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CRITERIA FOR EMF HEALTH RISK ASSESSMENT

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INVITED PAPER

Abstract — The International EMF Project was established at WHO in 1996 to provide a forum for a coordinated international response to health concerns raised by exposure to electromagnetic fields (EMF). Research on EMF has been *ad hoc* and in many cases uncoordinated. Unreplicated research has been placed at the same level as high quality research that establishes results in a scientifically valid manner. Because of this the EMF issues have now reached a high level of concern among the general public and workers. This needs to be addressed at the international level, since the problem is truly global in nature. Research objectives are needed with a clear focus on improving our database of science used for health risk assessments. This paper indicates how the International EMF Project will evaluate scientific reports, identify the scientific database needed to make health risk assessments, and assess health hazards using criteria given in IARC monographs.

INTRODUCTION

Biological effects and possible health consequences of exposure to electromagnetic fields (EMF) need to be assessed according to an appropriate set of guidelines. Through the International EMF Project[1], WHO is collaborating with its specialised agency on cancer research, the International Agency for Research on Cancer (IARC), and other international organisations, including the International Commission on Non-Ionizing Radiation Protection (ICNIRP), government agencies and independent research institutions, to assess health effects of exposure to static and time-varying electric and magnetic fields in the frequency range 0–300 GHz. The Project incorporates a framework for identifying gaps in knowledge, establishing a research agenda to enlarge the scientific database and completing reviews of the literature in a manner that leads to scientifically defensible conclusions on possible health risks from EMF exposure. The International EMF Project provides a global focus on the EMF issues and facilitates progress towards scientifically acceptable solutions. It is particularly important that the scientific community, general public and workers are reassured that the Project is addressing all the health concerns in a logical and coordinated manner so that they will have confidence in the final results.

One of the greatest problems in assessing health risk has been the lack of consistency of results in the EMF scientific database. Results of many studies have not been replicated and so reports which could have important implications for health have remained unsubstantiated. While exact replication of studies may not be necessary, additional studies are needed to support the same conclusions. A major goal of the International EMF Project will be the identification of a research agenda, the results of which would provide a better scientific database on which health risk assessments can be made, and the encouragement of funding agencies to support this research. The results of research from this agenda will be added to reviews of published literature prior to publication. Major independent reviews of the literature will assist in this process.

Another aim of the International EMF project is to evaluate health risk from EMF exposure. This paper provides information on how these evaluations will be carried out and particularly the criteria on research needs, and the evaluation of scientific reports and health hazards from EMF exposure.

SCIENTIFIC DATABASE NEEDED TO EVALUATE HEALTH RISK

The database needed to evaluate whether exposure to any physical or chemical agent produces a carcinogenic risk has been described by the International Agency for Research on Cancer[2] and is summarised by Cardis and Rice[3]. Effectively the same type of scientific database can be used for determining any risk to health from EMF exposure. The following describes the database for EMF which will be used in the International EMF Project. Studies reporting both positive and negative effects will be critically evaluated to determine whether the effect studied is related to EMF exposure. Criteria for this evaluation are described below.

Studies in humans

Epidemiological studies contributing to the evaluation of EMF health effects are of two main types: cohort studies and case-control studies. While there are other categories such as correlation studies, randomised clinical trials and case reports in humans, they rarely give details of EMF effects or information for health risk evaluation. Cohort studies relate estimates of individual EMF exposures to the occurrence of the studied health

effect(s) in a group of individuals and provide an estimate of relative risk (ratio of incidence or mortality in those exposed to the incidence or mortality in those not exposed) as the main measure of the association. Case-control studies compare the exposure of individuals with and without the disease.

Exposure assessment

A major concern with EMF epidemiological studies has been exposure assessment. Since laboratory studies have been unable to establish mechanisms for health effects occurring at low or 'environmental' EMF exposure levels, or any clear concept of the dose measurement at these levels, exposure assessment has been determined using various methods. In many cases, surrogate or proxy measures have been used as an index of EMF exposure. Examples of the measures that have been used for low frequency (50–60 Hz) fields are given below.

