Health Sciences

Exponent®

EMF and Health: Comprehensive Review and Update of the Scientific Research September 2007 through January 2010

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Acronyms and Abbreviations

AC	Alternating current
ACIGH	American Conference of Governmental Industrial Hygienists
ALL	Acute lymphocytic leukemia
ALS	Amyotrophic lateral sclerosis
BCTC	British Columbia Transmission Project
BCUC	British Columbia Utilities Commission
CI	Confidence interval
E-field	Electric field
EC	European Commission
ELF	Extremely low frequency
EMF	Electric and magnetic fields
EMI	Electromagnetic interference
G	Gauss
GHz	Gigahertz
HPA	Health Protection Agency
Hz	Hertz
IARC	International Agency for Research on Cancer
ICD	Implantable cardiac defibrillator
ICES	International Committee for Electromagnetic Safety
ICNIRP	International Commission on Non-Ionizing Radiation Protection
ILM	Interior to Lower Mainland Project
kV/m	Kilovolts per meter
LPD	Lymphoproliferative disorder
µT	MicroTesla
mG	Milligauss
MPD	Myeloproliferative disorder
MPE	Maximum permissible exposure
NHL	Non-Hodgkin's lymphoma
NRPB	National Radiological Protection Board of Great Britain
NTP	National Toxicology Program
OR	Odds ratio
RR	Relative risk
ROW	Right-of-way
SCENIHR	Scientific Committee of Emerging and Newly Identified Health Risks
SSI	Swedish Radiation Protection Authority
TWA	Time-weighted average
UK	United Kingdom
US	United States
USEPA	U.S. Environmental Protection Agency
V/m	Volts per meter
VITR	Vancouver Island Transmission Reinforcement Project
WHO	World Health Organization

Introduction

Exponent was requested by the British Columbia Transmission Corporation (BCTC), to prepare a summary of the current status of research related to extremely low frequency (ELF) electric and magnetic fields (EMF) and health. Exponent has prepared reports for BCTC to fulfill similar requests in the past, including "*VITR EMF Health Report Exhibit 1-37 - Response to Evidence Presented by Dr. Magda Havas*" (Exponent, 2005) and "*EMF and Health: Review and Update of the Scientific Research*" (Exponent, 2007). These reports were filed with the British Columbia Utilities Commission (BCUC) in the Vancouver Island Transmission Reinforcement (VITR) Project and the Interior to Lower Mainland (ILM) Project proceedings, respectively. Exponent, 2007 also fulfilled the BCUC Directive in its VITR Decision that required BCTC to monitor and report on the science every two years to allow residents to keep up to date with major developments in the field of EMF research.

This report serves to update Exponent's 2007 Report, which evaluated the impact of recent research on the conclusions of the World Health Organization's (WHO) comprehensive risk assessment that reviewed research through approximately December, 2005 (WHO, 2007). Of note, two interim update reports have been prepared for BCTC by Exponent since the 2007 Report (i.e., reports dated August 8, 2008 and February 3, 2009); the goal of these reports was to provide a brief description of recently published studies, not to provide a comprehensive assessment of the current status of the research. This report was prepared, therefore, to evaluate research published since the time of Exponent's 2007 Report (i.e., September 2007 through January 2010), including the studies described in the 2008 and 2009 interim updates, to determine if there are any new developments that would justify changes to conclusions in Exponent, 2007, and previous weight-of-evidence reviews. This report also fulfills the BCUC Directive to monitor and report on the science on a regular basis. During this period, approximately 24 relevant scientific studies were published and 3 scientific organizations prepared evaluations of the scientific evidence.

This report follows the same general structure and discusses the same scientific topics as the Exponent 2007 Report. Sections 1 and 2 of this report follow the format of Sections 1 and 2 of Exponent's 2007 Report, with minimal changes. These sections provide the reader with a framework for understanding the discussion in later sections. Section 1 provides background information on EMF, and Section 2 outlines the standard scientific methods used to evaluate research. Section 3 summarizes the conclusions of recent weight-of-evidence reviews of ***extremely low frequency*** (ELF) EMF prepared by scientific organizations. Section 4 provides an evaluation of relevant epidemiology and *in vivo* experimental

studies published from September 2007 through January 2010 identified through a systematic review of the literature. These studies are organized within Section 4 by the health outcome of interest (leukemias and lymphomas, other cancers, reproductive and developmental outcomes, and neurodegenerative disease) and within those sections by study type (epidemiology and experimental research in animals [*in vivo*]). Sections 5 and 6 address additional topics relevant to a risk assessment of EMF (electromagnetic interference and possible effects on flora and fauna, respectively). A glossary of scientific terms is included at the end of the report to provide additional clarification. Words that appear in the glossary are shown in ***bold italics*** on their first appearance in the body of the text.

Research related to ELF EMF and health has generated considerable public concern throughout its history in part because of the confusing manner in which the results of studies are published and reported on by the media. There are several topics that receive considerable attention from the public and regularly generate questions and confusion. To facilitate an understanding of these frequently mentioned topics, we have included a discussion of each issue in Appendix 1. These topics are identified by a footnote in the body of the report.

1 Background: Electric and magnetic fields

Electric and magnetic fields are produced by both natural and man-made sources that surround us in our daily lives. Man-made EMF is found wherever electricity is generated, delivered, or used, including near power lines, wiring in homes, workplace equipment, electrical appliances, power tools and electric motors, to name a few. In North America, EMF from these sources changes direction and intensity 60 times, or cycles, per second —a frequency of 60 Hertz (Hz)— and is often referred to as power-frequency or ELF-EMF.[1] Natural sources of EMF include the earth's static magnetic field and the electrical fields created by the normal functioning of our nervous and cardiovascular system.

Electric fields occur as the result of the ***voltage*** applied to electrical conductors and equipment. Electric field levels are expressed in measurement units of volts per meter (V/m) or kilovolts per meter (kV/m); 1 kV/m is equal to 1,000 V/m. Electric fields are easily blocked by most objects such as buildings, walls, trees, and fences. As a result, the major indoor sources of electric fields are the many appliances and equipment we use within our homes and workplaces. Electric field levels increase in strength as voltage increases and are present even if an electrical device is turned off; field strength diminishes quickly, however, as one increases distance from the source.

Magnetic fields are produced by the movement of electric currents. Magnetic field levels are expressed as magnetic flux density in units called gauss (G), or in milligauss (mG), where 1 G equals 1,000 mG.[2] The magnetic field level associated with a particular object (e.g., an appliance or power line) depends largely on various operating characteristics of the source and on the amount of current (i.e., electricity) flowing through the object. Unlike electric fields, magnetic fields are only present when an appliance or electrical device is turned on, or a power line is energized. Similar to electric fields, magnetic fields diminish in strength quickly as distance increases from the source, but (unlike electric fields) they are not easily blocked by conductive objects.

[1] EMF from electrical facilities in countries outside North America operate at a frequency of 50 Hz.

[2] Scientists also refer to magnetic flux density at these levels in units of microtesla (μT). Magnetic flux density in milligauss units can be converted to μT by dividing by 10, i.e., 1 milligauss = 0.1 μT.

ELF-EMF is ubiquitous in modern society because of the abundance of electrical sources in our environments. Every person can be thought of as having an "average" EMF exposure defined by the environments where they are spending time, the sources they encounter in those locations, and the duration of any exposures; any substantial changes to these variables may result in a change in one's average exposure. If someone worked as a welder for a period of time or lived in a home with faulty wiring, for example, their average EMF exposure may be elevated during these periods. This ubiquitous and changing nature of EMF exposure makes it difficult to describe and quantify.

Electric fields in the home range up to approximately 0.010 kV/m in the center of rooms (away from appliances) and up to 0.25 kV/m near appliances (WHO, 1984). In most homes, the magnetic field level measured in the center of rooms (away from appliances) is approximately 1 mG, resulting from wiring within the home, appliances, and any power lines outside the home (Zafanella, 1993). Based on a sample taken in the United States, the estimated daily average exposure is approximately 1-2 mG for about 76% of the population (Zaffanella, 1997). While higher magnetic field levels are measured near distribution and transmission lines, the distance of most buildings from a power line's right-of-way (ROW) reduces the effect of these sources on the magnetic field levels measured inside a home or office, since the intensity of magnetic fields diminishes quickly with distance from the source. In fact, the strongest sources of magnetic fields encountered indoors are electrical appliances. For example, a study by the United States Environmental Protection Agency (EPA) in 1992 reported the median magnetic field at 6 inches from a sampling of appliances was 6 mG (baby monitor), 7 mG (color televisions), 9 mG (electric oven), 14 mG (computers), 90 mG (copier), 200 mG (microwave ovens), 300 mG (hair dryer), and 600 mG (can opener).[3]

The term of reference for this report is power-frequency EMF or the fields produced by the generation, transmission and use of electricity.[4] This focus is scientifically critical. It is generally accepted in the scientific community that the frequency of electromagnetic energy is a key factor in its interaction with living things. ELF fields of 50- or 60-Hz, for example, have

[3] Mobile phones and their antennas, wireless communication networks, and radios of all types (AM, FM, police and fire) operate using radio frequency (RF), which are a part of the electromagnetic spectrum.

[4] The major focus of the review is magnetic field exposure. Research has focused on magnetic fields because, among other reasons, conductive objects shield electric fields, and so power lines have little effect on the potential long-term average exposure of nearby residents.

very long wavelengths and, as a result, impart very low energy when interacting with cells and living organisms. The interaction of ELF-EMF with matter is very different than that of higher frequency fields in the ***electromagnetic spectrum*** such as microwaves (2 billion Hz) or solar energy, because of the interrelated nature of frequency, wavelength, energy, and biological response. Therefore, only studies of ELF-EMF are relevant to assessing the potential biological and health effects of power-frequency fields.

