

evidence of carcinogenicity in humans but evidence suggesting lack of carcinogenicity in experimental animals, and this is consistently and strongly supported by a broad range of other relevant data, exposure may be classified in this group.

### **IARC Evaluation**

In 2001 IARC held a carcinogen identification and classification review of static and ELF electric and magnetic fields. The review was published in 2002. From this review, ELF magnetic fields were classified as 2B; a possible human carcinogen. This was based on limited evidence from epidemiological studies of childhood leukaemia, and less than sufficient or inadequate evidence from animal studies; no mechanism has been identified.

Limited evidence of carcinogenicity in humans is usually based on evidence in humans which is considered credible, but chance, bias and confounding cannot be ruled out with reasonable confidence. *Thus a 2B classification means that other explanations for the relationship between exposure to ELF magnetic fields and childhood leukaemia cannot be excluded.*

It is also important to note that in addition to ELF magnetic fields, coffee, gasoline engine exhaust, glass wool, pickled vegetables and styrene are examples of agents that have also been classified as 2B or "Possible human carcinogens".

The main concern raised from the scientific reviews is that there has been little or no support for ELF magnetic fields causing, promoting or progressing cancer from the laboratory studies or from the analysis of possible mechanisms of interaction of these fields. In fact the weight of evidence from the laboratory studies is strongly against exposure to ELF magnetic fields leading to cancer. This makes the epidemiological evidence much less convincing; so much so that no international standards setting agency, including WHO, has felt that the epidemiological evidence is credible or convincing enough to use as a basis for limiting human exposure to ELF magnetic fields.

### **WHO Review Process**

Since the IARC review, WHO/HQ has been updating reviews of all the ELF biological effects. This process involved convening working groups on specialized topics to draft chapters, including hosting special meetings in countries having large research programs (but results not available in English, e.g. Russia and China), in order to bring together all of the worlds literature on the topic. This resulted in a draft that was reviewed by institutions and specialists world wide.

In October 2005, WHO convened a Task Group to review this draft and finalize the text. Experts on the Task Group were identified on the basis of their expertise, particularly their publications and standing in the scientific community, the range of expertise needed for the review, and WHO's special requirement that there be geographical and gender representation. All members of the Task Group are approved by the Executive Director for the Sustainable Development and Healthy Environments Cluster.

An important aspect of the review is that it is an in-depth, weight-of-evidence, critical review and evaluation of EMF peer-reviewed publications of research conducted world wide. All study reports must have detailed descriptions of methods used, all data and analyzes of results and conclusions. In addition studies must have been replicated or be in agreement with similar studies. Finally all studies with either positive or negative findings are assessed equally. These criteria ensure the highest standards and most reliable review conclusions and recommendations.

The ELF Fields Task Group review will be published in the Environmental Health Criteria (EHC) series by WHO. It represents the highest level of health risk assessment review in WHO. A particularly important feature of the EHC monograph are chapters giving a summary of the report and recommendations for further research that will allow better health risk assessments to be made in the future. Part of the mandate of the Task Group is to make recommendations on sound public health policy from the available scientific evidence. Chapter 13 of the EHC is devoted to recommendations for national authorities on what protective measures should be applied to protect the public from any health consequences of ELF field exposure.

While it would be inappropriate for me to provide the detailed recommendations prior to publication of the EHC by WHO, the basic recommendation for national authorities have been provided by WHO at various scientific meetings, most recently in Brazil (2006). These will be discussed below. However it is important to briefly explain the role of WHO staff members working on the International EMF Project.

#### **Role of WHO Staff**

WHO staff facilitate and implement the program of work agreed by the EMF Project's International Advisory Committee. They form part of the non-voting secretariat at all meetings and expert groups, including EHC reviews. In addition they compile fact sheets and reports published after comments by IAC and outside experts and give presentations summarizing the conclusions of WHO meetings or expert groups. WHO staff also ensure compliance with WHO's conflict of interest policies (Committee membership, funding, etc). In summary the final conclusions and recommendations are those of the committees and not WHO staff members.

#### **Draft Conclusions of WHO EHC Review**

The final recommendations and conclusions of the Task Group cannot be changed following the meeting held in October 2005. So, although the Task Group draft is going through a detailed scientific and language editing process, the final conclusions of the review are generally known since WHO staff have provided summaries of these at various meetings. These can be briefly summarized, not necessarily with the exact wording of the text, as follows:

1. It is established that high strength ELF fields induce electric currents and fields in tissues. This can lead to nerve and muscle stimulation, and possible effects at the cellular level, and these need to be protected against by exposure limits.
2. The Task Group recognized that the ICNIRP (1998) guidelines provide adequate protection for all established health effects.



3. The epidemiological evidence suggests that chronic low-level exposure to ELF magnetic fields at field strengths above about 0.3 - 0.4  $\mu\text{T}$  (3-4 mG) is associated with an approximate doubling of the risk of childhood leukaemia.
4. While the overall the epidemiological evidence is very weak, it has been strengthened by more recent studies conducted since the IARC review in 2001.
5. The epidemiological studies are not supported by the experimental studies.
6. The epidemiological evidence cannot be used as a basis for standards (exposure limits)
7. If exposure to ELF magnetic fields were to cause leukaemia in children, estimates of exposure to these fields would roughly translates into an extra 100 – 2000 extra childhood leukaemia per year world wide.
8. The overall evidence suggests, in addition to adopting international exposure standards, that adopting precautionary measures is warranted, but that they should be at no, or very low cost.

In addition to the above, WHO has been working on a Framework for developing public health policy options in areas of scientific uncertainty for a few years, and so additional examples of precautionary measures that the Task Group considered appropriate are given below.

#### **Recommendations on Precautionary Measures**

WHO is drafting a "Framework for Developing Public Health Policy Options in Areas of Scientific Uncertainty" as a guide for regulators and other decision-makers. A copy of the draft of this Framework was provided to the EMF Project's International Advisory Committee (IAC) in June 2006 is attached as Annex 2. It should be noted that the comments of the IAC still need to be incorporated but the basic principles on which the Framework is based will remain unchanged.

Combining the WHO and Task Group recommendations, they can be briefly summarized as follows:

- Adopt and ensure compliance with international guidelines (ICNIRP)
- Take no or very low cost measures to reduce ELF magnetic fields:
  - ✓ Electrical industry should consider ways to generate and distribute electricity in ways that minimize ELF field exposure
  - ✓ Governments should consider changes to their electrical wiring codes for all buildings that would lead to reduced ELF field exposures by occupants
  - ✓ Manufacturers should redesign electrical appliances to reduce ELF fields
  - ✓ The public should be informed of measures that will allow them to reduce their personal exposures to ELF

WHO strongly recommends that national authorities adopt international standards that limit human exposure to EMF, and encourages the use of precautionary measures that lead to exposure reductions in the population. Reducing the exposure limit values in the ICNIRP (1998) guidelines as a precautionary measure is specifically NOT recommended by WHO. This is because such arbitrary reductions undermine or devalue the credibility of the science-based limits, and the extensive scientific research (in which 100s of millions of dollars have been invested), for no apparent

health benefit. In particular, the draft Framework (Annex 2) recommends against the adoption of quantitative magnetic field exposure limits at, e.g., 3 or 4 mG because:

- there is too much uncertainty in the interpretation of the epidemiological studies to be confident that these are indeed the appropriate levels;
- simplistic application of limits at these low levels is likely to have costs hugely disproportionate to any health benefit

In recommending precautionary approaches, an overriding principle is that any actions taken should consider both the potential health benefits and the costs of action or lack of action, using a cost-benefit or cost-effectiveness analysis. As applied to the reduction of magnetic fields associated with electric system, this means that the precautionary measures should not compromise the essential health, social and economic benefits of electric power. In light of the current scientific evidence and given the important remaining uncertainties, implementing precautionary procedures to reduce exposures is reasonable and warranted, but not if it negatively impacts on the health, social and economic benefits of electric power.

The costs of implementing exposure reductions will vary from one country to another, making it very difficult to provide a general recommendation for balancing costs against risk for ELF fields. However, given the weakness of the evidence for a link between exposure to ELF magnetic fields and childhood leukaemia and the limited potential impact on public health, the benefits of exposure reduction on health are unclear and thus the costs to reduce exposure should be very low.

The draft WHO Framework on Policy Options (Annex 2), scheduled to be published before the end of 2006 or early 2007, stresses that the benefit of precautionary actions should be carefully evaluated. Key to such an evaluation is a cost-effectiveness analysis and an assessment as to whether the precautionary measures, when implemented, would lead to any significant exposure reduction in the population. It should be remembered that most of a person's exposure to ELF magnetic fields comes from use of electrical appliances, not from power lines, so attempts to reduce exposures from power lines may have little impact on overall exposure.

### **The Gradient Report**

I have been provided a copy of the Gradient report (Jan. 2006) and find it basically sound in terms of the science review and other information provided. It provides a good basis for developing policy options on precautionary measures that reduce exposure to ELF magnetic fields.

There is one puzzling aspect of the Gradient method for deriving the 100 mG screening level. Appropriate caveats in their analysis have been noted: "This screening level is likely to be highly conservative (i.e., health protective), because it is unknown how far above the reported (no adverse effects level) NOAEL an actual frank, deleterious effect might be found in laboratory-animal experiments. Moreover, the safety factors applied to the animal NOAEL to calculate this MF value assumed that humans are greater than 100-fold more sensitive than animals, when in fact available data are just as consistent with an assumption of equivalent sensitivity or less sensitivity. Such alternative assumption would predict a screening level larger than 100 mG."

However, while it is true that exposures to ELF magnetic fields up to 10,000 mG have not shown any effect on cancer in animals, it is also true that no study has established that any level of magnetic field exposure causes or leads to cancer. Within the Gradient report there are strong arguments that ELF magnetic fields are incapable of any interaction that could lead to cancer. Thus it is extremely conservative to say that 10,000 mG is the NOAEL. A NOAEL should only be determined by finding an effect then reducing the exposure level until the effect does not occur.

Determination of NOAELs for exposure limitation is normally only applied to chemicals, not EMF. Further, developing NOAELs leads one to expect that there will be real health benefits with the very large safety factors incorporated into the limit, when in fact the overwhelming weight of scientific evidence suggests that no health benefit will result.

### **Comments on the Draft BMPs**

Given the assumptions in the Gradient derivation of the screening level it is already extremely conservative and there is no scientific reason to indicate that this level should be any lower than 100 mG.

The recommended 100 mG screening level is even more conservative than the safety factor of 100 suggests because, as noted in the draft BMP and Gradient report; the screening level has additional implicit safety factors that derive from applying it at the edge of the right of way (RoW) of transmission lines (since people generally live beyond the RoW), and from estimating it at times of peak load, and as a maximum 24-hour-average MF.