Magnetic field measurement

Spot (a single measurement in a given position), peak (maximum field) and 24 h average (placing a magnetic field measuring device in a room for 24 h and taking the time-weighted average of the reading) field measurements have been performed in residences in some of the major studies as estimates of personal exposure. This method may take some account of fields from house wiring and domestic electrical appliances, but not of exposures received away from residences.

Distance to power lines

Proximity of residences to high voltage power line corridors has been used as a measure of a person's magnetic field exposure. This measurement of exposure assumes that high voltage transmission lines are the dominant contributor to exposure and so does not account for field contributions from inside or outside residences.

Wire codes

The original study by Wertheimer and Leeper[4] used a combination of factors that related to the amount of electric current flowing through wires or conductors. Since the magnitude of the current relates to the strength of the magnetic field, the type of wiring (distribution or transmission line, number and thickness of wires) and distance of the wiring from the residence was used as a surrogate for the measure of electric and magnetic field exposure. This technique is called 'wire coding', and, in a more refined form, has now been used in a number of subsequent studies[5]. This method has the advantage of being able to classify a home as high, medium or low current configuration from the exterior. However, it cannot account for domestic field exposures unless additional measurements are taken.

Historic magnetic fields

Recent studies, e.g. Feychting and Ahlbom[6], have used power company records and maps to calculate the magnetic field strengths that would have been produced in the past from high voltage transmission lines. These fields are calculated using historical line current loadings, configuration of the conductors, and distance of the residence from the line. Typically, historical measures of field exposure are determined at the time of diagnosis of the cancer or as the average magnetic field for a number of years prior to diagnosis. When this method is checked against measured magnetic fields at a given location, they correlate reasonably well. However, this technique cannot account for a person's magnetic field exposure from local distribution lines (even though they may be underground), or determine the contribution from household wiring and appliances. Further, there is no way of checking the accuracy of calculated historic fields.

Job classification

Many occupational studies have used various combinations of job title, type and duration of work, and workplace field levels to categorise exposure or compile an exposure index. This method assumes that occupational exposure far exceeds residential or other non-occupational exposures, and so no account of these is normally taken.

For epidemiological studies involving radiofrequency field (RF) exposure, similar surrogates or direct measures have been used. They vary from job titles with some local field measurements to distance from RF sources. Some studies have attempted to estimate the specific absorption rate (SAR) for the study populations. It is generally agreed that RF exposure in certain occupations far exceeds those in residences. The exception would be during use of such devices as mobile telephones. Here near-field RF exposures exceed any environmental levels.

In order for the evidence from studies to be evaluated, the method of exposure assessment should be reported in detail. If a surrogate is used, it needs to be documented and validated. Details of exposure metrics should be provided and preferably address issues such as the field strengths, how they were measured, their characteristics, how or if transients were considered, night-time versus daytime exposure, or domestic (including non-occupational exposures: shopping centres, schools) versus occupational exposure. This is extremely important when accumulating evidence for causality. A good description of wire codes and their relationship to measured and historic magnetic fields, and prediction of field exposure classification or per-

sonal exposure, is given in Reference 5. Further information on RF field dosimetry in epidemiological studies is given by Repacholi[7].

Study quality

When evaluating the quality of human studies, it is not necessary to assess all reports in detail. Those judged to be inadequate or irrelevant to the evaluation are generally omitted. Brief mention may occur when the information is useful to supplement other reports or when they provide the only data available.

It is necessary to take into account the possible roles of bias, confounding and chance in the interpretation of study results. Bias is the operation of factors in the study design or execution that lead erroneously to a stronger or weaker association than exists between exposure and the disease under study. Confounding occurs in situations where the relationship with the disease is made to appear stronger or weaker than it truly is as a result of an association between the apparent causal factor and another factor that is associated with either an increase or decrease in the incidence of the disease. Lack of clarity in the reporting of these factors can decrease the credibility and final weight given to the results of the study.