2 Methods for evaluating scientific research

2.1 Heath risk assessment approach

The standard process for evaluating a body of research to understand the potential health implications of exposure is referred to as health risk assessment, which consists of several, sequential steps.[5] The process starts with systematically evaluating the body of research and identifying any possible risks associated with an exposure (***hazard identification/weight-of-evidence review***).[6] A follow-up to hazard identification is the question, "if the exposure does cause any health risks, at what level do they occur?" (***dose-response assessment***). A risk assessment then characterizes the exposure circumstances of the situation under analysis (***exposure assessment***). Finally, using the findings from the hazard identification and dose-response assessment as a basis, a summary evaluation is provided (***risk characterization***).

2.2 Hazard identification/weight-of-evidence review

Science is more than a collection of facts; rather, it is a method of obtaining information and of reasoning to ensure that the information is accurate and correctly describes physical and biological phenomena. Many misconceptions in human reasoning occur when people casually observe and interpret their observations and experience (e.g., if a person develops a headache after eating a particular food, he or she may mistakenly ascribe the headache to the food). The proximity or co-occurrence of events or conditions, however, does not guarantee a causal relationship. Scientists use systematic methods to evaluate observations and assess the potential impact of a specific agent on human health.

The scientific process involves looking at *all* the evidence on a particular issue in a systematic and thorough manner (i.e., a weight-of-evidence review or hazard identification). This process is designed to ensure that more weight is given to studies of better quality and that studies with a

[5] Some of the scientific panels that have reviewed EMF research have described the risk assessment process in the introductory sections of their reviews or in separate publications (ICNIRP, 2002; IARC, 2006; SCENIHR, 2007; SSI, 2007; WHO, 2007; HCN, 2009).

[6] The terms "weight-of-evidence review" and hazard identification are used interchangeably in this report to denote a systematic review process involving experimental and epidemiologic research to arrive at conclusions about possible health risks.

given result are not selected out from the available evidence to advocate or suppress a preconceived idea of an adverse effect. Three broad steps define a weight-of-evidence review: a systematic review of the published literature to identify relevant studies, an evaluation of each study to determine its strengths and weaknesses, and an overall evaluation of the data, giving more weight to higher-quality data and study designs.

Data from several types of studies must be evaluated *together* in a weight-of-evidence review, including epidemiologic observations in people, experimental studies in animals (***in vivo***), and experimental studies in isolated cells and tissues (***in vitro***). ***Epidemiology*** and experimental studies complement one another because the inherent limitations of epidemiology studies are addressed in experimental studies and *vice versa*. Similar to puzzle pieces, the results of epidemiology and experimental studies are placed together to provide a picture of the possible relationship between exposure to a particular agent and disease.

Epidemiology is the discipline that studies the patterns of disease occurrence in human populations and the factors that influence those patterns. Epidemiology studies are critical for determining the causes of disease. Epidemiology studies are observational in nature, in that they examine and analyze people in their normal lives with little control over the many factors that affect disease. Such studies are designed to quantify and evaluate the ***association*** between exposures (e.g., a high fat diet) and health outcomes (e.g., coronary artery disease). An association is a statistical measure of how things vary together. Scientists may report, for example, that people with coronary artery disease eat a diet that is lower in fat compared to people without the disease (i.e., a negative association). Or, scientists may report that persons with coronary artery disease eat a diet that is higher in fat compared to persons without the disease (i.e., a positive association).

Epidemiology studies can help suggest factors that may contribute to the development of disease but, in the vast majority of situations, they cannot be used as the sole basis for drawing inferences about ***cause-and-effect relationships***. Additional research needs to be considered. Continuing with our example from above, just because one epidemiology study finds a positive association between high fat diets and coronary artery disease, we cannot conclude that fat (or any component of fat) causes coronary artery disease without further research. This additional

research includes studies with experimental research designs, as well as additional epidemiology studies with improved designs.

In contrast to epidemiology studies, experimental studies are conducted under controlled laboratory conditions designed to test specific hypotheses. For example, with regard to *in vivo* studies, factors such as food, housing and temperature are precisely measured in both the exposed and unexposed groups and the exposure in the exposed group is strictly controlled. Generally, experimental studies are required to establish cause-and-effect relationships, but the results of experimental studies by themselves may not always be directly extrapolated to predict effects in human populations. Therefore, it is both necessary and desirable that biological responses to agents that could present a potential health threat be explored by epidemiologic methods in human populations, as well as by experimental studies in the research laboratory.

A weight-of-evidence review is essential for arriving at a valid conclusion about causality because no individual study is capable of assessing causality independently. Rather, evaluating ***causation*** is an inferential process that is based on a comprehensive assessment of all the relevant scientific research. The final conclusion of a weight-of-evidence review is a conservative evaluation of the strength in support of a causal relationship. If a clear causal relationship is indicated by the data, the conclusion is that the exposure is a known cause of the disease. In most cases, however, because of limitations in study methods, the relationship is not clear and the exposure is characterized as probably related, possibly related, unclassifiable, or probably not related. Few exposures are categorized as known or unlikely causes.

2.3 Evaluating epidemiology studies

This section briefly describes the main types of epidemiology studies and the major issues that are relevant to evaluating their results. The two main types of epidemiology studies are cohort studies and case-control studies (Figure 1).

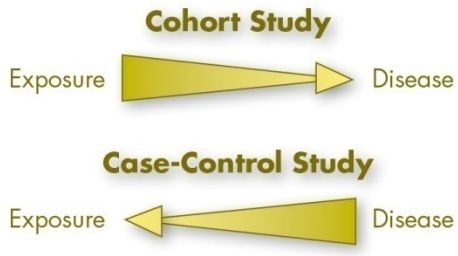

Figure 1. Basic design of cohort and case-control studies

A ***case-control study*** is a type of epidemiology study that compares the characteristics of people that have been diagnosed with a disease (i.e., cases) to a similar group of people who do not have the disease (i.e., controls). The prevalence and extent of past exposure to a particular agent is estimated in both groups to assess whether the cases have a higher exposure level than the controls, or *vice versa*.

In a case-control study, an ***odds ratio*** (OR) is used to estimate the comparison (or statistical association) quantitatively. An OR is the ratio of the odds of exposure among persons with a disease to the odds of exposure among persons without a disease. If an OR is equal to 1.0, the general interpretation is there is no statistical association between the exposure and disease. If the OR is greater than 1.0, the inference is that the exposure may increase the risk of the disease (Figure 2).

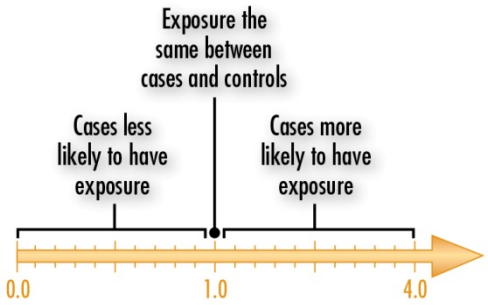

Figure 2. Interpretation of an odds ratio (OR) in a case-control study

Each OR is reported with a ***confidence interval*** (CI), which is a range of OR values that have a specified probability of occurring if the study is assumed to be repeated a large number of times. A 95% CI, for example, provides the range of values that are likely to occur in 95% of repeated experiments. In short, a CI tells one how confident the scientist is about the OR calculated from the data; if the CI includes 1.0, for example, one cannot statistically exclude the possibility that the OR is 1.0, meaning the odds of exposure are the same in the case and control groups.

A ***cohort study*** is the reverse of a case-control study – researchers study a population without disease and follow them over time to see if persons with a certain exposure develop disease at a higher rate than unexposed persons. Cohort studies are evaluated statistically in a similar manner as case-control studies, although the risk estimate is referred to as a ***relative risk*** (RR). The RR is equal to the rate of disease in the exposed group divided by the rate of disease in the unexposed group, with values greater than 1.0 suggesting that the exposed group has a higher rate of disease.

A RR or OR value is simply a measure of how often a disease and exposure occur together in a particular study population – it does not mean that there is a known or causal relationship. Before any conclusions can be drawn, all studies of the relationship between that exposure and disease must be identified and evaluated to determine the possible role that other factors such as chance, bias, and confounding may have played in the study's results.

- ***Chance*** refers to a random event, like a coincidence. An association can be observed between an exposure and disease that is simply the result of a chance occurrence. Statistics, such as the CI, are calculated to determine whether chance is a likely explanation for the findings.
- ***Bias*** refers to any error in the design, conduct, or analysis of a study resulting in a distorted estimate of an exposure's effect on the risk of disease. There are many different types of bias; for example, ***selection bias*** may occur if the characteristics of cases that participate in a study differ in a meaningful way from the characteristics of those subjects that do not participate (e.g., if cases that live near a power line are more likely to participate in the study than controls because they are concerned about a possible exposure, cases will tend to live closer to power lines than controls just because of this selection process).
- ***Confounding*** is a situation in which an association is distorted because the exposure being studied is associated with other risk factors for the disease. For example, a link between coffee drinking in mothers and low birth weight babies may be observed in a study. Some women who drink coffee, however, also smoke cigarettes. When the smoking habits of mothers are taken into account, coffee drinking may not be associated with low birth weight babies because the confounding effect of smoking has been removed.

As part of the weight-of-evidence review process, each study's design and methods are critically evaluated to determine if and how chance, bias, and confounding may have affected the results, and, as a result, the weight that should be placed on the study's findings.