As the product of multiple precautionary reductions of the recommended ICNIRP exposure limit, the 100 mG screening level recommended by Gradient is inconsistent with one specific recommendation of the draft Framework document. However, the 100 mG value is high enough that it is unlikely to require extremely expensive measures, and it is thus consistent with the principle of requiring only no cost and low cost measures to reduce exposures where risk is unproven and the relevant characteristic of the exposure, if any, is unknown.

It is noted that CT has adopted legislation requiring that overhead power lines be sited away from certain locations where children congregate, such as residential areas, schools and playgrounds, and that the DPH has recommended that magnetic fields be as low as possible in these areas. As a result the latest draft of the BMPs states: *"Consistent with this announced policy, the Council will examine the feasibility of reducing MF exposure to the greatest extent possible in the aforementioned areas, if MF values are below 100 mG at the edge of the RoW."*

Unless the concept of "feasibility" includes economic as well as engineering considerations, a policy of reducing exposure "to the greatest extent possible" would ignore a cost-benefit balance, and would be inconsistent with WHO's recommendation that only low cost and no cost exposure reduction measures be considered. Such a standard or guideline is potentially even more costly than the 10 mG screening level proposed in an earlier draft, since there could well be situations

where it will be “possible” to reduce fields below 10 mG by the implementation of costly engineering measures.

Moreover, in evaluating how much precautionary engineering is prudent, one must consider whether it will be truly effective in reducing children's overall ELF magnetic field exposure, remembering that power lines normally provide less than half the exposure children receive. As already stated above, the 100 mG screening level is extremely cautious and very highly protective for all the public, including children. There is no reason to add yet another factor of 10 for children.

It will be of benefit to all stakeholders to have a clear policy on construction of new power lines. If it is agreed that 100 mG should be the screening level at the edge of the RoW, this should be respected. Then allow the power companies to take on board the responsibility to lower fields even further in areas where children gather, if this is technically feasible and at no or very low cost.

It is important that the screening level is not perceived as a population exposure limit, but as a construction guide for new transmission lines. Public perception of the screening level as a population exposure limit, established as a precautionary measure would be of concern because

1. The application of exposure limits (or guidelines) for new facilities that are much lower than those commonly associated with existing facilities can be perceived to “discriminate” against people living near the existing facilities. When only low or no cost measures are required to reduce fields associated with new lines, such a discrimination charge is unwarranted, because the reconstruction of existing lines to meet such standards will always be very expensive. However, once the regulators lose sight of, or de-emphasize, cost considerations in favour of field reductions for new lines, the perception of discrimination is much more reasonable.
2. Some will conclude that because precautionary measures are being used there must be a health concern that is being concealed. People could then worry that exposure to ELF magnetic fields above those levels from any sources could be dangerous. The introduction of precautionary measures has to be done with care so as not to provoke unwarranted public alarm. See the attached draft WHO Framework for guiding public health policy options in areas of scientific uncertainty, for more information with respect to these considerations.

#### **Comments on the CT DPH Submission**

The Connecticut Department of Public Health has taken a very much more cautious approach to protection of the public, especially children, from ELF magnetic fields than suggested in the Gradient report and the Siting Council's initial drafts of the revised BMPs. This may be due to the CT legislation mentioned above. However, in its review of the science, the DPH has indicated greater acceptance of reported positive study results than the Gradient report, or indeed than the weight-of-evidence approach taken in any WHO multidisciplinary task group review. WHO accepts only high quality studies reporting all information necessary for the study to be properly evaluated, but does not accept studies that have not been replicated or confirmed by quality studies investigating similar outcomes.

Rather than give a detailed critique of the science according to the DPH, I comment on a few key issues raised by DPH, using the WHO reports as a basis.

*"The DPH has a goal of maintaining EMF levels from electrical generation to within 2 fold of background (6 mG or below) as a means to keep potential risks to a minimum. This target level of 6 mG, also corresponds to the apparent effect level derived from an epidemiological meta-analysis (Greenland, et al., 2000) which has the most developed quantitative dose-response information."*

As noted in the Gradient report, Greenland (2005) has since published an analysis of bias in the EMF studies and concluded that the results allowed for no other sources of uncertainty than random error (i.e., population size). This means that other sources of bias still need investigation before the epidemiological studies can provide more credible evidence. This was noted in the IARC (2002) report and the draft WHO EHC on ELF. A recent paper by Kheifets et al (2006) addresses the concerns about the 3-4mG cut points, and posits that "establishment of arbitrary numeric exposure limits undermines the value of both the science-based numeric EMF exposure standards for acute exposures and precautionary approaches."

DPH states that the 100 mG target does not represent sound science but rather relies on one animal study of questionable relevance to public health. As stated above however, the 100 mG screening level represents an extremely conservative level based on the science. In fact the data suggest the screening level should be significantly higher. Further, the animal study conducted by the US National Toxicology Program (NTP) was of very high quality. The fact that it could not expose the animals to transients or irregular waveforms does not detract from the applicability of the results, as noted in my discussion on mechanisms below.

*DPH states that "the risk is uncertain because the statistical associations with leukaemia are not well supported by animal toxicology studies. However, the animal studies are not uniformly without effects, and it is inappropriate to place a great deal of weight on the animal studies because of their limitations and inconsistent results. Thus, the concerns raised by epidemiological associations are not mitigated by the animal studies or uncertainties regarding the EMF mechanism of action."*

In fact, all national and international reviews have found that the animal studies do not establish that exposure to ELF magnetic fields cause, promote or progress cancer. DPH seems to undervalue the results of the many large animal studies that have been conducted. As noted above, animal study results are highly valued by IARC and WHO. They represent biological systems that have become reliable test beds for testing agents for carcinogenic potential (IARC, 1995, see US National Toxicology Program web site)

*DPH notes that "EMF is much more complex than testing a toxic chemical where the main exposure variables are the dose route, dose level and timing of exposure. In the case of EMF there is the additional complexity that EMF has properties not only of frequency (60 Hz) and intensity (mG level), but it also varies with respect to magnetic field vector (linear vs. circular or elliptical) and the occurrence of harmonics and*

*transients (spikes in intensity). These additional properties are associated with EMF that comes from power lines and household appliances."*

This statement is true and was recognized early in WHO's EMF Project. It was also recognized that it would be impossible to test all combinations of EMF fields. This is why the approach was taken by the WHO EMF Project to evaluate all possible mechanisms of action of EMF and determine the thresholds at which they would have an adverse impact at the molecular, cellular and whole animal level. Reviews of mechanisms of action have not shown that, at exposure levels encountered in our living environment, magnetic fields, (including fields containing transients from switching and changes to wave shape) can produce signals above the noise levels within cells. Thus the cell does not recognize any internal changes from environmental ELF exposure because the extent of change caused by the ELF fields is well below the normal changes occurring within the cell. These points, which were well described in the Gradient report, have influenced scientists in evaluating whether the epidemiological studies are truly identifying an effect on childhood leukaemia. The fact that environmental ELF fields do not appear to have the ability to produce signals in cells strong enough to affect is a factor influencing whether scientists believe that the epidemiological studies are truly identifying an effect on childhood leukaemia.

The CT DPH states that "The animal laboratory studies, both positive and negative, should not receive a great deal of emphasis because of the limitations and testing difficulties described above."

To the contrary, that a specialized international agency on cancer (IARC) puts significant emphasis on animal studies to determine whether an agent is carcinogenic or not should indicate that animal study data are important. IARC has noted (Repacholi and Cardis, 1995) that if animal studies from two different species show an agent is carcinogenic, then it is highly likely that this agent is carcinogenic to humans. To date there have been no exceptions found to this premise. Further, as mentioned above, the fact that the animal studies could not conduct exposures to every combination of ELF does not negate their applicability to health risk assessment.

Target or screening levels were deliberately not included as a recommendation in the WHO review because there is absolutely no scientific basis for them.

### **Final Remarks**

It is always difficult for health authorities to know what level of precaution is appropriate to protect their citizens. Richer countries are able to afford a higher level of protection against uncertain risks than poorer countries. However, the overriding principle is that whatever precautionary measures are adopted, they should be cost-effective. This can only be determined by conducting a proper assessment of the costs, benefits and effectiveness of the measures.

As an example, a few years ago the Italian Government considered that public exposures should be reduced to about the 3-4 mG level, mainly because they put more credence in the epidemiological studies than would be the case if a proper health risk assessment was completed, and it was pressured by some concerned citizens who believed the science was underestimating the true health risk. However the Italian

Government found that implementing this policy would cost some \$65 billion for the very unlikely possibility of saving 2-3 childhood leukaemia cases in the whole of Italy each year (Italy, 2002). As a result the Government did not follow through with this exposure reduction program.

A similar worst case health impact analysis of childhood leukaemia cases from exposure to ELF magnetic fields, which would assume that such fields really do cause leukaemia, could be performed for the State of Connecticut. If the CT population is about 3.5 million, and there is a truly a doubling of the risk of childhood leukaemia from exposures of 3-4 mG and above, and assuming ELF magnetic field exposures for people in CT are similar to that of the USA as a whole, then exposure to ELF magnetic fields from all sources might cause 1 extra case of childhood leukaemia in the whole of CT every couple of years.

Finally, as shown in Annex 2, *options should be selected considering the following criteria:*

- *Based on an examination of the potential health **benefits and costs** of action or lack of action, using cost-benefit or cost-effectiveness analysis as discussed above.*
- *Protection should be proportional to the **level of evidence***
- *Allowing for **social and cultural factors** which lead society to regard some risks as more serious than others.*
- ***Proportionate** to the level of protection desired in society in general, recognizing that risk can rarely be reduced to zero.*
- ***Consistent** with similar measures already taken for other health risks.*
- ***Non-discriminatory** in their application, treating comparable situations in comparable ways.*
- ***Subject to periodic review**, in the light of new scientific evidence.*

*Scientific evidence influences option selection: stronger evidence, particularly of a pervasive, severe or irreversible health effect, supports more intervention. Weaker evidence tends to support selection of less interventionist actions. Where there are no or low-cost options that reduce exposure, they can be implemented with little further debate after due consideration of what constitutes "low-cost" and the potential impact on public concern. As the cost of the option and the uncertainty of a health benefit increases, the importance of an analysis of the cost-effectiveness increases.*

In addition, given that, on average power lines contribute less than half of people's exposure to ELF magnetic fields, this needs to be considered among these criteria. Also it is easy to adopt policies that require transmission line construction to minimize exposure, but will this really have any significant reduction on the total exposure to the populations? This needs to be properly evaluated before embarking on costly exposure reduction policies.