For epidemiological studies to be informative for the evaluation of health risks related to EMF exposure the following aspects should be addressed:

(1) Hypotheses to be tested, study population, disease(s) and exposure assessment should be well defined at the outset by researchers. Cases of disease should be identified in such a way that it is independent of EMF exposure, and exposure should be assessed in a way that is not related to disease status.
(2) Researchers should take into account, in both the study design and analysis, any variables (confounders) that could influence the risk of the disease and may also be related to EMF exposure. While there are few known confounders for EMF study diseases of interest, these should be dealt with in the study design, such as by carefully matching cases and controls, and in the analysis by statistical adjustment.
(3) In EMF studies, categorising the study population into different levels of exposure has been difficult, especially since the studied diseases are rare. Not only is the problem compounded because they are based on populations with narrow ranges of exposure, but exposure misclassification can bias the results towards the null. Thus there is need for a range of exposures in the study population. The problems of exposure assessment need to be addressed as described above.
(4) A problem with the early case-control EMF epidemiological studies was control selection bias[5]. In case-control studies, controls should be selected to match as closely as possible the cases under study for characteristics related to the disease excluding exposure to EMF. The participation rate should be high in both cases and controls and the approach used for selecting the controls should be well described and not be likely to introduce bias.
(5) Researchers should report the basic data on which conclusions are reached, even if sophisticated statistical analyses are employed. As a minimum, the number of exposed and unexposed cases and controls in a case-control study, and the number of cases observed and expected in a cohort study, should be provided. Tabulations by time since exposure began and other temporal factors are also important. In a case-control study, the effects of any factors other than exposure should also be reported. When investigating cancer in a cohort study, data from all cancer sites and all causes of death should be given to reveal the possibility of reporting bias.
(6) Statistical methods used to obtain absolute rates of cancer or other diseases, estimates of relative risk, confidence intervals and significance tests, and to adjust for confounding, should be clearly identified by the researchers. Any statistical methods used should be those that are appropriate for the experiment.

Animal studies

All known human carcinogens studied adequately in experimental animals have produced positive results in one or more animal species[2]. In general, if adequate data are absent from human studies, it is biologically plausible and prudent to regard studies that provide sufficient evidence of carcinogenicity in animals, as evidence of carcinogenic risk in humans[2]. However, the animal models need to be relevant to cancers reported in humans. The possibility that EMF may cause cancer through a species-specific mechanism which does not operate in humans should also be considered. Consistency of positive results using a variety of animal models is important.

An assessment of disease from exposure to EMF involves several considerations of qualitative importance. These include the experimental conditions under which the study was performed (exposure regimen, animal species, strain, sex, age, and duration of follow-up), the consistency of the results across species and target organs, spectrum of disease outcomes (e.g. for cancer, the spectrum of neoplasm response from pre-neoplastic lesions and benign tumours to malignant neoplasms), and the possible role of modifying factors.

Complete characterisation of EMF exposure and related environmental factors is essential for animal studies. Good laboratory practice[8] suggests that factors such as exposure, animal care, pathology and statistical analyses, should be checked by an independent quality

control unit and a report of their findings provided for inclusion in the final publication.

Since the probability that a disease will occur may depend on the species, sex, strain, age of the animal, and the duration of exposure, evidence of an increase in disease with level of exposure strengthens the inference of a causal association. The form of the dose–response relationship is important and may vary widely. For carcinogenesis, both DNA damage and increased cell division are important aspects.

Statistical analysis

If human studies suggest, for example, a 25% increase in a rare cancer, the animal studies should be sensitive enough to detect this small effect. The animal model should be sufficiently well characterised so that the basic level of cancer incidence is known, and that it is low enough to detect small increases from exposure to EMF, if they occur.

When considering statistical analyses of long-term animal experiments, adequate information should be given for each treatment group. These include the numbers of animals studied and the number examined histologically, the distribution of disease types, and survival time. Types of analyses and statistical methods used should be those generally appropriate and refined for this purpose[9].