A formal procedure for classifying scientific data has been developed by the International Agency for Research on Cancer (IARC). The IARC classifies epidemiology studies and *in vivo* studies as providing sufficient, limited, or inadequate evidence (Figure 3) in support of carcinogenicity, or evidence suggesting a lack of carcinogenicity. In epidemiology studies, the role of chance, bias, and confounding on the observed association must be ruled out with reasonable confidence to designate the evidence as "sufficient." If the role these factors may play in the calculated statistical association cannot be ruled out with reasonable confidence, then the data is classified as providing limited evidence. Inadequate evidence describes a data set

that lacks quality, consistency, or power for conclusions to be drawn regarding causality. The categories on the left in Figure 3 (e.g., known, probable) are based on the combined evaluations of epidemiology and animal studies. Other biological data relevant to the evaluation of carcinogenicity and its mechanisms are considered, depending on the relevance to the agent under study.

	Epidemiology Studies				Animal Studies			
	Sufficient evidence	Limited evidence	Inadequate evidence	Evidence suggesting lack of carcinogenicity	Sufficient evidence	Limited evidence	Inadequate evidence	Evidence suggesting lack of carcinogenicity
Known Carcinogen	✔							
Probable Carcinogen		✔			✔			
Possible Carcinogen		✔				✔	✔	
Not Classifiable			✔			✔	✔	
Probably not a Carcinogen				✔				✔

Sufficient evidence in epidemiology studies—A positive association is observed between the exposure and cancer in studies, in which chance, bias and confounding were ruled out with "reasonable confidence."

Limited evidence in epidemiology studies—A positive association has been observed between the exposure and cancer for which a causal interpretation is considered to be credible, but chance, bias or confounding could not be ruled out with "reasonable confidence."

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

Evidence suggesting a lack of carcinogenicity in epidemiology studies—There are several adequate studies covering the full range of levels of exposure that humans are known to encounter, which are mutually consistent in not showing a positive association between exposure to the agent and any studied cancer at any observed level of exposure. The results from these studies alone or combined should have narrow confidence intervals with an upper limit close to the null value (e.g. a relative risk of 1.0). Bias and confounding should be ruled out with reasonable confidence, and the studies should have an adequate length of follow-up.

Sufficient evidence in animal studies—An increased incidence of malignant neoplasms is observed in (a) two or more species of animals or (b) two or more independent studies in one species carried out at different times or indifferent laboratories or under different protocols. An increased incidence of tumors in both sexes of a single species in a well-conducted study, ideally conducted under Good Laboratory Practices, can also provide sufficient evidence.

Limited evidence in animal studies—The data suggest a carcinogenic effect but are limited for making a definitive evaluation, e.g. (a) the evidence of carcinogenicity is restricted to a single experiment; (b) there are unresolved questions regarding the adequacy of the design, conduct or interpretation of the studies; etc.

Inadequate evidence in animal studies—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 a lack of carcinogenicity in animal studies—Adequate studies involving at least two species are available which show that, within the limits of the tests used, the agent is not carcinogenic.

Figure 3. Basic IARC method for classifying exposures based on evidence for potential carcinogenicity

2.3.1 Association vs. causation

An association is a relationship between two events, a finding that they occur together more often than expected by chance. A reported association between a particular exposure and disease, however, is not sufficient evidence to conclude that the exposure is a cause of the disease. Rather, an association is a finding from a particular study; evaluating causation is an inferential process that combines the totality of evidence (including epidemiology studies that have measured associations) in a weight-of-evidence review. For example, we may find in a particular study that children with respiratory infections are significantly more likely to have eaten ice cream than children without respiratory infections; in other words, there is a positive association between exposure to ice cream and respiratory infections that is not likely to be due to chance. We obviously could not conclude, however, that ice cream is a cause of respiratory infections based upon this information alone. While this example is simplistic, epidemiologic associations must always be evaluated with caution before determining that statistical results confirm cause and effect.

In order to support a cause-and-effect relationship, the overall data, or evidence, must present a logically coherent and consistent picture. Various guidelines have been used to assist in the evaluation of the plausibility of a cause-and-effect relationship between a particular exposure and disease. These guidelines, commonly referred to as *Hill's criteria* after the British physician who outlined them (Hill, 1965), typically form the foundation of causal inference (Rothman and Greenland, 1998). Since the publication of Hill's criteria in 1965, numerous revisions and updates have been suggested (e.g., Susser, 1991), although the basic tenets remain the same. As described in Table 1, Hill's criteria are used as an analytic framework in the weight-of-evidence review process (e.g., ICNIRP, 2002; USEPA, 2005).

Each criterion cannot be addressed with a simple "yes" or "no," nor are the criteria as a whole meant to be an inflexible set of rules; rather, they serve as guidance for weighing the evidence to reach a decision about the plausibility of a cause-and-effect relationship. The more firmly these criteria are met by the data, the more convincing the evidence. For example, the presence of a dose-response relationship provides weight in support of a cause-and-effect relationship, but by itself does not indicate a cause-and-effect relationship. Referring to the hypothetical example discussed above, the totality of the evidence would more strongly suggest that ice cream may be

a cause of respiratory infections if: 1) strong associations were also found in other epidemiology studies and these associations showed a dose-response relationship, 2) animals with high ice cream intake also had an increased incidence of respiratory infections, and 3) an organism was isolated from the ice cream that could cause the infection.

Table 1. Hill's guidelines for evaluating causation in epidemiologic data

Strength	The stronger the association between the disease and the exposure in question, the more persuasive the evidence. Some epidemiologists think that a relative risk of 3 or more (i.e., the risk of disease is at least 3 times higher in individuals with the exposure compared to individuals with no exposure) indicates a strong association. Smaller relative risks are more likely to be influenced by bias or confounding.
Consistency	Consistent results across different study populations and study designs are more convincing than isolated observations.
Specificity	The evidence for causation is stronger if the exposure produces a specific effect.
Dose-response	If the risk of disease increases as the exposure level increases (e.g., from low to high exposure), the exposure is more likely to be related to the disease.
Biological plausibility	Epidemiologic results are much more convincing if they are coherent with what is known about biology. That is, the evidence is stronger if scientists know of a biological mechanism that can explain the effect.
Temporality	The data must provide evidence of correct temporality. That is, the exposure must be documented to have occurred before the observed effect, with sufficient time for any induction period related to the disease.
Coherence	The association should be compatible with existing theory and knowledge.
Prevention of effect	Causation is likely if the disease has been shown to be prevented by the removal of the exposure through an intervention or prevention program.
Analogy	Established causal relationships observed with similar diseases and/or exposures provide more weight for a causal relationship.

This presentation of Hill's guidelines was adapted from the original source: Hill AB. The environment and disease: Association or causation. Proc R Soc Med. 58:295-300, 1965.

2.3.3 Meta- and pooled analyses

In epidemiologic research, the results of smaller studies are difficult to distinguish from the random variation that normally occurs in data. ***Meta-analysis*** is an analytic technique that combines the published results from a group of studies into one summary result. A ***pooled analysis***, on the other hand, combines the raw, individual-level data from the original studies and analyzes the data from the studies together. These methods are valuable because they increase the number of individuals in the analysis, which allows for a more robust and stable

estimate of association. Meta- and pooled analyses are also important tools for qualitatively synthesizing the results of a large group of studies.

The disadvantage of meta- and pooled analyses is that they can convey a false sense of consistency across studies if *only* the combined estimate of effect is considered (Rothman and Greenland, 1998). These analyses typically combine data from studies with different study populations, methods for measuring and defining exposure, and definitions of disease. This is particularly true for analyses that combine data from case-control studies, which often use very different methods for exposure assessment and the selection of cases and controls. Therefore, in addition to the synthesis or combination of data, meta- and pooled analyses should be used to understand what factors cause the results of the studies to vary, and how these factors affect the associations calculated from the data of all the studies (Rothman and Greenland, 1998). For example, in a meta-analysis of childhood leukemia and magnetic field exposures, Greenland et al. (2000) performed analyses to assess how excluding particular studies from the group impacted the results of the meta-analysis.

In summary, meta- and pooled analyses are a valuable technique in epidemiology, but the quality of the underlying studies and the consistency and robustness of the results should always be taken into consideration.

2.3.4 Exposure estimation for EMF

One of the most crucial aspects in the review of any epidemiology study is an evaluation of how exposure was measured. A good exposure metric should measure the element that is believed to cause the disease at the appropriate time in the disease process. Estimating exposure to EMF is difficult since: 1) EMF is ubiquitous; 2) exposure is often estimated retrospectively; and 3) there is currently no accepted biological mechanism for carcinogenicity or any other disease process, so the appropriate exposure metric and timing is unknown. In the absence of substantive knowledge about a specific mechanism by which magnetic fields could affect normal cells, the focus on long-term exposures is based upon the standard assumption that exposures that affect the development of cancer require repeated exposures at elevated levels, as does tobacco smoke, alcohol, sunlight, chemicals and other agents in the environment that are known to cause cancer. Investigators have commonly used different types of magnetic field measurements and

calculations to estimate a person's long-term average exposure, i.e., their ***time-weighted average (TWA)*** exposure. One method of estimating a person's TWA exposure is to sum all magnetic field exposures encountered during the day (e.g., while at work or school, at home, at a grocery store, shopping, etc.), weight each estimate by the number of hours in that environment, and divide that value by the total number of hours.

Historical exposure to magnetic fields has been estimated in epidemiology studies using a variety of surrogates, including:

1) Ratings of potential magnetic field exposure from power lines based on the number and thickness of power line conductors and their distance to nearby residences (***wire code categories***);

2) Instantaneous, ***spot measurements*** in particular locations of a home;

3) Recordings of magnetic fields over 24- or 48-hour periods using either measurements in a room where a person spends most of his or her time or using a measurement device that is carried by the person; and

4) Calculated field levels based on information on loading, height, configuration, etc. of nearby transmission lines.