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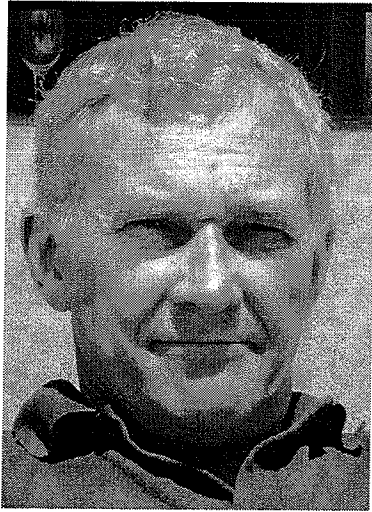
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**RESUME**

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**October 2006**

**Annex 1**

## RESUME

### ACADEMIC QUALIFICATIONS:

1. University of Western Australia 1965  
B.Sc. Physics.
2. University of London, England 1969  
M.Sc. Radiation Biology.
3. University of Ottawa, Canada 1980  
Ph.D. Biology.

### PUBLICATIONS

Over 200 scientific publications, reports and conference proceedings in various areas of research and radiation protection (see attached list).

### HONOURS

1. Health Physics Society, W.G. Morgan Lectureship for "Outstanding international contribution to radiation field" June 1993
2. Italian Radiation Protection Society - awarded honorary life membership, 1994
3. International Commission on Non-Ionizing Radiation Protection (ICNIRP) Awarded Chairman Emeritus, May 1997
4. Belarus State Medical University, Honorary Doctorate of Medical Sciences, 4 July 2002)
5. Russian Academy of Medical Sciences, awarded the Speransky Gold Medal for "Great (2004)
6. Radiological Research Centre of the Russian Academy of Medical Sciences, awarded the N.W. Timofeef-Ressovsky Medal for "Valuable contribution to research on the effects of non-ionizing and ionizing radiation on human health and the environment". Medical Moscow 19 October 2004
7. Member, Editorial Review Board, Australasian Physical and Engineering Sciences in Medicine Journal since 1995

### PROFESSIONAL SOCIETY MEMBERSHIP:

Australian Radiation Protection Association - member since 1984, Fellow since 1992, Vice President 1986 - 1988, President 1988 - 1990, Past President 1990 - 1992.

Health Physics Society (Full member) since 1970.

Australasian College of Physical Scientists and Engineers in Medicine (Fellow) since 1984, Chairman (S.A. Branch) 1984 - 1986, Vice President 1987 - 1989, President 1989 - 1991, Past President 1991 - 1993.

Australian Institute of Physics (Fellow) since 1974.

Canadian Radiation Protection Association (Full member) (1969-1981).  
Canadian Association of Physics - past president of Medical and Biological Physics Division  
(1978) program chairman of Divisions Annual Meeting 1977.

Bioelectromagnetics Society - full member since 1987, member of Honours Committee since  
1992.

Italian Radiation Protection Society - awarded honorary life membership in 1994.

#### **EMPLOYMENT RECORD SUMMARY:**

1. Australian Atomic Energy Commission 1964-65  
Summer student in Physics.
2. State X-Ray Laboratory, Perth, Western Australia 1965-68. Radiation Protection  
Physicist carrying out surveys on all X-ray equipment and radioisotope users in  
medical and industrial facilities.
3. Saskatchewan Cancer Commission, Regina 1969-71. Hospital Physicist concerned  
with radiotherapy treatment planning, consultant in radiation safety for the medical  
diagnostic X-ray equipment in the Grey Nun's Hospital, consultant to the nuclear  
medicine department of the Allan Blair Clinic.
4. Health and Welfare Canada, Radiation Protection Bureau 1971-1982.  
(a) 1971-1974 Head, Medical X-ray Program  
(b) 1975-1982 Head, Non-Ionizing Radiation Program  
Section head of programs involved with research, measurement, and biological and  
health effects of radiation. Development of standards for both ionizing and non-  
ionizing radiation.
5. Royal Adelaide Hospital, Adelaide, South Australia.  
January, 1983 - July 1991. Chief Scientist responsible for radiation research,  
development of new therapeutic techniques using radiation, radiation safety officer  
for Hospital, conduct of research projects involving radiation.

6. Australian Radiation Laboratory (seconded from Royal Adelaide Hospital)  
Federal Department of Health, Housing & Community Services  
Lower Plenty Road, Yallambie, Victoria, 3085, Australia.  
July, 1991 - July 1995. Manager and principal investigator of large research programs on the epidemiology of childhood cancer and animal studies to determine if exposure to radiofrequency or 50 Hz fields are involved in carcinogenesis.
7. Radiation Specialist, World Health Organization, 1211 Geneva 27, Switzerland. Managing the International Electromagnetic Fields Project and the Global Ultraviolet Radiation Project (INTERSUN) August 1995 to October 1998.
8. Coordinator, Occupational and Environmental Health, World Health Organization, 1211 Geneva 27, Switzerland. since October 1998 December 2001.
9. Coordinator, Radiation and Environmental Health, World Health Organization, 1211 Geneva 27, Switzerland. till 30 June 2006.
10. Visiting professor, University of Rome "La Sapienza"  
Rome, Italy from 1 November 2006

#### **INTERNATIONAL ACTIVITIES:**

- (i) ICNIRP: Inaugural Chairman of the International Commission on Non-Ionizing Radiation Protection May 1992 -May 1996. Chairman Emeritus of the International Commission on Non-Ionizing Radiation Protection since May 1996. ICNIRP is an independent scientific body chartered to review the scientific literature and provide advice on protection from exposure to all non-ionizing radiations and fields. ICNIRP was formed from the membership of IRPA/INIRC as described below.
- (ii) IRPA/INIRC: Member of the International Radiation Protection Association's (IRPA) International Non-Ionizing Radiation Committee since 1978. Chairman of Committee 1988-1992. This Committee is now the ICNIRP which was formed from it and interacts with the World Health Organisation (WHO), International Labour Office (ILO), International Commission on Radiological Units (ICRU), International Electrotechnical Commission (IEC), and Commission of the European Communities (CEC), to produce health criteria documents, safety codes, standards of radiation exposure and other publications in the NIR field. Within this Committee I am/was:
  - 1) Member of International Technical Program Committee for International Radiation Protection Association Congress (IRPA-7), Sydney, April, 1988.
  - 2) Convenor of International Non-Ionizing Radiation Workshop, Melbourne, April, 1988 (an INIRC/IRPA project).
  - 3) Member of International Technical Program Committee for IRPA-8 Congress, Montreal, May 1992.

- 4) Member of International Technical Program Committee for IRPA-9 Congress, Vienna, 1996.
- (iii) IEC: Member of the following International Electrotechnical Commission Committees for Canada until Dec. 1982:
- a) TC 62/SC 62D on Electromedical Equipment
  - b) TC 27 on Industrial Electroheating Appliances
  - c) TC 61 on Safety of Household Appliances
- (iv) AIUM: Member of the Biological Effects Committee of the American Institute for Ultrasound in Medicine until 1982.
- (v) IOMP: Canadian Delegate to the International Organization on Medical Physics (up to December, 1982).
- (vi) HPS: Health Physics Society Delegate to the International Radiation Protection Association Congress. (Paris 1977, Jerusalem 1980).
- (vii) WHO:
- a) Task Force participant to World Health Organization meeting on ultrasound (London, U.K. 1976).
  - b) Task Force participant to WHO meetings on electric and magnetic fields, and regulations and enforcement procedures for non-ionizing radiation (Freiberg, Germany 1978).
  - c) Task Force participant to WHO meeting for Environmental Health Criteria on microwave/RF (Geneva, Switzerland 1978).
  - d) Review group chairman for WHO meeting on microwave/RF criteria (Washington, D.C. 1979).
  - e) Participant in WHO review meeting on microwave/RF health criteria (Geneva, Switzerland 1980).
  - f) Task Force participant for WHO meeting for Environmental Health Criteria on lasers and optical radiation health criteria (Paris, France 1982).
  - g) Task Force chairman for WHO meeting for Environmental Health Criteria on ultrasound health criteria (Geneva, Switzerland 1982).
  - h) Task Force chairman of WHO meeting for Environmental Criteria on ELF electromagnetic fields health criteria (Geneva, Switzerland 1984).
  - i) Task Force rapporteur of WHO meeting for Environmental Health Criteria on magnetic fields health criteria (Kiev, USSR 1986).
  - j) Invited speaker on "Research and Development" for WHO Congress on Medical Devices Washington D.C. June 1986.

- k) Task Group chairman of WHO meeting for Environmental Health Criteria on Electromagnetic Fields in the range of 300 Hz to 300 GHz, Ottawa, Canada 22-26 October, 1990.
  - l) Secretariat for WHO meeting for Environmental Health Criteria on Ultraviolet Radiation, Geneva, Switzerland, 8-11 December 1993.
- (viii) International School of Radiation Damage and Protection Ettore Majorana Centre for Scientific Culture, Erice, Sicily.
- a) 3 lectures given to the School on Biological Effects and Dosimetry of Non-Ionizing Electromagnetic Radiations (March, 1981).
  - b) 2 lectures to School on Biological Effects and Dosimetry of Static and ELF Electromagnetic Fields (November, 1983).
  - c) Co-Director of School on Applications, Biological Effects and Dosimetry of Ultrasound (September, 1985).
  - d) 1 lecture to School on Optical Sources, Lasers & Synchrotron Radiation: Biological Effects and Hazard Potential (May 1989).
  - e) Director of School on Biological Effects Pulse Modulated RF fields (November, 1999).

## **RESEARCH EXPERIENCE**

### **1968 - 1969**

London University - Maintenance of cultured cell lines in mice, design and construction of apparatus for treating cell suspensions to ultrasound, care and handling of laboratory rodents over their lifetime, intraperitoneal injection of ascites cancer cells in mice, use of conventional laboratory techniques for treating and handling cell suspensions, use of cell electrophoresis, statistical analysis of experimental requirements and results. **Awarded M.Sc.**

### **1973 - 1980**

Ottawa University - Human lymphocyte culture techniques, cell concentration and viability methods, preparation and use of radioisotopes, use of mitogens, incorporation and analysis of radioactive precursors in cells, immunofluorescence techniques, autoradiography, fluorescence analysis of unwinding DNA, conventional and fluorescence microscopy, electron microscopy preparation and observational techniques, use of sterile techniques in laboratory procedures, statistical analysis of data. **Awarded Ph.D.**

### **1983 - 1991**

Royal Adelaide Hospital - Design and participation in development of new clinical techniques using medical lasers, performance of clinical trials for laser tonsillectomy and port wine stain removal, licensed by the IMVS to work with laboratory animals

for the development of clinical laser techniques, management and supervision of the clinical laser evaluation and teaching program.

### **1991-1995**

Australian Radiation Laboratory (seconded from Royal Adelaide Hospital) - Manager and principal investigator of large animal studies to investigate the carcinogenic influence of exposure to radiofrequency and power frequency fields.