EVALUATION OF THE SCIENTIFIC LITERATURE

Literature for review should have been published in scientific, peer reviewed journals. Reports passing peer review should be free of most common deficiencies in methodology, analysis and conclusions. Unfortunately, the rigour of peer review varies widely among scientific journals. While peer review adds confidence in the study results, for health risk assessment, additional review is necessary to evaluate study design, conduct and analysis of each report, and to compare them with the results of other studies. Peer reviewed reports not published in scientific journals may be considered, but conference abstracts are of little value in health risk assessment as they generally receive no prior peer review, contain sparse information useful for a proper evaluation, and cannot be considered as the final outcome of an experiment until all results are available and properly analysed.

Criteria for acceptance

Certain criteria should be met if individual studies reporting positive or negative effects are to be accepted into the body of established scientific literature. These criteria should be viewed as a whole; no individual criterion is either necessary or sufficient for the conclusion that there is a causal relationship between exposure and a disease.

(1) Study techniques, methods and conditions should be as completely objective as possible using methodology or biological systems appropriate to endpoints studied. Safeguards such as double blind techniques, blind scoring or codes should be employed. Within every study there should be appropriate corresponding controls. The sensitivity of the study should be adequate to ensure a reasonable probability that an effect would be detected, if indeed any exists.
(2) All data analyses should be fully and completely objective, no relevant data deleted from consideration and appropriate analytical methods used. Data from experiments within the same study should be internally consistent, within normal statistical variability. Where data are reported as ratios, the underlying data should be reported as well, or available for in-depth analysis.
(3) The published description of methods should be given in sufficient detail that a critical reader would be convinced that all reasonable precautions were taken to meet requirements 1 and 2.
(4) Results should demonstrate an effect of the relevant variable at a high level of statistical significance ($p > 0.05$) using appropriate tests.

ASSESSMENT OF HEALTH RISK

Biological effect versus health hazard

In its constitution WHO defines health as the state of complete physical, mental and social well-being and not merely the absence of disease or infirmity. Criteria are needed to identify which EMF-induced biological effects are then to be considered a hazard to human health. Living systems respond to many stimuli as part of the process of living: such responses are examples of biological effects. The fact that a biological change is observed or suspected to occur in humans, does not by itself indicate that the environment which produces the change is hazardous. Some biological effects are inconsequential; neither hazardous or beneficial. The time course of the effect should be determined, i.e. under what conditions the effect disappears after cessation of exposure, or if exposures are additive even after a rest period, or whether effects are permanent, such as the induction of cancer.

Interactions leading to measurable biological effects which remain within the range of physiological compensation of the body and do not detract from the physical and mental well-being of humans, should not be considered as hazardous. Interactions which lead to biological effects outside the normal range of compensation of the body may be an actual or potential health hazard. If it is determined that certain EMF exposure conditions

exist which have a finite probability of being unsafe for a very small population of particularly sensitive individuals, this should be addressed.

Reports of subjective effects (symptoms without comcomitant signs — reactions that are difficult to measure quantitatively, e.g. headaches) are useful for identification of health consequences only if the studies are conducted in a truly scientific manner, are shown to be statistically significant and a direct causal relationship is demonstrated. Subjective effects, if substantiated, can detract from the physical and mental well-being of a person, and should be considered as a health hazard.

Factors in assessing health risk

How can scientists evaluate the confusing and contradictory laboratory and epidemiological studies? Hill[10] developed a set of criteria that have been widely accepted when evaluating epidemiological studies. These have been elaborated further by Miller[11] and Repacholi and Stolwijk[12], and have been incorporated into the assessment of the scientific literature by WHO[13,14]. Under these criteria, strength and consistency of the association between EMF exposure and biological effects, evidence of a dose–response relationship, evidence provided by laboratory studies, and plausibility that biological systems exposed to EMF fields manifest biological effects, are all examined.

When evaluating a database for risk of cancer, or for any other health outcome from EMF epidemiological studies, the following questions need to be addressed:

(1) The strength of association between exposure and risk: is there a clearly associated risk with exposure? A strong association is one with a risk ratio (RR) of 5 or more. For tobacco smoking, many of the RRs were in excess of 10. However, the EMF studies of 50–60 Hz exposures, for example, suggest a RR of about 1.5 for childhood leukaemia[5]. This is a weak association, which is more susceptible to bias and confounding than stronger associations, and alone suggests that more evidence is needed to reach any valid conclusions. Supporting evidence of cancer in laboratory animals exposed to EMF fields would be important to increase confidence that the epidemiological studies could be indicating a real risk.