In general, studies that estimate long-term exposure using personal magnetic field measurements are preferred because they estimate exposures from all magnetic-field sources and directly estimate what a person is exposed to. The other methods only potentially capture exposure from one type of source. In an analysis of children from five Canadian provinces, the children wore personal exposure meters, which took single readings each minute for 48 hours to estimate the child's 48-hour average magnetic field exposure (Armstrong et al., 2001). Since this type of measurement may be cost prohibitive in some locations, the investigators evaluated what proxy exposure measures might best predict the child's 48-hour average magnetic field exposure. Stationary 24-hour measurements in a child's bedroom were a good predictor of 48-hour personal exposure, and spot measurements around the perimeter of the child's home were a moderately good predictor. Wire code categories, on the other hand, were not found to be an accurate predictor of a child's exposure (Armstrong et al., 2001).

It is important to note that estimates of magnetic field exposures in epidemiology studies, while given in units of mG, are not the same as the magnetic field values at a single, fixed location, such as at the edge of a transmission line ROW. The difference is that the exposure estimate in epidemiology studies is intended to reflect a person's exposure to magnetic fields from all sources at all locations over a long period of time. It is evident then that brief encounters with higher magnetic fields (for example, walking under a distribution or transmission line, at home in front of a refrigerator or television, or at a grocery store near the freezer) would not significantly alter the long-term exposure of a person to magnetic fields, as reflected in their TWA exposure, because they spend such a small fraction of their time at these locations.

Much of the research on EMF is related to occupational exposures, given the higher range of exposures encountered in the occupational environment. The main limitation of these studies, however, has been the methods used to assess exposure, with early studies relying simply on a person's occupational title (often taken from a death certificate) and later studies linking a person's full or partial occupational history to representative average exposures for each occupation (i.e., a job exposure matrix). The latter method, while an advance over earlier methods, still has some important limitations, as highlighted recently in a review summarizing an expert panel's findings by Kheifets et al. (2009).[7] While a person's occupation may provide some indication of the overall magnitude of their occupational magnetic field exposure, it does not take into account the possible variation in exposure due to different job tasks within occupational titles, the frequency and intensity of contact to relevant exposure sources, or variation by calendar time. While recent studies have attempted to incorporate this detailed information, it remains a significant limitation of epidemiology studies related to EMF.

2.4 Evaluating experimental research

2.4.1 General research methods

Experimental studies of humans, animals, and cells and tissues complement epidemiology studies. Both epidemiologic and experimental approaches are needed because, although people

[7] Kheifets et al. (2009) reports on the conclusions of an independent panel organized by the Energy Networks Association in the United Kingdom in 2006 to review the current status of the science on occupational EMF exposure and identify the highest priority research needs.

are the species of interest, they have large variations in their genetic makeup, exposures, dietary intake, and health-related behaviors. In laboratories, these variables can be controlled to provide more precise information regarding the effects of an exposure. In epidemiology studies, it is difficult to control for these variables because scientists are merely observing individuals going about their ordinary lives. Taken together, epidemiology, *in vivo*, and *in vitro* studies provide a more complete picture of a possible disease etiology than any one of these study types alone.

A wide variety of approaches is available for assessing the possible adverse effects associated with exposures in experimental studies. The two general types of experimental studies are studies of the effects of planned exposures on human volunteers (usually short-term studies) or whole animals (usually long-term studies, i.e., *in vivo* studies), and studies of isolated cells and tissues, i.e., *in vitro* studies. *In vitro* studies are designed to evaluate the way that the exposure acts on cells and tissues outside of the body, also known as the mechanism of action.

In vivo studies

Studies in which laboratory animals receive high exposures in a controlled environment provide an important basis for evaluating the safety of environmental, occupational, and drug exposures. These approaches are widely used by health agencies to assess risks to humans from medicines, chemicals and physical agents (Health Canada, 1994; WHO, 1994; IARC, 2002 preamble; USEPA, 2002; USEPA, 2005). From a public health perspective, long-term (chronic) studies in which animals undergo exposure over most of their lifetime, or during their entire pregnancy, are of high importance in assessing potential risks of cancer and other adverse effects. In these long-term studies, researchers examine a large number of anatomical sites to assess changes and adverse effects in body organs, cells, and tissues.

These data are used in the hazard identification step of the risk assessment process to determine whether an environmental exposure is likely to produce cancer or damage organs and tissues. Health Canada mandates that lifetime *in vivo* studies or *in vivo* studies of exposures during critical sensitive periods are conducted to assess potential toxicity to humans (Health Canada, 1994). Furthermore, the EPA's position is that, "…the absence of tumors in well-conducted,

long-term animal studies in at least two species provides reasonable assurance that an agent may not be a carcinogenic concern for humans" (USEPA, 2005, pp. 2-22).

In vitro studies

In vitro studies are used to investigate the mechanisms for effects that are observed in living organisms. The relative value of *in vitro* tests to human health risk assessment is less than that of *in vivo* and epidemiology studies. This is because responses of cells and tissues outside the body may not reflect the response of those same cells if maintained in a living system, so their relevance cannot be assumed (IARC, 1992). It may be difficult to extrapolate from simple cellular systems to complex, higher organisms to predict risks to health because the mechanism underlying effects observed *in vitro* may not correspond to the mechanism underlying complex processes like ***carcinogenesis***. In addition, the results of *in vitro* studies cannot be interpreted in terms of potential human health risks unless they are performed in a well-studied and validated test system. For these reasons, the IARC and other agencies treat data from *in vitro* studies as supplementary to data obtained from epidemiology and *in vivo* studies.

Convincing evidence for a mechanism that explains an effect observed in experimental or epidemiology studies can add weight to the assessment of cause-and-effect, and in some cases may clarify reasons for different results among species, or between animals and humans. *In vitro* studies are not used, however, by any health agency to assess risks to human health directly. For this reason, this report emphasizes epidemiology studies and experimental research conducted *in vivo* and relies on the conclusions of scientific panels with regard *in vitro* data.

2.4.2 Experimental methods for cancer

Cancer research in the laboratory includes studies of various stages of cancer development. Research has established that cells may take several steps to change from ordinary cells to the uncontrolled growth typical of cancer. Cancer usually begins with a mutation, that is, an irreversible change in the genetic material of the cell. This is also known as ***initiation*** or induction. Other steps, or stages, must occur for a cancerous cell to develop into a tumor, one of which often is referred to as ***promotion***. Some exposures affect both of these stages, and are

known as complete carcinogens. Other types of exposures affect only initiation, or only promotion. The failure of early EMF research to produce mutations in the DNA of cells *in vitro* was a factor in directing scientists to focus on studies of promotion.

In vitro assays isolate specific cells or microorganisms in glassware in the laboratory to assess the likelihood that exposure to the agent can cause mutations, a step necessary in the initiation of cancer. Initiation tests have also been developed in animals, in which scientists expose them for less than lifetime periods to determine whether an exposure caused changes typical for early cancers in specific tissues such as liver, breast, or skin.

Other tests are designed to ascertain whether a specific exposure can stimulate tumor growth (i.e., promotion) in an animal in which cellular changes typical of initiation have already occurred. Studies of promotion include two steps: first, exposing the experimental animals to a chemical known to initiate cancer, and second, exposing the animals to the agent to be tested as a promoter. The occurrence of cancer in animals exposed to an initiator and promoter is compared to the occurrence of cancer that develops in animals exposed only to the initiator.

2.4.3 Experimental methods for developmental toxicity

Studies in animals are also used to assess whether an exposure can pose a risk to the unborn children of pregnant women. Experimental studies in pregnant animals provide a means for isolating the exposure in question from the myriad of other factors that can affect prenatal development. The results of these well-controlled *in vivo* studies are used by regulatory agencies to assess prenatal risk and help set human exposure limits (NTP, 2007; USEPA, 1998; USEPA, 1991).

To test the potential for an exposure to affect fetal development, pregnant mammals such as mice, rats, or rabbits are exposed from the time the embryo is implanted in the uterus to the day before delivery. Variations in study design include preconception exposure of the female in addition to exposure during gestation, and even further exposure after the animal is born. Protocols generally specify that doses be set below the levels known to cause maternal toxicity, that unexposed controls are maintained at the same time period, and that the animals' health is monitored throughout the study. Endpoints measured include maternal body weight and weight

change, the numbers and percent of live offspring, fetal body weight, the sex ratio, and external, soft tissue, or skeletal variations and malformations. The uterus can also be examined to assess the number of implantations and fetuses that have been lost, as an indication of miscarriage (USEPA, 1998).

2.4.4 Evaluating the cumulative body of experimental evidence

Key factors in evaluating individual experimental studies include the details of the protocol; the plan for selecting animals and conducting and analyzing the study; the adequacy of the dose levels selected; the way in which the study was actually conducted, including adherence to good laboratory practices in animal housing and monitoring; and the evaluation of the effects on toxicity, tumors, or malformations, considering both biological and statistical issues (USEPA, 2005).

As an example of a protocol, consider the long-term *in vivo* study, a major tool for determining whether a chemical can produce cancer in humans. Standard protocols usually specify at least 50 animals of each sex per dose level, in each of three different dose groups. One of these is a high level dose group termed the "maximum tolerated dose," which is close to, but below, the level that increases mortality or produces significant morbidity. Additional dose levels are used below this maximum. An unexposed group, or control, is maintained under the same conditions during the same time period for comparison. This study design permits a separate evaluation of the incidence rate for each tumor type in the exposed group compared to the unexposed control group. Statistical methods are used to assess the role of chance in any differences in the rates between exposed and unexposed, or among the dose groups. If effects are observed in a study, other studies are considered because similarity of results in different studies, laboratories, and species strengthens the evidence.