### **SUMMARY OF RESEARCH GRANTS**

- 1988 Research Fund, Royal Adelaide Hospital** - \$4000 to investigate the use of sapphire tips with Nd:YAG lasers for tonsillectomy.
- 1989 South Australian Health Commission** - \$250,000 to investigate the clinical efficacy of treatment of port-wine stains and telangiectasias using the copper bromide laser.
- 1990 Electricity Commission of New South Wales** - \$125,000 to investigate the feasibility of conducting a childhood cancer study in Australia to determine if there is a cause-effect relationship with exposure to 50 Hz magnetic fields.
- 1991 Electricity Supply Association of Australia** - \$80,000 to investigate the feasibility of conducting a large, lifetime animal study in Australia to determine if exposure to 50 Hz magnetic fields is associated with the process of carcinogenesis.
- 1992 Electricity Supply Association of Australia** - \$1,002,000 to conduct a study on E1-PIM-1 mice to determine if exposure to 50 Hz magnetic fields is associated with carcinogenesis.
- 1992 Telecom Research Laboratories** - \$200,000 to conduct a study on mice to determine if RF field (900 MHz) exposure is associated with the process of carcinogenesis.

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- Alexander Meves and Michael Repacholi (2005). Does Ultraviolet Radiation Affect Vaccination Efficacy? Submitted to *Int J Dermatol*.
- Repacholi M. 2006 Key radiation projects at the World Health Organization (WHO). (2005) *Acta Med. Nagasaki* 50: 33-36
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- T.E. van Deventer, D. Simunic, M Repacholi, EMF standards for human health, chapter in *Handbook of Biological Effects of Electromagnetic Fields*, 3<sup>rd</sup> ed., F. Barnes and B Greenebaum, eds. (to be published September 2006)

Eric van Rongen, Richard Saunders, Emilie van Deventer and Michael Repacholi (2006) Static fields: Biological effects and mechanisms relevant to exposure limits. Health Physics In press

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Robyn M Lucas, Mike H Repacholi, Anthony J McMichael (2006) Is the current public health message on UV exposure correct? Bulletin of the WHO 86 (6), 485-491.

Esther S. Hong, Hajo Zeeb, Michael H. Repacholi (2006) Albinism in Africa as a public health issue. BioMed Central (in press)

Shunichi Yamashita and Michael Repacholi (2006) Chernobyl Telemedicine Project, World Health Organization, Geneva

Burton Bennett, Michael Repacholi and Zhanat Carr (editors). (2006) Health Effects of the Chernobyl Accident and Special Health Care Programmes. World Health Organization, Geneva

Cardis et al (2006) Cancer consequences of the Chernobyl accident: 20 years after. J Radiol. Prot. 26: 127-140

Kjell Hansson Mild, Mike Repacholi, Emilie van Deventer and Paolo Ravazzani (Editors) Electromagnetic Hypersensitivity. Proceedings of the International Workshop on EMF Hypersensitivity, Prague, Czech Republic, October 25-27, 2004. World Health Organization, EMF\_NET, Geneva (2006).

**Annex 2: Unformatted Draft WHO Framework provided to the EMF Project's International Advisory Committee for final review in June 2006. (It should be noted that this draft will undergo changes, particularly to the ELF and RF case studies, but the basic principles on which the Framework are based will remain)**

# **Framework**

## **Guiding public health policy options in areas of scientific uncertainty**

**5. With particular reference to  
Electromagnetic Fields**

**Draft for IAC Review**



For further information and comments contact:

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Radiation and Environmental Health Unit  
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Geneva 2006

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## PREFACE

The World Health Organization (WHO) exists to promote health, defined as:

**“a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity.”**

This Framework specifically considers potential health risks where there is significant scientific uncertainty. It presents an approach for applying precautionary measures that is rational and practical, that is informed by science, and that is consistent with public-health values and the WHO mission to promote and protect health. It recognizes the potential benefits new and conventional technologies bring to society and the differing needs of developed and developing countries.

As an international public health agency, WHO is cautious in its conclusions on health and safety issues, and bases its recommendations on sound and established scientific evidence. At the 1999 Conference of European Health Ministers<sup>1</sup>, WHO was asked to: “...elaborate guidelines on risk communication, having regard to relevant international work in this field and taking into account the need to rigorously apply the Precautionary Principle in assessing risks and to adopt a more preventive, pro-active approach to hazards.” At the Fourth Ministerial Conference on Environment and Health in Budapest (2004)<sup>2</sup>, the Ministerial Declaration states: "We call upon WHO to ensure that guidelines are developed with the aim of balancing the distribution of benefits and costs of environmental health measures and weighing up the health improvements and other benefits against anticipated costs..." In parallel with these actions at the European level, WHO's International EMF Project has developed this Framework in the particular context of electric and magnetic fields (EMF).

### Case studies

This Framework is illustrated with case studies concerning EMF in the extremely low frequency (ELF) and radio frequency (RF) ranges.

- Extremely low frequency (ELF) fields are produced by the generation and distribution of electricity and its use in electrical devices. The case studies in this document primarily address the generation and distribution of electricity.
- Radio frequency (RF) fields are produced by technologies such as broadcast radio and TV, industrial heating applications and mobile communications system. The case studies in this document address mobile phones and their base stations that provide the telecommunications services.

The case studies on ELF fields are well developed in this Framework because a full risk assessment has been completed. Even though a full risk assessment of RF fields has yet to be completed, examples of precautionary options are provided for mobile telecommunications based on current knowledge. These were selected due to public interest in the safety of the technology but do not represent a change to the policy or advice in previous WHO statements.

<sup>1</sup> [http://www.euro.who.int/eehc/conferences/20021010\\_2](http://www.euro.who.int/eehc/conferences/20021010_2)

<sup>2</sup> <http://www.euro.who.int/budapest2004>

Meetings that have contributed to the development of this framework include:

- a WHO Workshop on "Application of the Precautionary Principle", with particular reference to EMF, co-sponsored by the European Commission and US National Institute for Environmental Health Sciences, held in Luxembourg, 24-26 February 2003<sup>3</sup>;
- a Workshop entitled "Dealing with uncertainty: how can the precautionary principle help protect the future of our children?", co-organized by WHO and AFSSE (French Agency for Environmental Protection) held in Paris, 11-12 September 2003, part of the preparation of the European 4<sup>th</sup> Ministerial Conference on Environment and Health<sup>4</sup>;
- a Workshop on "Guiding Public Health Policy in Areas of Scientific Uncertainty" at the University of Ottawa, Canada, July 11-13, 2005, in collaboration with the McLaughlin Centre for Population Health Risk Assessment<sup>5</sup>.

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<sup>3</sup> [http://www.who.int/peh-emf/meetings/Lux\\_PP\\_Feb2003/en/index.html](http://www.who.int/peh-emf/meetings/Lux_PP_Feb2003/en/index.html)

<sup>4</sup> [http://www.euro.who.int/healthimpact/MainActs/20030709\\_2](http://www.euro.who.int/healthimpact/MainActs/20030709_2)

<sup>5</sup> [http://www.who.int/entity/peh-emf/meetings/ottawa\\_june05/en/index.html](http://www.who.int/entity/peh-emf/meetings/ottawa_june05/en/index.html)



## 1. Introduction to the Framework

### 1.1 Motivation

In the public health arena, priority is usually given to controlling risks that are clearly established, i.e. involving risks factors with a clear causal relationship to known diseases. Such an understanding may take decades to develop. However, rapid technological developments produce an ever-increasing variety of new agents and exposure situations whose health consequences are less clear, and societies increasingly wish to address these uncertain consequences.

Waiting for conclusive evidence of a health threat can have unfortunate consequences<sup>6</sup>. Therefore, where an agent is ubiquitous or the potential harm great or the possible effects are irreversible, it is sensible to consider taking precautions before a cause-effect relationship has been established. Precaution can be integrated into existing public-health policy and complement conventional disease-prevention actions, which are usually taken only after a cause-effect relationship has been established.

However, care must be taken to have a due process when establishing policies based on precaution. Not all suggested health risks turn out to exist. Indiscriminate use or overuse of precautionary measures may cause innovations with undoubted benefits to not be developed, or the benefits they bring to be delayed<sup>7</sup>. Further, it may lead to widely differing national policies and increased public anxiety.

These competing factors have motivated WHO to build a framework to guide public-health policy options in areas of scientific uncertainty using a rational and well-accepted process. This Framework gives clear guidance and is designed to prevent what could otherwise be confusion and excesses in either direction.

#### **Case study on the benefits of technology: EMF**

Most technologies that produce EMF bring considerable benefits to society. Broadcast radio and TV bring cultural, educational and democratic benefits; mobile communication systems bring specific safety benefits and undoubtedly save lives, as well as the general benefits of improved communication. The benefits of a public electricity supply are obvious.

### 1.2 Intended audience

This Framework has been developed for decision-makers in national and local governmental authorities, regulators as well as other stakeholders who are responsible for the development of policies, strategies, regulations and operational procedures within their areas of responsibility. These stakeholders have responsibility for deciding how to implement this Framework in their country based on their own cultural, economic and political factors. It is understood that the priority given to uncertain health consequences may be dealt with differently in developed and developing countries.

<sup>6</sup> See e.g. Gee, 2001 in Further Reading

<sup>7</sup> See e.g., Cross, 1996 in Further Reading.

### *1.3 Uncertainty in science*

Conventional scientific methods distinguish between “established” and “uncertain” effects of exposures to agents. In this case, established effects usually require the development of quantitative standards that limit exposure.

However, no science is ever absolutely certain. There are different types of uncertainty:

- There may be uncertainty about some of the details of a known effect, for example, the precise nature of the hazard, the exact exposure threshold or the resultant extent of harm. This type of uncertainty always exists to some degree even for “established” effects and is allowed for when setting guidelines or standards by introducing safety factors.
- There may be some scientific evidence of an adverse health effect, but insufficient for establishing a causal relationship between the exposure and the effect. The evidence can vary from little more than speculation up to almost enough scientific evidence to regard the effect as established.
- There may be little scientific evidence because the necessary research has not been done. This can be described as “ignorance” but some extrapolation may be possible from understanding of other agents or exposures<sup>8</sup>.

This Framework deals with situations where there is uncertainty of the second and third types, that is, there is insufficient scientific evidence to be confident that there actually is any health effect. The role of science is not confined only to describing “established” effects, but also to identifying gaps in knowledge. Scientific uncertainties can be reduced by further scientific research. Robust outcomes are usually achieved by repeated or replicated results.