(2) How consistent are the studies of association between exposure to EMF fields and the risk of cancer? Do most studies show the same risk for the same disease? Using the example of smoking, essentially all epidemiological studies of smoking demonstrated an increased risk for lung cancer. Studies may show statistically significant associations between some types of cancers and some types of exposures, but others do not. Alternatively, studies reporting an association between cancer may be inconsistent with each other in their types or sub–types. The ability of the study design to identify true risk without bias and confounding should be weighed.

(3) Is there a dose–response relationship between exposure to EMF fields and the risk of cancer? Again, the more a person smokes, the higher the risk of lung cancer. Do the EMF field exposure studies demonstrate a dose–response relationship between measured, calculated, or estimated EMF fields and cancer rates?

(4) Is there laboratory evidence for an association between exposure to EMF and the risk of cancer? When warnings that smoking caused lung cancer first appeared, the epidemiological evidence was very strong but the laboratory evidence was ambiguous. It was known that cigarette smoke and tobacco contained carcinogens, but no study had demonstrated cancer from smoking in laboratory animals. This problem has now been overcome and laboratory evidence linking smoking to cancer is stronger. Thus, the evidence is considered much stronger if effects can be demonstrated in animals rather than cells or tissues alone, since whole animals are able, through various mechanisms, to amplify, minimise or negate the effects of exposure to physical agents. The weight assigned to studies of whole animals is greater than the weight assigned to studies of isolated tissues and cells because of the absence of systemic regulatory controls and mechanisms in cells and tissues.

(5) Are there plausible biological mechanisms for a link between EMF field exposure and the risk of cancer? When it is understood how an agent causes disease, it is easier to interpret ambiguous epidemiological evidence and to design better and more powerful epidemiological studies. For smoking, while the direct laboratory evidence connecting smoking with cancer was initially weak, the association was highly plausible because there were known cancer causing agents in tobacco smoke. The biological significance of responses observed *in vitro* should not be assumed unless it has been demonstrated that similar responses do occur *in vivo* and are relevant to human health effects.

Evaluation of carcinogenicity

Assessment of health effects such as cancer will receive special attention within the International EMF Project as there are many reports that exposure to EMF fields may be associated with increased cancer risk. Evaluations of the strength of evidence for carcinogenicity arising from human and animal data will be based on the criteria developed by the IARC[2]. However, it has been noted that the US Environmental Protection Agency[15] has released draft guidelines for comment on the procedures for assessing carcinogenesis.

EPA suggests placing more weight on mechanisms of action. The procedures to be used in the International EMF Project for evaluating cancer risk from EMF exposure have been elaborated by Cardis and Rice[3].

Within the International EMF Project, final assessments of health risk will be made by formally constituted WHO Working Groups comprising scientists from all appropriate disciplines, with representation by gender and from various geographical regions. Working Group members are appointed by the Executive Director of WHO's Programme on Environment and Health.

IARC[2] 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. A classification may change as new information becomes available.

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 will identify the specific exposure or activity which is considered most likely to be responsible for any excess health risk. 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 neoplasms or of an appropriate combination of benign and malignant neoplasms in (a) two or more species of animals or (b) 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 neoplasms 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 neoplasms or lesions of uncertain neoplastic potential, or of certain neoplasms 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 pre–neoplastic 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 categorisation 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

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 (possibly 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 suggest-

ing 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.

CONCLUDING REMARKS

This paper indicates the type of research (i.e. characteristics of a scientific database) needed to assess health risk, the basis by which literature reviews are conducted to reach scientifically valid conclusions, and the criteria to assess health risk from exposure to EMF fields within in the International EMF Project. Details on progress of the International EMF Project can be found on its home page at: http://www.who.ch/programmes/peh/efm/emf_home.htm.

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