Specific methods are used to reduce subjectivity and avoid systematic error, or bias, in scientific experiments (NRC, 1997). These are summarized in Table 2, including the random assignment of subjects to control or comparison groups, the unbiased collection of information (e.g., researchers are not aware of, or are "blind" to the exposure), and the need for replication of results. Again, as with *Hill's criteria*, each guideline for evaluating causation in experimental studies is not met with a simple "yes" or "no," rather, they serve as guidance for weighing the

evidence to reach a decision about cause-and-effect. The more firmly these criteria are met by the studies, the more convincing the evidence.

Table 2. Criteria for evaluating experimental studies as applied to EMF exposures

Avoiding unwanted effects	Experimental techniques should be chosen to avoid effects of intervening factors such as microshocks, noise, corona discharges, vibrations and chemicals.
Exposure classification	Extreme care should be taken to determine the effective EMF field, voltage, or current in the organism.
Sensitivity	The sensitivity of the experiments should be adequate to ensure a reasonable probability that an effect would be detected if it existed.
Objectivity	The experimental and observational techniques, methods and conditions should be objective. "Blind" scoring (where the investigator making the observations is unaware of the experimental variable being tested) should be used whenever there is a possibility of investigator bias. "Double-blind" protocols (where neither the investigator making the observations nor the experimental subject are aware of the experimental variable being tested) should be used in studies of people when the experimental subjects' perceptions may be unwittingly influenced.
Statistical significance	If an effect is claimed, the result should be demonstrated at a level where chance is an unlikely explanation.
Consistency	The results of a given experiment should be internally consistent among different ways of analyzing the data, and consistent across studies with respect to the effects of interest.
Quantifiable results	The results should be quantifiable and replicable. In the absence of independent confirmation, a result should not be viewed as definitive.
Appropriateness of methodologies	The biological and engineering methodologies should be sound and appropriate for the experiment.

3 Conclusions of weight-of-evidence reviews on EMF

Scientists, scientific organizations, and regulatory agencies worldwide use the weight-of-evidence approach to assess the health risk associated with exposures. These expert groups have included many scientists with diverse skills that reflect the different research approaches required to answer questions about health. Using a weight-of-evidence approach as an analytic framework, each group has provided its scientific consensus based on a review of the evidence.

3.1 Weight of evidence reviews by national and international scientific agencies

The following scientific organizations have assembled multidisciplinary panels of scientists to conduct weight-of-evidence reviews and arrive at conclusions about the possible risks associated with ELF-EMF (in ascending, chronological order of their most recent publication):[8]

- The **National Institute for Environmental Health Sciences** (**NIEHS**) assembled a 30-person Working Group to review the cumulative body of epidemiologic and experimental data and provide conclusions and recommendations to the United States government (NIEHS, 1998, 1999).

- The **International Agency for Research on Cancer** (**IARC**) completed a full carcinogenic evaluation of electric and magnetic fields in 2002.

- The **International Commission on Non-Ionizing Radiation Protection** (**ICNIRP**), the formally recognized organization for providing guidance on standards for non-ionizing radiation exposure for the WHO**,** published a review of the cumulative body of epidemiologic and experimental data on ELF-EMF in 2003.

- The **Federal-Provincial-Territorial Radiation Protection Committee (FPTRPC)**, an intergovernmental, Canadian committee assembled to harmonize the standards and practices for radiation protection within federal, provincial and territorial jurisdictions, conducted a review in 1998 and an update in 2005 (FPTRPC 1998; FPTRPC 2005).

[8] We are aware of other summaries of the EMF research that have been published over the past 2-1/2 years. With an increase in transmission infrastructure development and the advent of the Internet, various reviews and summaries have been released on an ongoing basis. This update is restricted to summaries that used a weight-of-evidence approach, and for which a multidisciplinary scientific panel reviewed the epidemiologic and experimental evidence (either in its entirety or since the organization's previous report), and offered conclusions about causality. Other reviews and summaries, which did not follow this approach, are not addressed because they do not assist in making science-based risk assessments and conclusions. In particular, a highly publicized report by the BioInitiative Group is discussed in the Appendix 1.

- The **National Radiological Protection Board** (**NRPB**)[9] of the United Kingdom (UK) issued full evaluations of the research in 1992, 2001 and 2004, with supplemental updates (1993, 1994a) and topic-specific reports (1994b; 2001b; HPA, 2006) published in the interim.

- The **World Health Organization (WHO)** released a review in June 2007 as part of its International EMF Program to assess the scientific evidence of possible health effects of EMF in the frequency range from 0 to 300 GHz.

- The SSI of the **Swedish Radiation Protection Authority**, using other major scientific reviews as a starting point, evaluated recent studies in consecutive annual reports (SSI, 2007; SSI, 2008).

- The **Health Council of Netherlands (HCN)**, using other major scientific reviews as a starting point, evaluated recent studies in consecutive annual reports (HCN, 2001; HCN, 2004; HCN, 2005; HCN, 2006; HCN, 2009a).

- The **Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR)** issued a report in March 2007 and March 2009 updating previous conclusions (SSC, 1998; CSTEE, 2001) to the Health Directorate of the European Commission (SCENIHR, 2007; SCENIHR, 2009).

The most comprehensive assessment of EMF was conducted by the WHO and published in June 2007; their report updated a previous evaluation of EMF by the IARC in 2002. Exponent's 2007 Report focused on the conclusions of WHO (2007) and provided an update by reviewing literature published December 2005 (the approximate cut-off date for WHO) through September 2007. While a few scientific organizations have published updates or statements since September 2007, no comprehensive risk assessment of the caliber of WHO (2007) has been published. For this reason, this report will again focus on describing and updating the conclusions of the WHO (2007), while noting the other scientific organizations that have published material since September 2007.

From September 2007 through January 2010, several international scientific organizations have published updates and statements with regard to ELF-EMF (IARC, 2008; SSI, 2008; HCN, 2009a; HPA, 2009; Health Canada, 2010; ICNIRP, 2009; SCENIHR, 2009). In Canada, the

[9] The NRPB merged with the Health Protection Agency (HPA) in April 2005 to form its new Radiation Protection Division.

FPTRPC released a statement from their Working Group in November 2008 (FPTRPC, 2008). [10] Health Canada also issued an updated document regarding EMF in January 2010 (Health Canada 2010). The ICNIRP released draft exposure guidelines for ELF-EMF in July 2009, and posted a consultation draft for comments. While the ICNIRP panel stated that they relied heavily on previous reviews of the literature related to long-term health effects and EMF, they provided relevant conclusions as part of the drafting of these guidelines. An annual update from the Swedish health organization was also published during this time period as well as an update by the Netherlands health organization (SSI, 2008; HCN, 2009a). In a letter addressing a related topic, the Director of the HPA reiterated their position with regard to ELF-EMF and appropriate precautionary measures (HPA, 2009). The SCENIHR provided a brief update to their opinions based on a thorough review of research they identified as relevant (SCENIHR, 2009). Also, of note in the 2008 IARC World Cancer Report, which describes the incidence and causes of cancer, a chapter on electromagnetic radiation described the evidence related to ELF fields (IARC, 2008).

Overall, the published conclusions of scientific review panels have been consistent. None of the panels concluded that electric or magnetic fields are a known or likely cause of any adverse health effect at long-term low-level exposures found in the environment. As a result, no standards or guidelines have been recommended to prevent this type of effect. Existing guidelines from ICNIRP include limits on short term exposures at levels higher than those associated with electrical facilities in publicly accessible areas.

Most of the uncertainty and controversy surrounding magnetic fields is still related to the research on childhood leukemia. Some epidemiology studies reported that children with leukemia were more likely to live closer to power lines, or have higher estimates of magnetic field exposure, compared to children without leukemia; other epidemiology studies did not report this statistical association. When a number of the relevant studies were combined in a single analysis, no association was evident at lower exposure levels but a weak association was reported between childhood leukemia and estimates of average magnetic field exposures greater

[10] Health Canada refers to the FTPRPC as the authority on issues related to EMF. The FPTRPC established an ELF Working Group to carry out periodic reviews, recommend appropriate actions and provide position statements that reflect the common opinion of intergovernmental authorities.

than 3-4 mG (Ahlbom et al., 2000; Greenland et al., 2000). These pooled analyses provide some evidence for an association between magnetic fields and childhood leukemia; however, because of the inherent uncertainty associated with observational epidemiology studies, the results of these pooled analyses were considered to provide only limited epidemiologic support for a causal relationship; chance, bias and confounding could not be ruled out with reasonable confidence. Further, *in vivo* studies have not found that magnetic fields induce or promote cancer in animals exposed for their entire lifespan under highly controlled conditions, nor have *in vitro* studies found a cellular mechanism by which magnetic fields could induce carcinogenesis.

Considering all the evidence together, the WHO, as well as other scientific panels, classified magnetic fields as a *possible* cause of childhood leukemia (NRPB, 2001a; IARC, 2002; ICNIRP, 2003; HCN, 2004; WHO, 2007). The term "*possible*" denotes an exposure for which epidemiologic evidence points to a statistical association, but other explanations cannot be ruled out as the cause of that statistical association (e.g., bias and confounding) and experimental evidence does not support a cause-and-effect relationship (Figure 3).

Despite additional research, it has not prompted scientific organizations to recommend that the classification of "possible carcinogen" be changed to any other IARC category such as " probable" or "known human carcinogen" (SSI, 2008; FPTRPC, 2009; HPA, 2009; ICNIRP, 2009; SCENIHR, 2009). The WHO and these more recent views have stressed the importance of reconciling the epidemiologic data on childhood leukemia and the lack of evidence from experimental studies through innovative research. Just like any other cancer, researchers believe that the development of childhood leukemia is influenced by a multitude of different factors, e.g., genetics, environmental exposures, and infectious agents (Buffler et al., 2005; McNally et al., 2006).