### *1.4 Guiding principles*

This Framework has been developed using a number of guiding principles:

- **The goal of protecting public health from uncertain, potentially far-reaching hazards must guide the process of decision making from the very beginning.** It is better to anticipate possible health problems than to mitigate adverse impacts after they occur.
- **Science is the fundamental basis for application of this Framework.** Application of precaution to public health policies should build on rigorous scientific assessment and the accompanying uncertainties.
- **Precaution should be seen as an overarching approach.** Traditionally, separate processes are identified, such as hazard identification, risk assessment, and risk management. Precaution has often been linked to the risk-management stage only, and has been regarded as an additional process, invoked or triggered only when a certain level of evidence is exceeded. The basic premise of this Framework is that precaution should be viewed as an overarching philosophy that is to be applied to all aspects of assessing and managing an actual or potential health risk. The

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<sup>8</sup> K Morgan. Development of a Preliminary Framework for Informing the Risk Analysis and Risk Management of Nanoparticles. *Risk Analysis*, 25(6):1621- 1635, December 2005.

various stages are closely integrated, and precaution is an approach that informs every stage and for all risks, rather than being triggered only under specific circumstances.

- **Decisions about precautionary measures should be informed by proper consideration of the likely consequences of each measure.** Factors considered should include the strength of the scientific evidence, technical feasibility, estimated health benefits, economic benefits and costs, non-monetary societal costs, effect on public concern and political realities.
- **Public concern may be a trigger for reviewing an exposure situation.** The debate on whether precautionary action is warranted, and if so what action is appropriate, often takes place when a potential, unproven risk factor is causing public concern. This is entirely legitimate as long as the decisions are made in accordance with the principles that underlie this Framework. However, when precautionary measures are selected and implemented without due process, or in an arbitrary way merely to placate public concern, greater and not less public concern can follow<sup>9</sup>

**Case study on the role of public concern: RF**

While no health risk has been established for radio-frequency technologies, and suggestions of risks from scientific studies are currently weak, there is considerable public concern in many countries about exposure from mobile-phone base stations. Such concern, rather than uncertainty in the scientific findings, has been driving calls for precautionary measures.

- **A partnership approach between key stakeholders is important.** Perspectives based on social and cultural factors and ethical values constitute the context that ultimately determines the policy decisions<sup>10</sup>. Decisions taken will be more credible and accepted if interested and affected parties participate in the evaluation of risks and interventions. How this is done will vary from risk to risk, from stakeholder to stakeholder, and from country to country<sup>11</sup>.

**Case study on stakeholders: RF and ELF**

Stakeholders should include government, academics, citizen groups, other affected professionals such as planners and real estate professionals, school administrators and industry, including the electricity industry and appliance manufacturers for ELF and the mobile-phone manufacturers and telecommunications operators for RF.

- **The transparency of the whole process should be promoted through communication and consultation with stakeholders at all appropriate stages.** Within the regulatory process, the application of precaution should be transparent to all stakeholders and should maintain the link between scientific evidence of potential harm and action. All risk-management action should ensure the

<sup>9</sup> Wiedemann and Schütz. The Precautionary Principle and Risk Perception: Experimental Studies in the EMF Area. *Environmental Health Perspectives*. 113(4):402-405.

<sup>10</sup> JR Masuda and T Garvin, Place, Culture, and the Social Amplification of Risk, *Risk Analysis* 26(2):437-454, April 2006

<sup>11</sup> On Science And Precaution In The Management Of Technological Risk, Volume I: A Synthesis Report of case studies, EUR 19056/EN, May 2001 and Volume II: Case Studies, Joint Research Centre Institute for Prospective Technological Studies (JRC-IPTS), EUR 19056/EN/2, November 2001.

effectiveness of regulatory decisions, and seek to secure the trust of all stakeholders.

- **This Framework is not based on ‘zero risks’** but aims to achieve lower or more acceptable risks or hazards. It is a rational decision rule, based on societal values, and aims to use the best science and processes to make wiser decisions.

### **1.5 Relationship to other frameworks**

As exemplified below, there are many differing formulations and terminology regarding the precautionary principle in international law<sup>12</sup>. The *precautionary principle* is usually seen as the philosophical basis and the *precautionary approach* as its practical application.

<p><b>The Ministerial Declaration Calling for Reduction of Pollution (1987)</b> <i>"In order to protect the North Sea from possibly damaging effects of the most dangerous substances, a precautionary approach is addressed which may require action to control inputs of such substances even before a causal link has been established by absolutely clear scientific evidence"</i></p>
<p><b>The Rio Declaration on Environment and Development (1992)</b> <i>"In order to protect the environment the <b>Precautionary Approach</b> shall be widely applied by states according to their capabilities. Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation".</i></p>
<p><b>Treaty on European Union (Maastricht Treaty) (1992)</b> <i>"Community policy on the environment... shall be based on the <b>precautionary principle</b> and on the principles that preventive actions should be taken, that the environmental damage should as a priority be rectified at source and that the polluter should pay."</i></p>
<p><b>United Nations Framework Convention on Climate Change (1992)</b> <i>"The Parties should take precautionary measures to anticipate, prevent or minimize the causes of climate change and mitigate its adverse effect. Where there are threats of serious or irreversible damage, lack of full scientific certainty should not be used as a reason for postponing such measures, taking into account that policies and measures to deal with climate change should be cost-effective so as to ensure global benefit at the lowest possible cost."</i></p>
<p><b>Convention on the Protection and Use of Transboundary Watercourses and International Lakes (1992)</b> <i>"The precautionary principle, by virtue of which action to avoid the transboundary impact of the release of hazardous substances shall not be postponed on the ground that scientific research has not fully proved a causal link between those substances, on the one hand, and the potential transboundary impact, on the other hand..."</i></p>
<p><b>European Environment Agency (2004)</b> <i>"The <b>Precautionary Principle</b> provides a framework, procedures and policy tools for public policy actions in situations of scientific complexity, uncertainty and ignorance, where there may be a need to act before there is strong proof of harm in order to avoid, or reduce, potentially serious or irreversible threats to health or the environment, using an appropriate level of scientific evidence, and taking into account the likely pros and cons of action and inaction."</i></p>

<sup>12</sup> Precaution from Rio to Johannesburg: Proceedings of a Geneva Environment Network roundtable, GE 2002-01920/E, 2002.

A formal treatment of the precautionary principle by the European Commission was published in a Communication in 2000 (EC, 2000). This states: “Where action is deemed necessary, measures based on the precautionary principle should be, inter alia:

- proportional to the chosen level of protection;
- non-discriminatory in their application;
- consistent with similar measures already taken;
- based on an examination of the potential benefits and costs of action or lack of action (including, where appropriate and feasible, an economic cost/benefit analysis);
- subject to review in the light of new scientific data;
- capable of assigning responsibility for producing the scientific evidence necessary for a more comprehensive risk assessment.”

This Framework incorporates most of the guiding principles enunciated by the European Commission, but differs by incorporating precaution at both risk assessment and risk management stages.

A number of countries have incorporated precaution into their decision making processes, some in an informal way, and others using a formal approach<sup>13</sup>.

- The Government of Canada has developed a “Framework for the Application of Precaution in Science-Based Decision Making About Risk”. This Framework outlines guiding principles for federal regulatory activity to protect health and safety, as well as the environment and natural resources.
- In New Zealand, the Resource Management Act (1991) requires specific considerations of risks that are defined as “of low probability but high potential impact”.
- In Switzerland, the Precautionary Principle is enshrined in law and is a well-established instrument of risk analysis.
- In the UK, the Interdepartmental Liaison Group on Risk Assessment (ILGRA) has published *The Precautionary Principle: Policy and Application* (2002). The purpose of ILGRA is to help secure coherence and consistency within and between policy and practice in risk assessment as undertaken by Government, and help disseminate and advance good practice. ILGRA reports to Ministers.

Under the umbrella of the United Nations Educational and Scientific Organization (UNESCO) the World Commission on the Ethics of Scientific Knowledge and Technology (COMEST, 2005) proposed a clear definition of the precautionary principle and provide clarification of the possible uses of this principle, aiming at offering an ethical platform to ensure proper risk management and correct information to the public and to policy makers, in view of the impact of new technologies.

The COMEST report stated the following as a working definition of the precautionary principle (p.14).<sup>14</sup>

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<sup>13</sup> See Further Reading

<sup>14</sup> *The Precautionary Principle*, World Commission on the Ethics of Scientific Knowledge and Technology (COMEST), UNESCO, March 2005

### Precautionary Principle, a working definition

When human activities may lead to morally unacceptable harm that is scientifically plausible but uncertain, actions shall be taken to avoid or diminish that harm.

*Morally unacceptable harm* refers to harm to humans or the environment that is

- ◆ threatening to human life or health, or
- ◆ serious and effectively irreversible, or
- ◆ inequitable to present or future generations, or
- ◆ imposed without adequate consideration of the human rights of those affected.

The judgement of *plausibility* should be grounded in scientific analysis. Analysis should be ongoing so that chosen actions are subject to review.

*Uncertainty* may apply to, but need not be limited to, causality or the bounds of the possible harm.

*Actions* are interventions that are undertaken before harm occurs that seek to avoid or diminish the harm. Actions should be chosen that are proportional to the seriousness of the potential harm, with consideration of their positive and negative consequences, and with an assessment of the moral implications of both action and inaction. The choice of action should be the result of a participatory process.

The COMEST report also discusses what the precautionary principle (PP) is not (p.16).

To avoid misunderstandings and confusions, it is useful to elaborate on what the PP is not. The PP is not based on 'zero risks' but aims to achieve lower or more acceptable risks or hazards. It is not based on anxiety or emotion, but is a rational decision rule, based in ethics, that aims to use the best of the 'systems sciences' of complex processes to make wiser decisions. Finally, like any other principle, the PP in itself is not a decision algorithm and thus cannot guarantee consistency between cases. Just as in legal court cases, each case will be somewhat different, having its own facts, uncertainties, circumstances, and decision-makers, and the element of judgement cannot be eliminated.

The COMEST description of what the Precautionary Principle is and is not enunciates the principles on which this Framework is based.