With regard to other cancerous and non-cancerous outcomes, however, the WHO and other scientific organizations have not found any consistent associations or concluded that there is a cause and effect link (WHO, 2007; SSI, 2008; HPA, 2009; ICNIRP, 2009; SCENIHR, 2009). Although some questions remain, the epidemiologic evidence does not support a cause-and-effect relationship between magnetic fields and adult leukemia/lymphoma or brain cancer, with

the data being described as inadequate or weak (WHO, 2007; SCENIHR, 2009). Scientific organizations have concluded that there is strong evidence in support of *no* relationship between magnetic fields and breast cancer and cardiovascular disease (WHO, 2007; SSI, 2008; ICNIRP, 2009). With regard to miscarriage, two epidemiology studies reported a statistical association between peak magnetic field exposure and miscarriage, although a serious bias in how these studies were conducted was identified and various scientific panels concluded that these biases preclude making any conclusions about associations between magnetic field exposure and miscarriage (HCN, 2004; NRPB, 2004; WHO, 2007; ICNIRP, 2009).

An association between some neurodegenerative diseases (i.e., Alzheimer's disease and Amyotrophic Lateral Sclerosis [ALS]) and estimates of higher average occupational magnetic field exposure has been reported. Scientific panels have described this research as weak and inadequate and recommended more research in this area (SCENIHR, 2007; WHO, 2007; ICNIRP, 2009; SCENIHR, 2009; HCN, 2009b).

In summary, reviews published by scientific organizations using weight-of-evidence methods have concluded that the cumulative body of research to date does not support the idea that electric or magnetic fields cause any long-term adverse health effects at the levels we encounter in our everyday environments.

The Working Group of the FPTRPC concluded the following with respect to ELF-EMF and health in a statement released in 2008:

> In summary, it is the opinion of the Federal-Provincial-Territorial Radiation Protection Committee that there is insufficient scientific evidence showing exposure to EMFs from power lines can cause adverse health effects such as cancer.

The FPTRPC conclusion is consistent with statements by Health Canada on their website, which were updated in January 2010 (http://www.hc-sc.gc.ca/hl-vs/iyh-vsv/environ/magnet-eng.php). The website concludes, "In summary, when all of the studies are evaluated together, the evidence suggesting that EMFs may contribute to an increased risk of cancer is very weak."

3.2 Standards and guidelines for limiting exposure to EMF

3.2.1 Status of EMF guidelines

Two international scientific organizations, ICNIRP (1998) and the International Committee for Electromagnetic Safety (ICES, 2002), have published guidelines for limiting public exposure to EMF. The health outcomes examined in most EMF epidemiology and *in vivo* studies primarily have addressed magnetic fields, mainly because structures and vegetation provide some shielding that limits residential exposure to electric fields from power lines; however, these EMF guidelines recommend limits for both electric and magnetic fields. Following a thorough review of the scientific literature related to short- and long-term adverse effects, the ICNIRP posted a "consultation draft" of their review and proposed guidelines on their web site in July 2009 to replace their 1998 ELF-EMF guidelines. The draft was posted to solicit input from the scientific community. The document did not recommend substantive changes to the exposure limits for the public from those in their 1998 document.

These guidelines set limits at high field levels to protect against the short-term direct, acute health effects (i.e., perception, annoyance, and the stimulation of nerves and muscles) that can occur at these high levels of magnetic and electric fields. Although the ICNIRP and ICES have the same objectives[11] and used similar methods, the recommended limits for exposure of the general public to EMF at the frequencies used to transmit electricity differ, as seen in Table 3. Exposure standards were set based on acute effects – those that occur from short-term exposure to high levels – because both organizations judged that evidence for effects from long-term exposure to ELF-EMF was insufficient for setting exposure standards. These guidelines are the same as those reported in Exponent 2005 and remain unchanged despite additional research and reviews.

[11] The scope of ICES is the "Development of standards for the safe use of electromagnetic energy in the range of 0 Hz to 300 GHz relative to the hazards of exposure to man … to such energy." ICES encourages balanced international volunteer participation of the public, the scientific and engineering community, agencies of governments, producers, and users. ICNIRP is an independent group of approximately 40 experts assembled from around the world. It is the formally recognized, non-governmental organization charged with developing safety guidance for non-ionizing radiation for the WHO, the International Labour Organization, and the European Union.

Table 3. Reference levels for whole body exposure to 60-Hz fields: general public

Organization recommending limit	Magnetic fields [a]	Electric fields [a]
ICNIRP restriction level	833 mG	4.2 kV /m
ICES Maximum permissible exposure (MPE)	9,040 mG	5 kV/m 10 kV/m [b]

a. Both organizations judged that evidence for effects from long-term exposure was insufficient for setting exposure standards.

b. This is an exception within transmission line ROWs because people do not spend a substantial amount of time in ROWs and very specific conditions are needed before a response is likely to occur (i.e., a person must be well insulated from ground and must contact a grounded conductor) (ICES, 2002, p.27).

The ICNIRP recommends a residential exposure limit to magnetic fields of 833 mG and an occupational exposure limit of 4,200 mG (ICNIRP, 1998). The ICES recommends that magnetic field exposures be limited to 9,040 mG (ICES, 2002). Magnetic field levels in ordinary environments are far too low to cause acute effects.

As Table 3 shows, there is some difference between the electric field limits of ICNIRP and ICES. The ICNIRP guideline for general public exposure is 4.2 kV/m, and the ICES guideline for general public exposure is 5 kV/m.

In Canada, there are no national standards or guidance for limiting residential or occupational exposure to 60-Hz ELF EMF based on either acute or long-term health effects. Rather, the only Canadian standards specify maximum levels and duration of exposure to *radio frequency fields*, that is, fields with a frequency over 3,000 Hz (Health Canada, Safety Code 6). Health Canada, which monitors the scientific research on EMF and human health as part of its mission to improve the health of Canadians, takes the following position:

> At present, there are no Canadian government guidelines for exposure to EMFs at ELF. Health Canada does not consider guidelines for the Canadian public necessary because the scientific evidence is not strong enough to conclude that exposures cause health problems for the public. Some national and international organizations have published health based exposure guidelines for EMFs at ELF. However, these guidelines are not based on a consideration of risks related to cancer. Rather, the point of the guidelines is to make sure that exposures to EMFs do not cause electric currents or fields in the body that are stronger than the ones produced naturally by the brain, nerves and heart. EMF exposures in Canadian homes, schools and offices are far below these guidelines (Health Canada, 2010).

The sections below discuss the similarities and differences between the ICNIRP and ICES standards, and the public health implications of the differences.

3.2.2 Similarities between ICES and ICNIRP guidelines

In both the ICES and ICNIRP standard setting process, a group of scientists conducted extensive reviews of the scientific research regarding health effects. The scientists reviewed the epidemiologic and experimental evidence and concluded that the evidence was insufficient to warrant the development of standards on the basis of hypothesized long-term health effects, such as cancers. Each organization reached a consensus that the most sensitive endpoints – the substantiated adverse effects that would occur at the lowest level of exposure – are short-term reactions to electrostimulation of nerve and muscle. These are direct, acute reactions to high levels of exposure, not severe or life-threatening events.

Each organization developed its recommended exposure limit in two steps. The first step was to identify the lowest level of electrical forces inside the body that is likely to produce the stimulation of nerve and muscle. This internal level, or dose, is further lowered by safety factors to develop what is referred to as the ***basic restriction.*** As the term indicates, the basic restriction is the internal 'dose' recommended for exposed populations. This internal level is the foundation of both the ICNIRP and ICES standards because both electric and magnetic fields can induce electrical forces in the body.

The ICNIRP and ICES basic restrictions are set well below the value at which an adverse effect was observed in experiments; as a result, these exposure limits are conservative.[12] This is because they incorporate dose reduction factors, known as ***safety factors,*** to account for potential sources of uncertainty. For example, both groups consider the potentially higher sensitivity in vulnerable groups as a reason for using a safety factor.

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[12] In this context "conservative" means that if the reference level (i.e., the screening level) is exceeded, it does not necessarily follow that the basic restriction is exceeded. ICNIRP explains: "In many practical exposure situations external power frequency electric fields at the reference levels will induce current densities in central nervous tissues that are well below the basic restrictions. Recent dosimetry calculations indicate that the reference levels for power-frequency magnetic fields are conservative guidelines relative to meeting the basic restrictions on current density for both public and occupational exposures" (ICNIRP, 1999).

The second step in the standard setting process involves developing the ***reference level***. A reference level is developed because a basic restriction cannot be directly measured. The reference level is the measurable level of electric fields at the location of interest; these levels are outside of the body, and are used as a screening value to maintain the internal level identified as the basic restriction.

3.2.3 Differences between the two guidelines

While both the ICNIRP and ICES standards are designed to protect against short-term reactions to electrostimulation of nerve and muscle, they are based on different aspects of the data (Reilly, 2005). ICES estimates an internal field that would lead to a 1 percent reaction level in the most sensitive tissue, and then applies a safety factor of 3, whereas ICNIRP identified an adverse effect level that is 28 times higher than ICES, does not specify the probability of effect on any specific tissue, and applies a safety factor of 50. Table 4 shows the main factors responsible for the differences in electric field limits between the two standards.[13] These differences also affect the magnetic fields limits.[14]

[13] The WHO (2007) acknowledges that the guidance recommended by ICNIRP is more restrictive than that recommended by ICES. As the WHO (2007) notes, "The major factor responsible for this difference [between the standards] is the cut-off frequency … at which thresholds for electric field strength and induced current density begin to rise."

[14] The derivation of the magnetic field standard is not further addressed in this report other than the note above that the standard is based on short-term effects due to the inadequate evidence for long-term effects. The exposures of the public to magnetic fields from transmission lines are more than 10- to 100-fold lower than the ICNIRP limit.