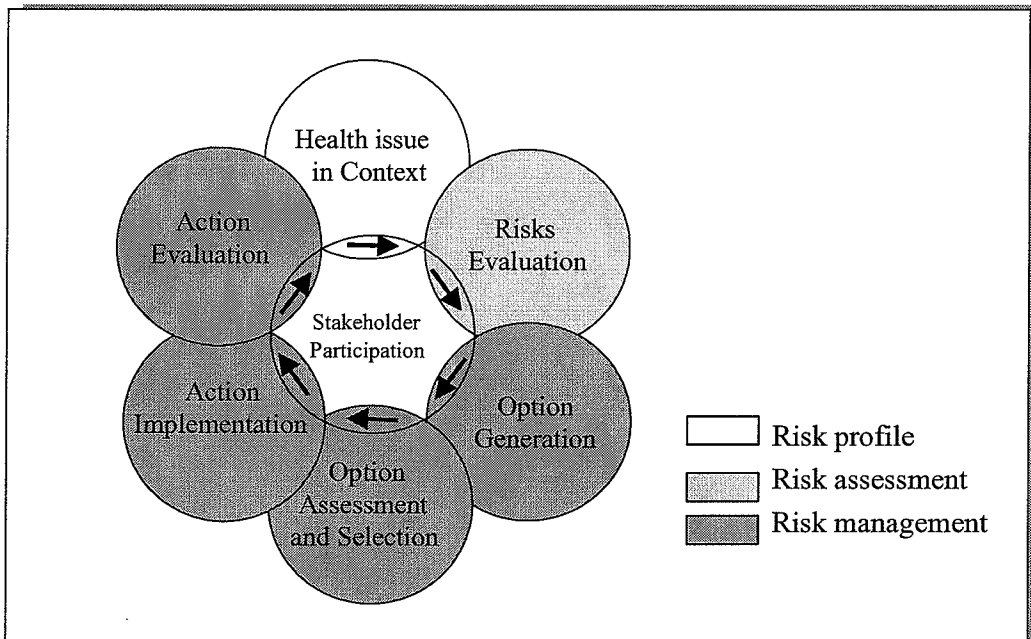
## **2. Applying the Framework**

The process of identifying, assessing and managing risks can helpfully be described in terms of a number of steps, although in reality, these steps overlap and merge into each other. One such analysis, used as a basis for this Framework, is described in the US Presidential/ Congressional Commission on Risk Assessment and Risk Management (1997)<sup>15</sup>, though other descriptions are just as valid. This particular

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<sup>15</sup> Framework for Environmental Health Risk Management, The Presidential/Congressional Commission on Risk Assessment and Risk Management, Final Report, Volume 1, 1997, pp. 23-24.

analysis splits the process into six stages, which are followed in an iterative way, with stakeholder involvement at each stage (Figure 1).



**Figure 1 - Dealing with risk: A risk analysis process**

The Presidential/Congressional Commission on Risk Assessment and Risk Management discusses treatment of uncertain risks at several points and this section takes each of the six stages and describes how that this Framework applies to that stage.

### **Applying the Framework in practice**

Before starting to apply this Framework in a particular country, it is useful to determine:

- What is the legislative framework that provides for the process to commence?
- Which department, agency, or other group has the responsibility?
- Who are the appropriate scientific experts, government or agency representatives, and other stakeholders?

#### **2.1 Health issue in context**

A starting point of placing the health issue in context is consideration of both the nature of the potential hazard and the actual exposure. In this Framework the social and political contexts are added to such considerations and the public is encouraged to

contribute to the formulation of criteria to determine how seriously risks are regarded. In particular, many societies will perceive situations as more serious<sup>16 17</sup>,

- if the risks affect **vulnerable populations** such as the infirm and the elderly or the economically deprived. The child and the foetus are often afforded an even higher level of protection because of their possible increased vulnerability, greater potential for exposure over their lifetime, and because they represent the future of the society.
- if the distribution and magnitude of risk and consequent adverse health outcomes are **inequitable**, particularly where risks fall on groups who are already less privileged or unable to take protective actions.
- if exposures are **ubiquitous**, because even a health risk that, for an individual, is relatively small and thus difficult to detect, may have significant public-health consequences if it affects many people.
- if the nature of the health effect causes **particular dread**, such as cancer. Other maladies, such as headaches and sleeplessness, are not life threatening and are often treatable, but can nevertheless have a profound influence on an individual's well-being and productivity.
- if the risks are **poorly understood** or outside normal experience.
- if the risks are **involuntary** or outside the control of the exposed individual. Societies and individuals generally tolerate higher risks if they are voluntary.

#### **More acceptable and less acceptable risks**

- Smoking or rock climbing are voluntary risks largely within the person's own control: higher risks are accepted. (*Voluntary*)
- Driving a car brings an obvious benefit and some, albeit limited, control over the risk: higher risks are accepted. (*Voluntary/imposed*)
- Travel in trains or aeroplanes are voluntarily adopted risks but largely outside the individual's control (and may harm many people at once): regulators usually require the risks to be lower. (*voluntary/Imposed*).
- Clean water supplies are critical for public health and largely outside the control of the individual so high standards are required to reduce the risks to very low acceptable levels. (*Imposed*)

<sup>16</sup> See Slovik 1987 in Further Reading

<sup>17</sup> Kheifets L, Repacholi M, Saunders R, van Deventer E, "Sensitivity of Children to EMF", *Pediatrics* Vol. 116 No. 2 August 2005, pp. 303-313



### **Case study on acceptability of risks: ELF and RF**

Electricity that produces ELF fields brings undeniable benefits to society. However, ELF magnetic fields have been classified as “possibly carcinogenic” by the International Commission for Research on Cancer (IARC). The evidence that led to this classification was solely the epidemiological evidence concerning childhood leukaemia<sup>18</sup>. In this case the acceptability of the risk relates to the fact that the disease affects children and that cancer attracts particular dread. The exposure (e.g. from power lines) is largely involuntary and there is evidence that, in some situations, the exposure burden may fall disproportionately on lower socio-economic status groups.

Mobile communications delivers important social, economic and personal safety benefits and, to date, all expert reviews have concluded that there are no established adverse health consequences at RF exposures below the international guidelines.<sup>19</sup> RF exposure from mobile phones is largely voluntary, and such technology brings clear benefits to the user, but societies are nonetheless still particularly concerned about exposure to children. In contrast, RF exposures from base stations is largely involuntary, but of less scientific concern because of the very low levels of exposure.

## **2.2 Risk evaluation**

For traditional risk assessment:

- The overall evaluation is based on the weight-of-evidence. The science must be rigorous, with input provided by many specialized disciplines, and mainly based on publications in peer-reviewed journals.
- Scientific uncertainties in the assessment of risk should be identified and clearly stated. Uncertainties can exist at every level of risk assessment: the existence of a hazard, the magnitude of exposure, and the relationship of dose to disease incidence or severity.
- Assumptions necessary for the assessment of risk should be identified and clearly stated. When evidence is limited, science-based assumptions or extrapolations are often used; for example, extrapolating known effects at high exposures to possible effects at lower exposures.

This Framework places emphasis on identifying the uncertainties, including considering what is not known in addition to what is known but uncertain. A description of where key scientific evidence (e.g. epidemiological or toxicological studies) is missing or inadequate is especially important. Also, the relevance of the available evidence to real-life exposure situations needs to be carefully scrutinized.

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<sup>18</sup> <http://www.who.int/mediacentre/factsheets/fs205/en/>

<sup>19</sup> paraphrase of [http://www.who.int/peh-emf/meetings/ottawa\\_june05/en/index4.html](http://www.who.int/peh-emf/meetings/ottawa_june05/en/index4.html)

## The use of scientific evidence

Things to remember:

- An abundance of data does not automatically mean a high degree of knowledge.
- Failure to demonstrate an adverse effect does not rule out its possible existence, since the test system used may not have been sensitive enough to detect any effect
- Failure to demonstrate an adverse health effect in a limited timeframe does not rule out the possibility that there may be some consequence sometime in the future
- Results of diverse studies (cellular, animal, and epidemiology) must be considered together before drawing conclusions about possible health risks. Consistent evidence from these very different types of studies increases the degree of certainty about a true effect or the absence of an effect.<sup>20</sup>

## Case study on uncertainties: ELF

There is uncertainty whether the epidemiological evidence with regard to childhood leukaemia reflects causality or not. This uncertainty stems from:

- the likelihood that some amount of bias may be present
- the possibility that confounding may be present
- the absence of reliable supporting evidence from in vivo or in vitro experiments
- limited plausibility derived from consideration of mechanisms.

All these uncertainties are already captured by the IARC 2B classification as “possibly carcinogenic”.

If magnetic fields are a cause of childhood leukaemia, the chief uncertainties in assessing the risk are:

- Uncertainty as to the relevant aspect or metric of exposure. Long-term time-weighted average exposure in the home has been used in epidemiology but in part for pragmatic reasons, and may be a marker for some other aspect of exposure.
- Uncertainty as to exposure-response relationship. If long-term average is indeed the correct metric, it is not known whether there is a threshold (at 0.3 - 0.4  $\mu\text{T}$  or any other value) or a smooth function, and if a smooth function, what shape.
- Uncertainty as to the for disease causation/promotion relevant period and duration-response relationship

In view of these uncertainties, a possible working assumption is that measures aimed at reducing any aspect of average exposure to children across the population would indeed reduce the risk if there is one; but a recognition that any specific measure that reduces exposure is unlikely to reduce precisely the relevant aspect of exposure.

<sup>20</sup> <http://www.who.int/peh-emf/about/WhatisEMF/en/index2.html>

### Case study on uncertainties: RF

The chief uncertainties in assessing the RF risk are:

- Only few diseases have been studied
- Potential susceptibility of children has been suggested, but crucial data is lacking
- Few people have been exposed for more than 10 years, thus long term effects are uncertain.
- Technology is rapidly changing making evaluation more difficult

In view of these uncertainties and wide spread exposure some precaution is warranted

### 2.3 Option generation

Options for precautionary action are not limited to traditional quantitative exposure limits, and various alternatives should be identified and evaluated in the decision-making process. If this is done at the initial stages of a potential problem, for example when a new technology is proposed, it is more likely that alternative courses of actions can be identified that preserve societal benefits while averting potential health hazards.

This Framework encourages consideration of a full range of alternatives and options. It includes options involving individual choice, behaviour modification, education, voluntary initiatives and market incentives. Where removing or reducing the exposure is not feasible, options to minimize the seriousness of the health outcome (e.g. increased medical surveillance) or to reduce scientific uncertainties should be evaluated.

#### General examples of policy options

- A **decision to take no formal action** may be an appropriate response in cases where the risk is considered too small or the evidence too weak.
- **Further scientific research** is always an appropriate response to fill gaps in knowledge, and allow for a better assessment of risk in the future. It can help identify potential problems or strengthen the view that there is not a problem.
- A **protection program** is useful if it is transparent in monitoring the results of research and measurement, and informs the decisions being made by standard-setters, regulators, and others. This provides an early warning measure.
- **Consultation, communication and engagement programmes** can be used to help people voice their concern, understand the issues, become involved in the process and express their own choices about what to do.
- **Labelling** can sometimes be used to alert people to the exposure level from a device or technology and allow people to choose the lower exposure option.
- Methods designed to produce **reductions in exposure** or, in the extreme, banning the source of exposure altogether are options to be used when the degree of scientific certainty of harm is high, when the costs of limitations or bans are low, or both. Reducing exposure might include, for example, industry codes of practice, or economic incentives.
- **Voluntary behavioural change** may be chosen to avoid or reduce exposure, if easily achievable.

- **Special measures** may be appropriate for possibly vulnerable populations or groups.
- **Numerical standards** are formal steps taken to limit both the occurrence and consequences of potentially risky events and are usually based on established risks. These may be imposed with defined methods of showing compliance, or they may state the objectives to be achieved without being prescriptive.

**Case study on available options: ELF**

Possible precautionary measures for ELF will vary from country to country and may include:

- **No action**
- **Research**
  - Continued research to remove uncertainties in the science
  - Further research on sources and distribution of exposure in different countries to allow more informed option generation
- **Communications**
  - Increased provision of information to the public, particularly information on sources of exposure and ways of reducing exposure by individual lifestyle choices, to make it easier for members of the public to adopt individual precautionary approaches if that is their choice
- **Engineering measures**
  - Enforcement of approved wiring practices in distribution systems and buildings to reduce magnetic fields (this possibility arises because a major source of magnetic fields is ground currents, and ground currents sometimes arise from incorrect wiring)
  - Changes to distribution wiring practices to reduce ground currents (not all ground currents are accidental, many arise from the legitimate multiple grounding of neutral conductors)
  - Other engineering changes to distribution or transmission systems (it is possible to reduce fields by raising ground clearances, split-phase designs, undergrounding, etc)
  - Changes to design of domestic appliances to reduce magnetic fields
- **Land-use and planning measures**
  - Changes to reduce exposures from high-voltage overhead lines (this includes changes to procedures for assessing the need for and siting of new lines, and changes to rules on land use that affect homes and schools in proximity to power lines)
- **Exposure limits**
  - Exposure limits should be based on established effects and should not be reduced as a precautionary approach for ELF.

Options may need considering separately for retrospective and prospective application.

#### **Case study on available options: RF**

Possible precautionary measures for RF have been suggested in a WHO Fact Sheet (<http://www.who.int/mediacentre/factsheets/fs193/en/>). These include:

- **Governmental actions:** If regulatory authorities have adopted health-based guidelines but, because of public concerns, would like to introduce additional precautionary measures to reduce exposure to RF fields, they should not undermine the science base of the guidelines by incorporating arbitrary additional safety factors into the exposure limits. Precautionary measures should be introduced as a separate policy that encourages, through voluntary means, the reduction of RF fields by equipment manufacturers and to the public.
- **Hands-free-kits:** If individuals are concerned, they might choose to limit their own or their children's' RF exposure by limiting the length of calls, or using "hands-free" devices to keep mobile phones away from the head and body.
- **Avoid EMF interference:** Mobile phones may interfere with certain electro-medical devices, such as cardiac pacemakers and hearing aids. In hospital intensive care departments mobile phone use can be a danger to patients and should not be used in these areas. Similarly mobile phones should not be used in aircraft as they may interfere with its navigation systems.
- **Driving safety:** In moving vehicles there is a well established increase in the risk of traffic accidents while the driver is using a mobile phone, either a conventional handset or one fitted with a "hands free" device. Motorists should be strongly discouraged from using mobile phones while driving.
- **Consultations with the community on siting base stations:** Base station sites must offer good signal coverage and be accessible for maintenance. While RF field levels around base stations are not considered a health risk, siting decisions should take into account aesthetics and public sensibilities. Siting base stations near kindergartens, schools and playgrounds may need special consideration. Open communication and discussion between the mobile phone operator, local council and the public during the planning stages for a new antenna can help create public understanding and greater acceptance of a new facility.
- **Providing information:** An effective system of health information and communications among scientists, governments, industry and the public is needed to raise the level of general understanding about mobile phone technology and reduce any mistrust and fears, both real and perceived. This information should be accurate, and at the same time be appropriate in its level of discussion and understandable to the intended audience.
- **RF absorbing devices:** Scientific evidence does not indicate any need for RF-absorbing covers or other "absorbing devices" on mobile phones. They cannot be justified on health grounds and the effectiveness of many such devices in reducing RF exposure is unproven.

### **The role of exposure limits**

Guidelines setting quantitative limits on human exposures to environmental agents are normally introduced only on the basis of consistent, reproducible data, confirmed by different laboratories and establishing the levels of exposure to these agents that are harmful to humans. Exposure limits generally incorporate safety or reduction factors that allow for uncertainty. Such approaches, where justified by the scientific data, remain central to this Framework. It is never appropriate to implement precaution by additional, arbitrary reductions to exposure limits, which devalues their scientific credibility.

### **Case study on quantitative limits: ELF and RF**

For ELF and RF, there are international exposure guidelines published by ICNIRP<sup>21</sup>. These have been determined on the basis of established health effects, using scientific criteria developed over many decades. ICNIRP states that the evidence for ELF magnetic fields causing cancer or other health effects at lower levels is insufficient to set exposure limits. For example, quantitative ELF exposure limits at e.g. 0.3 or 0.4  $\mu\text{T}$  are not appropriate because:

- there is too much uncertainty in the interpretation of the epidemiological studies to be confident that these are indeed the appropriate levels;
- simplistic application of limits at these low levels is likely to have costs hugely disproportionate to any health benefit.

Similar arguments are applicable for RF.

## **2.4 Option assessment and selection**

### **Option assessment**

Option assessment for established risks is based on scientific, technical and economic information. Priority is given to preventing the risks, wherever possible, not just controlling them. Sometimes there is a requirement to remove or to reduce a risk to a specified level regardless of cost. More usually, however, option assessment for established risks is undertaken using a health-economics analysis to identify the most efficient way to achieve a particular exposure reduction or health protection goal.

#### **Assessment of costs**

Costs are not just financial but include other societal consequences as well, e.g., increased concern, or possible risk substitution, or diversion of scarce public health resources. Assessment should include any increase in a different aspect of exposure (risk offset), re-distribution of exposures among people or populations (risk transfer), or creation of new risks (risk transformation)<sup>22</sup>. It is important to avoid assuming that the consequences can be adequately expressed in terms of a single number representing a reduced exposure.

<sup>21</sup> See ICNIRP 1998 in Further Reading

<sup>22</sup> Alcock and Busby. Risk Migration and Scientific Advance: The Case of Flame-Retardant Compounds, Risk Analysis 26(2):369-381, April 2006.

Costs can be separated into three components: initial costs (actual costs of implementing the intervention), ongoing costs (any recurring costs directly created by the intervention or required to keep the benefits of the intervention in place) and consequential costs (costs created as a consequence of the intervention).

#### **Assessment of benefits**

The value a society places on the reduction of risk or disease assumes the reduction would actually occur, i.e. that there is a known risk. Where the risk is uncertain the benefit from removing the exposure has also to be considered uncertain. Nevertheless the effectiveness of different measures to prevent or reduce a potential adverse health effect needs to be estimated. To that end, health outcomes need to be clearly reported, for example as the number of fatalities avoided, reductions in disease incidence, or years of life lost. Effectiveness can be measured in terms of disability-adjusted life years (DALYs) gained by the option<sup>23</sup>.

Option assessment within this Framework extends the same principles to uncertain risks.

#### **Analysis of costs and benefits**

Cost-effectiveness analysis assesses the costs of different methods of achieving the same health benefit. Where different options produce different health benefits, a cost-benefit analysis is performed instead: the value to society of the health benefit is expressed in monetary terms, derived either from an observation of how much money a society is prepared to spend, or from the effect of health on economic productivity.

The cost-benefit or cost-effectiveness analysis should be performed at the level of the whole society. It will therefore encompass all costs regardless of who might bear them, be it industry, taxpayers or others. Costs always have consequences, not least through the established association between disposable income and health. On the other hand, actions often lead to unanticipated benefits. Proper application of the Framework should also address these consequences.

There will always be scientific and other uncertainties, in the assessment both of the costs and the benefits. All significant uncertainties and assumptions should be explicitly allowed for and declared in any cost-benefit calculation.

The analysis should recognize social factors whereby society may sometimes wish to err on the side of caution and incur greater costs, in excess of the expected benefit.

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<sup>23</sup> <http://www.who.int/healthinfo/boddaly/en/>

**Case study on assessing costs and benefits: ELF**

An indication of the costs and the benefits that will need considering for each option is given in the following table.

<b>Precautionary option for ELF</b>	<b>Benefits of using the option</b>	<b>Costs or negative impact of not using the option</b>
Take no action	No immediate costs incurred	No possibility of reducing burden of disease, if it exists.
Research	Potential to reduce or remove uncertainties and allow better decisions in future.	No progress towards removal of uncertainties and better knowledge in future. Research into other risk factors not available.
Communication	Increases the knowledge base and potential acceptability.	Possibility of creating undue alarm or concern. May have limited effectiveness where exposure is not easy to understand or is involuntary and hard to avoid
Remove wiring errors	May have safety benefits and potential exposure reduction	A significant part of the cost may be in identifying the errors. Costs for rewiring likely to be substantial.
Changes to grounding practices	Possible reduction in exposure to magnetic fields	Costs are likely to vary greatly when comparing new installations with changes to existing installations.
Burying power lines	Reduction of exposures, particularly for electric fields, and possibly for magnetic fields. Better aesthetics and real estate values.	Economic cost very high.
Changed appliance design	Lower exposures	Increased cost (or increased size or weight) of appliances is a factor. But this may be offset if presented as a consumer choice in combination with suitable information.
Use rights-of-way along power line corridors	Allows easier line maintenance	Costs may include non-use of land, devaluation of property, and compensation payments.

**Case study on assessing costs and benefits: RF**

An indication of the costs and the benefits that will need considering for each option is given in the following table.

<b>Precautionary option for RF</b>	<b>Benefits of the option</b>	<b>Costs or negative impact of not taking up the option</b>
Take no action	No immediate costs incurred	No progress towards removal of uncertainties
Research	Ability to remove uncertainties and allow better decisions in	No progress towards removal of scientific uncertainties and better



Precautionary option for RF	Benefits of the option	Costs or negative impact of not taking up the option
Communication	future. May be effective to better understand the technology and its deployment	knowledge in future. Possibility of creating undue alarm or concern.
Information on mobile phone SAR	Allows informed consumer choice	This is only one of several factors influencing exposure reduction and others may be more effective
Agreements on development of mobile networks between operators and national authorities	Increases transparency and acceptability, and provides consistent procedures for siting new base stations.	May not resolve all public concerns about individual base stations
Use of hands-free-kits	Reduced exposure to the head; voluntary and easy option to lower exposure for concerned users; low cost	Possible higher exposure to other parts of the body where the phone is located during use
Prohibition of mobile phone use while driving	No direct cost, significant reduction in car accidents	No reduction in car accidents, cost for authorities to police

Other precautionary options have been used by some countries. These include lowering the exposure limits (not recommended by this Framework) and policies on selective siting of base stations away from areas of public concern (e.g. schools and hospitals). In both cases, there is no evidence that public concern is reduced by these measures and in the case of selective siting, this often leads to reduced mobile phone coverage and could lead to increased personal exposure from the higher transmitted power from both base stations and mobile phones.