Table 4. Scientific basis of exposure limits for the general public at 60-Hz

Organization recommending exposure limit	Health and scientific basis	Threshold estimate for internal electric field (E-field) [a]	Safety factor
ICNIRP restriction level	Effect level, not a threshold, for acute changes in central nervous system excitability. Applies to head and torso.	500 mV/m[c]	50[b]
ICES maximum permissible exposure (MPE)	Threshold for median (50%) probability of changes in synaptic response in brain, the most sensitive tissue, reduced 3-fold to estimate threshold for a 1% response level. Applies only to head.	5.9 mV/m	3

a. The standard is based on the internal or *in situ* E-field, called a basic restriction in both of the guidelines. The actual exposure limits, expressed in kV/m, are based on the measured environmental level deemed likely to lead to that internal E-field.

b. The 50-fold safety factor is based on a 10-fold reduction to reduce it to a level deemed unlikely to cause effects, and an additional 5-fold for general public exposure. (ICNIRP, 1998 p. 509)

c. The ICNIRP basic restriction or the general public is 2 mA/m^2, but has been transformed to mV/m to facilitate comparison with the ICES level.

3.2.4 Implications for human health

The underlying question for people who make decisions about public health and safety is whether the ICNIRP reference value (4.2 kV/m) implies greater safety simply because it is lower and includes a larger "safety factor." In developing public health standards, safety factors are used when uncertainty is recognized, and the general rule is that smaller safety factors are needed as the relevant information on risk to humans is improved. As can be seen in Table 4, although ICNIRP uses a larger safety factor, it applies that factor to a higher level of exposure as the estimated threshold level. ICES uses a smaller safety factor, but has used highly specific data on human responses, leading to a lower, presumably more precise, estimated threshold level. It is essential to understand that for effects like these that have a threshold, the goal of the standard setting process is to set the exposure limit where no effects will occur in the population. Therefore, further lowering of the exposure limit is not expected to have any health benefit. For additional perspective on the question of the safety of exceeding ICNRIP exposure limits up to the level of the ICES limits, consider that ICNIRP states that EMF guidelines are

conservative,[15] and that the ICNIRP recommended limit for occupational exposure is 8.3 kV/m (ICNIRP, 1998).

3.3 Precautionary approaches

3.3.1 General definition

A precautionary policy for risk management of possible, but unproven, adverse effects emerged in Europe in the 1970s regarding environmental issues. The ***precautionary principle*** refers to the idea that, when evidence does not support the suggestion that an exposure is a cause of a particular disease but where a risk is perceived or uncertainty exists, precautionary measures may be taken that are proportional to the perceived level of risk, with science as the basis for estimating that risk. A key element of precautionary approaches is the recognition that a real risk from the exposure may not exist, and its necessary corollary is that the reduction of exposure may not decrease any adverse effects in the population.

The European Commission (EC) prepared a report to clarify what became known as "the precautionary principle" because it had been subject to controversy and variability in interpretation.[16] The EC report explained that the implementation of the precautionary principle should be science based, starting with a complete scientific evaluation, and the range of actions taken should depend on the extent of the risk and the degree of uncertainty surrounding the occurrence of adverse effects. The EC provided guidelines for the application of the precautionary principle or other risk management measures as five general principles: proportionality, non-discrimination, consistency, examination of costs and benefits of actions, and examination of scientific developments.[17]

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15 In this context "conservative" means that, if the reference level (the screening level) is exceeded, it does not necessarily follow that the basic restriction is exceeded. ICNIRP explains: "In many practical exposure situations external power frequency electric fields at the reference levels will induce current densities in central nervous tissues that are well below the basic restrictions. Recent dosimetry calculations indicate that the reference levels for power-frequency magnetic fields are conservative guidelines relative to meeting the basic restrictions on current density for both public and occupational exposures." (ICNIRP, 1999).

16 Commission of the European Communities, Communication on the Precautionary Principle, Brussels 03 February 2000 [http://europa.eu.int/comm./off/com/health_consumer/precaution.htm]

17 Proportionality: "Measures...must not be disproportionate to the desired level of protection and must not aim at zero risk."

A variant of the precautionary principle called "prudent avoidance" has been favored as a policy option for EMF by some national and local governments. The WHO describes this as "using simple, easily achievable, low to modest (prudent) cost measures to reduce individual or public EMF exposure, even in the absence of certainty that the measure would reduce risk" (WHO, 2002).

3.3.2 WHO recommendations regarding precautionary measures for EMF

The scientific evaluation completed by the WHO also discusses general policy strategies for risk management, and provides a summary table of different policy strategies worldwide specifically for EMF exposure in the general public (WHO, 2007, Chapter 13). The WHO recommended the following precautionary measures:

- Countries are encouraged to adopt international science-based guidelines.
- Provided that the health, social, and economic benefits of electric power are not compromised, implementing very low-cost precautionary procedures to reduce exposures is reasonable and warranted.
- Policy-makers and community planners should implement very low-cost measures when constructing new facilities and designing new equipment including appliances.
- Changes to engineering practice to reduce ELF exposure from equipment or devices should be considered, provided that they yield other additional benefits, such as greater safety or involve little or no cost.

Nondiscrimination: "comparable situations should not be treated differently and... different situations should not be treated in the same way, unless there are objective grounds for doing so."

Consistency: "measures...should be comparable in nature and scope with measures already taken in equivalent areas in which all the scientific data are available."

Examination of the benefits and costs of action or lack of action: "This examination should include an economic cost/benefit analysis when this is appropriate and feasible. However, other analysis methods...may also be relevant."

Examination of scientific developments: "The measures must be of a provisional nature pending the availability of more reliable scientific data"... "Scientific research shall be continued with a view to obtaining more complete data."

- When changes to existing ELF sources are contemplated, ELF field reductions should be considered alongside safety, reliability, and economic aspects
- Local authorities should enforce wiring regulations to reduce unintentional ground currents when building new or rewiring existing facilities, while maintaining safety. Proactive measures to identify violations or existing problems in wiring would be expensive and unlikely to be justified
- National authorities should implement an effective and open communication strategy to enable informed decision-making by all stakeholders; this should include information on how individuals can reduce their own exposure.
- Local authorities should improve planning of ELF EMF-emitting facilities, including better consultation between industry, local government, and citizens when siting major ELF EMF-emitting sources.
- Government and industry should promote research programs to reduce the uncertainty of the scientific evidence on the health effects of ELF field exposure. (adapted from pp. 372-373, WHO 2007)

In summary, the general recommendation of the WHO is as follows:

> Countries are encouraged to adopt international science-based guidelines. In the case of EMF, the international harmonization of standard setting is a goal that countries should aim for (WHO, 2006). If precautionary measures are considered to complement the standards, they should be applied in such a way that they do not undermine the science-based guidelines (p. 367).

3.3.3 Canadian perspective on precautionary approaches

The Government of Canada has published "A Framework for the Application of Precaution in Science-based Decision Making About Risk" (2003). One of the basic general principles is that sound scientific information must be the basis for both deciding whether or not to implement precautionary measures, and determining what precautionary measures, if any, are implemented. The document clarifies that "Scientific advisors should give weight to peer-reviewed science and aim at sound and reasonable evidence on which to base their judgments" (p. 8).

The FPTRPC stated the following with respect to precautionary measures in 2008: "In the context of power-frequency EMFs, health risks to the public from such exposures have not been

established; therefore, it is the opinion of the FPTRPC that any precautionary measures applied to power lines should favour low cost or no cost options" (FPTRPC, 2009).

Health Canada recommended no precautionary measures to the public in a 2010 statement: "You do not need to take action regarding daily exposures to electric and magnetic fields at extremely low frequencies. There is no conclusive evidence of any harm caused by exposures at levels found in Canadian homes and schools, including those located just outside the boundaries of power line corridors."

4 Human Health Research

This section summarizes an up-to-date assessment of the current literature to determine whether recent findings are consistent with the conclusions of the scientific panels presented in Section 3, particularly the conclusions of the WHO (2007) evaluation. Exponent 2007 reviewed the literature through September 2007; this assessment reviews literature published between September 1, 2007 and January 15, 2010. In carrying out this update, we considered the totality of the science (not just the new information) to determine if changes in the national and international health risk assessments were warranted. This assessment is carried out using a weight-of-evidence approach with standard epidemiologic principles and Hill's guidelines as an analytic foundation. All relevant research as identified below is taken into consideration and more weight is assigned to studies that are well-designed and conducted, because studies with better methods provide stronger evidence. Therefore, this assessment reflects the current knowledge of research related to EMF and the health concerns reviewed.

As noted by the ICNIRP and IARC, there has been no consistent or strong evidence to explain how EMF exposure could affect biological processes in cells and tissues. In addition, such data are supplementary to epidemiology and *in vivo* studies, and are rarely directly used by health agencies to identify hazards to human health. For that reason, this review systematically addresses epidemiology studies and *in vivo* studies, but relies largely on reviews and the conclusions of scientific panels with regard to studies of mechanism.

A structured literature review was conducted to identify new epidemiologic and *in vivo* peer-reviewed research published on 50 or 60 Hz alternating current (AC) ELF EMF between September 1, 2007 and January 15, 2010. A large number of search strings referencing the exposure and health outcomes of interest, as well as authors that regularly publish in this area, were included as search terms in a database known as PubMed.[18] This report focuses on the health outcomes that have received the most attention – cancer, reproductive or developmental effects, and neurodegenerative diseases. Many other health effects have been studied (suicide,

[18] PubMed is a service of the U.S. National Library of Medicine that includes over 17 million citations from MEDLINE and other life science journals for biomedical articles back to the 1950s. PubMed includes links to full text articles and other related resources (http://www.ncbi.nlm.nih.gov/PubMed/).

depression, electrical hypersensitivity, cardiovascular effects, etc.), but for brevity and because research on these topics evolves slowly, these topics are not summarized here. The WHO report provides a good resource for the status of research on these additional health effects (WHO, 2007). To be included, studies must assess EMF exposure beyond a self-reported job title.[19]

4.1 Cancer

4.1.1 Childhood leukemia

What was previously known about childhood leukemia?