The complexity of the assessment of costs and benefits should depend on the strength of evidence for a risk. Where, for example, the International Agency for Research on Cancer (IARC) or a body with similar mandate classifies an agent as “possibly carcinogenic” (or equivalent for non-cancer health outcomes), the analysis should be reasonably quantitative, as far as the scientific evidence permits. In this case, option assessment can include those options with very low costs. However, no matter how low the apparent cost of an intervention, at least a rudimentary cost-benefit analysis should be undertaken to ensure that an apparently “low cost” option really is low cost yet effective in achieving its intended benefit. Where the classification is less than this (e.g. insufficient evidence, IARC Group 3), the option assessment will inevitably be less quantitative and even lower cost options should only be considered.

### ***Option selection***

An appropriate option or options should be selected using the following criteria:

- Based on an examination of the potential health **benefits and costs** of action or lack of action, using cost-benefit or cost-effectiveness analysis as discussed above.
- Protection should be proportional to the **level of evidence**

- Allowing for **social and cultural factors** which lead society to regard some risks as more serious than others.
- **Proportionate** to the level of protection desired in society in general, recognizing that risk can rarely be reduced to zero.
- **Consistent** with similar measures already taken for other health risks.
- **Non-discriminatory** in their application, treating comparable situations in comparable ways.
- **Subject to periodic review**, in the light of new scientific evidence.

Scientific evidence influences option selection: stronger evidence, particularly of a pervasive, severe or irreversible health effect, supports more intervention. Weaker evidence tends to support selection of less interventionist actions. Where there are no- or low-cost options that reduce exposure, they can be implemented with little further debate after due consideration of what constitutes “low-cost” and the potential impact on public concern. As the cost of the option and the uncertainty of a health benefit increases, the importance of an analysis of the cost-effectiveness increases.

At one extreme, selecting the action of banning an agent or activity may depend on whether or not an alternative is available. If so, the implications of the alternatives for potential health effects, costs and benefits must be evaluated. All evaluations need to compare the benefits provided by the agent or activity with its potential detrimental effects. At the other extreme, taking no formal action is often assumed to be the most benign option. However, taking no formal action should also be evaluated employing a similar methodology, including any costs due to public opposition or increased anxiety, which itself is detrimental to well-being.

The weight of scientific evidence, political, environmental, social, economic and other factors will need to be made explicit when selecting actions on the basis of precaution. Transparency is key to the commitment and trust of stakeholders.

#### **Case study on option selection: ELF**

For ELF magnetic fields and childhood leukaemia, the epidemiological evidence suggests a relative risk of approximately 2, applying to children living in homes where the long-term average field (24 hours or longer) over the general volume of the house is 0.3 - 0.4  $\mu\text{T}$  or more. It would be proportionate to the general level of protection in society and consistent with other measures to act to reduce such a risk if it were known to be causal. However, childhood leukaemia is a rare disease, the prevalence of these exposures is low, and there is considerable scientific uncertainty as to whether a risk exists and/or is related to magnetic fields. Even after fully allowing for the legitimate desire by society to err on the safe side, only very low-cost measures will be justified.

Specifically:

- Exposure limits set at 0.3 - 0.4  $\mu\text{T}$  or similar levels are not scientifically justifiable. Exposure limits should continue to be based on effects scientifically regarded as “established” and reducing setting exposure limits as a precautionary measure is not justified.
- Any measures involving changes to engineering practice seem unlikely to be justifiable, unless they bring other benefits as well, such as greater safety, or unless local circumstances mean they are of particularly low cost.

- It seems unlikely that a precautionary approach to ELF alone could justify a change to distribution grounding practices, but ELF should be considered alongside safety, reliability and economics when changes are contemplated.
- Appliance manufacturers should investigate whether magnetic fields could be reduced at low cost, and whether offering consumer choice of low-field appliances could be an advantageous marketing strategy.
- Enforcing existing wiring codes so as to reduce unintentional ground currents must be sensible, but high costs in proactively seeking out and identifying existing errors and correcting them are unlikely to be justifiable.
- Route planning and land-use regimes for high-voltage power lines can incorporate genuinely low-cost options, but the costs and consequences of changes to existing regimes is so dependent on national circumstances that no generalization is possible.
- Continuing research is desirable to remove uncertainty in the future.
- Communication to the public allowing informed decision making seems eminently sensible and justifiable.

**Case study on option selection: RF**

When comparing costs and benefits, in order to decide on appropriate precautionary actions, the following factors need to be considered:

- The probability that there actually is a health risk is low, so there is a presumption that only interventions with correspondingly low costs are likely to be justified
- The potential consequences of any health risk could affect a large number of people because of the ubiquitous nature of the exposure. So where very low-cost ways of reducing exposure are available they should be adopted
- The technologies producing RF fields can bring substantial benefits to society; any reduction in these benefits as a consequence of a precautionary measure, e.g. through delayed availability of cellular communications, is not likely to be justified.

It therefore seems unlikely that precautionary interventions related to mobile-phone base stations would be justified unless supported by other reasons. However, further consideration should be given to the beneficial aspects of public consultation, including potential reduced public concern when considering changes to licensing regimes or planning policy.

With mobile-phone handsets, however, there are more possibilities with apparently genuinely low costs. It seems likely that, subject to any factors specific to national or local situations, the following would be justified:

- Greater availability of phone emission levels (SAR), e.g. clear display at point of sale, to allow greater informed consumer exercise of individual precaution
- Encouragement of continued reduction of power levels involved in mobile phones (this merely reinforces a trend driven by other objectives, e.g. improved battery life)
- Improvement in the design of hand-free kits, as well as greater provision of and encouragement of their use.

## **2.5 Action implementation**

In traditional risk-management frameworks, implementation may involve statutory, regulatory or voluntary requirements. In this Framework, the selected options may also include voluntary as well as mandatory measures. While mandatory measures can be implemented in the traditional way, implementation of voluntary measures may require further resources to inform, explain and promote these new measures through appropriate communication strategies.

A broader range of stakeholder involvement is required before implementation when the health benefits of the action become less clear and costs, financial or otherwise, become more burdensome. Society may determine that the benefits outweigh the actions needed to reduce uncertain risks.

The need for and content of a communication strategy should be considered at an early stage. These strategies may need to be reviewed and revised as the process continues. The International EMF Project has published a booklet<sup>24</sup> entitled "Establishing a dialogue on risks from electromagnetic fields" that provides considerable information on how to better understand people's concerns about risks and how to communicate in a way that will be most effective.

### **Case study on communication strategies: RF**

Codes of practice on procedures for stakeholder dialogue have been developed in many countries, including the UK<sup>25</sup> and Australia<sup>26</sup>, in response to public concerns over the siting of base stations. These codes utilize a range of different engagement techniques in recognition of the variety of stakeholders, issues and local contexts within which such dialogue is required. Experience has demonstrated that early dialogue with stakeholders such as local authorities or parents of school children is essential to respond effectively to potential concerns. In the UK procedures were developed by mobile-phone operators in conjunction with local and central government. In Australia, precautionary measures for mobile-phone network deployment have been formalized under the Australian Communications Industry Forum (ACIF) code of practice to include required methods of notification, consultation, and dialogue with local communities.

Some societies or sections of society are reticent to adopt precautionary measures in case this is seen as an admission that the health risk is real. In part, this concern relates to public perception of the issue. This concern can be reduced, though not necessarily completely removed, by sensitive communication. In part, however, the concern is legal: that adopting precautionary measures could be construed as an admission of liability; that it might be taken to imply responsibility for similar exposures prior to taking precautionary action; and that it may put the person, national authority or company taking such action in the position of having to justify, in a legal arena, why they took the actions they did, why they had not taken actions earlier, and why they did not go further. These concerns should clearly be addressed by government authorities lest they undermine the adoption of precautionary measures.

<sup>24</sup> See: Establishing a Dialogue on Risks from Electromagnetic Fields, WHO, Geneva.  
[http://www.who.int/peh-emf/publications/risk\\_hand/en/index.html](http://www.who.int/peh-emf/publications/risk_hand/en/index.html)

<sup>25</sup> <http://www.odpm.gov.uk/index.asp?id=1144926>

<sup>26</sup> See: [http://www.acif.org.au/documents\\_and\\_lists/codes/C564](http://www.acif.org.au/documents_and_lists/codes/C564)

It is for policy makers (and ultimately law-makers) to decide whether and how to apply precautionary measures. The policy reasons underlying any implementation of precautionary measures should be spelt out clearly and expressly distinguished from questions of legal liability also should be specifically addressed. Law-makers should make clear It should be specifically acknowledged that when in implementing precautionary measures are imposed by governmental authorities or are voluntarily implemented by , persons , national authorities or companies, those actions are not to be taken to be an admission or evidence of legal admitting liability for doing so for or for any consequences of not having taken these precautionary measures earlier; or to be even acknowledging that the precautionary measures imposed imposed or voluntarily implemented are either necessary, or appropriate, or effective..

**Case study on legal liability: ELF**

- Some electricity companies have been reluctant to adopt precautionary policies thinking that to do so would be seen as an admission that there was a health risk and that this might increase their legal liability.
- Other electricity companies have come to the opposite conclusion: that adopting precautionary measures shows that the company is behaving responsibly, and therefore reduces legal liability.

This Framework encourages the latter view.

**2.6 Action evaluation**

Evaluation of actions developed for established health risks generally concern compliance and enforcement. In this Framework, actions not requiring measurable compliance may need evaluation in more flexible ways, including their effect on public perception. Objective approaches need to be established to determine if precautionary action has provided any benefit or reduced any risk to society.

Action evaluation is not the final step in the risk management process within this Framework. Rather, the process is iterative and intended to be responsive to newly available information and to changing societal values. Actions should be subject to periodic monitoring and review to determine their effectiveness and relevance in the context of prevailing scientific evidence. As new information becomes available, the policy measures should be re-evaluated.

Overall, scientific uncertainty must not become a block to scientific advancement. Historically, society and public health have dramatically advanced through new technological achievements. Societal risks and benefits need to be objectively communicated so that all stakeholders can make informed decisions relative to the acceptance or rejection of such benefits and risks.

### 3. Further reading

#### 3.1 *Precautionary approaches internationally and in different countries*

A Canadian perspective on the Precautionary Approach/Principle  
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#### 3.2 *Case studies of relevant health issues*

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### ***3.3 Discussion of particular aspects of precautionary approaches***

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### ***3.5 Other Materials***

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