Magnetic fields are a "possible carcinogen" largely because of findings from case-control studies of childhood leukemia. Since 1979, approximately 35 studies from the United States, Canada, Europe, New Zealand and Asia have evaluated the relationship between childhood leukemia and some proxy of magnetic field exposure, including: long-term (48-hour) personal monitoring; spot or long-term (24- or 48-hour) measurements in structures and outdoors; and calculations using loading, line configuration, and distance of nearby power installations to estimate historical, residential exposure; and wire code categories. As a group of independent studies, they did not show a clear or consistent association between magnetic fields and childhood leukemia. The authors of the largest and most methodologically sound case-control studies did not conclude that their data provided much support for a relationship between magnetic field exposure and leukemia (Linet et al., 1997; McBride et al., 1999; UKCCS, 2000); included in this group is a Canadian study by McBride and colleagues (1999). When two independent pooled analyses combined the data from all of these case-control studies, however, results showed an approximate 2-fold ***statistically significant*** association between average magnetic field exposure above 3-4 mG and childhood leukemia (Ahlbom et al., 2000; Greenland et al., 2000). This means that children with leukemia were about 2 times more likely to have

[19] Studies that only report associations between the health outcome under investigation and job titles that are presumed to have high levels of magnetic field exposure were identified and scanned, but are not evaluated further in this report for several reasons. First, job titles are a crude method of estimating exposure because they do not capture the variety of a person's occupational history or the variety of exposures a person may encounter within one occupation. Furthermore, hypothesis-generating case-control analyses that calculate associations for many occupations are subject to the bias associated with multiple comparisons. These studies provide relatively little information in a weight-of-evidence review, particularly when studies are available with more thorough exposure evaluations (as is the case for the large number of studies related to magnetic field exposures).

had average magnetic field exposures above 3-4 mG than the children in the control group. Average exposures at this level are rare; according to the WHO, results from several extensive surveys showed that approximately 0.5 – 7 percent of children had time-averaged exposures in excess of 3 mG and 0.4 – 3.3 percent had time-averaged exposures in excess of 4 mG (WHO, 2007a).

No methodologically strong studies have been published since the pooled analysis that replicate this statistical association, although some recent studies suggest a promotional effect of magnetic fields at the same exposure level (i.e., approximately greater than 3-4 mG). As described in Exponent 2007, these studies reported that children with leukemia and estimates of average magnetic field exposures greater than 3-4 mG had poorer survival rates; children with Down's syndrome and childhood leukemia were more likely to have estimates of magnetic field exposure greater than 6 mG; and children with leukemia and a particular genetic polymorphism were more likely to live closer to an electrical installation.

The most significant limitation of these studies is their methods for estimating exposure, in that (at best) spot or long-term measurements and calculations post-diagnosis were used to approximate cumulative exposure pre-diagnosis in the absence of any information on the etiologically relevant exposure metric or window. Most studies have used a TWA exposure metric, meaning the average of all exposures encountered over the day, but it is possible that other metrics might be more biologically relevant to disease causation, such as the percentage of time above a certain threshold or exposure to peak magnetic fields.

Since the individual epidemiology studies and the pooled analyses are limited in many ways (including the way that they estimate exposure), it is unclear whether this association is causal in nature – i.e., whether exposure to magnetic fields in the range of 3-4 mG has any relationship with the development of childhood leukemia or whether the association is simply a consequence of an error in the study's design. Furthermore, *in vivo* studies do not provide any evidence to suggest that the association is causal in nature. These studies have not indicated any consistent increase in cancer in animals when they are exposed to high levels of magnetic fields over the course of their lifetime (see section "*In vivo* studies of carcinogenesis"), and there is no known mechanism by which magnetic fields cause cancer. Since chance, bias and confounding could

not be ruled out as an explanation for the association, the IARC concluded in 2002 that the data on childhood leukemia provided limited evidence of carcinogenicity. In 2007, the WHO reviewed studies published since the 2002 IARC review and concluded that the new epidemiology studies were consistent with the classification of limited epidemiologic evidence in support of carcinogenicity and, together with the largely negative *in vivo* and *in vitro* research, consistent with the classification of magnetic fields as a possible carcinogen.[20]

Since it is unclear whether the association is real, the WHO report evaluated other factors that might be partially, or fully, responsible for the association, including: chance, control selection bias, confounding from hypothesized or unknown risk factors, and misclassification of magnetic field exposure, as noted below.

- ✓ The WHO report concluded that chance is an unlikely explanation since the pooled analyses had a larger sample size and decreased variability.

- ✓ Control selection bias occurs when the controls that decide to participate in the study do not represent the true exposure experience of the non-diseased population. In the case of magnetic fields, the WHO speculates that controls with a higher socioeconomic status (SES) may participate in studies more than controls with a lower SES and, since persons with a higher SES may have lower magnetic field exposures or tend to live farther from transmission lines, the control group's magnetic field exposure may be artificially low. Thus, when the exposure experience of the control group is compared to the case group, it appears that there is a difference between the case and control group. The WHO concluded that control selection bias is probably occurring in these studies and would result in an overestimate of the true association, but would not explain the entire observed statistical association.

- ✓ The WHO panel concluded that it is less likely that confounding is causing the observed association, although the possibility that some yet-to-be identified confounder is responsible for the association cannot be fully excluded. Suggested risk factors that may be

[20] The WHO concluded the following: "Consistent epidemiological evidence suggests that chronic low intensity ELF magnetic field exposure is associated with an increased risk of childhood leukaemia. However, the evidence for a causal relationship is limited, therefore exposure limits based upon epidemiological evidence are not recommended, but some precautionary measures are warranted" (p. 355-6, WHO, 2007a).

confounding the relationship include SES, residential mobility, contact currents, and traffic density.[21]

- ✓ The WHO stated that the possible effects of exposure misclassification are the most difficult to predict. Most reviews have concluded that exposure misclassification would likely result in an underestimate of the true association, meaning the association we observe is lower than the true value; however, the extent to which this might occur varies widely and is difficult to assess (Greenland et al., 2000). The WHO concluded that exposure misclassification is likely present in these studies, but is unlikely to provide an entire explanation for the association.

What relevant studies have been published since Exponent 2007?

The association between magnetic fields and childhood leukemia remains unexplained. At the suggestion of the WHO, the possible effects of confounding, exposure misclassification, and control selection bias on the observed association have been studied (Kavet and Hooper 2009; Maslanyj et al., 2009; Mezei et al., 2008b, respectively), see Table 5. Another recent study evaluated a novel hypothesis related to a promotional effect of magnetic fields (Yang et al., 2008).

One confounding factor receiving interest is the residential contact current or voltage created by the connection of a residence's water system with the Earth. The hypothesis is that a child may experience a contact current while bathing from touching a metal plumbing fixture and a conductive drain and these contact currents may be responsible for the statistical link with childhood leukemia. In order for contact currents to result in a confounding effect on the association between childhood leukemia and high average magnetic field levels, two criteria must be fulfilled: 1) there must be an independent causal relationship between contact currents and childhood leukemia, and 2) there must be a strong association between residential magnetic fields and the voltage between bathtub plumbing fixtures and drains. The latter criterion was the focus of recent dosimetric research by Kavet and Hooper (2009), which measured average

[21] For example, if dwellings near power lines encounter higher traffic density and pollution from traffic density causes childhood leukemia, traffic density may cause an observed association between magnetic field exposure and childhood leukemia.

residential magnetic field levels (B_{avg}) and the voltage between bathtub plumbing fixtures and the drains (V_{bath}) in 15 residences in San Jose, CA. Within residences, B_{avg} was strongly 3correlated with V_{bath}; also, in a pooled analysis of data from this and other studies, strong associations were reported that between B_{avg} and V_{bath} between residences. These findings are consistent with prior research which indicates that residential magnetic fields are strongly influenced by a residence's grounding system (Zaffanella, 1997). These findings suggest that contact voltage has some of the characteristics of a confounding factor in the association between magnetic fields and childhood leukemia. More specific conclusions cannot be drawn, however, because no biological or epidemiologic research directly links contact currents with childhood leukemia.

To evaluate the extent of the exposure misclassification error, researchers used data from two large studies of EMF and childhood cancer in the United Kingdom and Germany to evaluate whether distance to nearby power lines is a valid substitute for measurements of magnetic field levels in the home (Maslanyj et al., 2009). These studies used 24-hour readings in the child's bedroom as well as spot measurements in the house to identify sources and characterize exposure. Results showed that distance is a poor predictor of magnetic field levels for both relatively low voltage (11-132 kV) and high voltage (220-400 kV) power lines. For example, nearly half of the homes within 50 meters of nearby high voltage lines had measured magnetic field levels of less than 1 mG, which is indistinguishable from background levels. Similar results were observed when 2 and 4 mG were used as cut-points to classify homes; only seven percent of homes with measured magnetic field levels above 2 mG were within 100 meters of a high voltage line. These findings suggest that in-home measurements are dominated by sources other than nearby power lines and, as a result, distance from power lines is not a good surrogate of magnetic field exposure. The findings also suggest there is misclassification of magnetic field levels among the study participants when distance is used as a surrogate. In many recent and past epidemiology studies of EMF and disease, residential distance from power lines was used as a surrogate for actual EMF measurements (e.g., Draper et al., 2005; Feizi and Arabi, 2007; Lowenthal et al., 2007; Huss et al., 2009; Yang et al., 2008). This recent publication reiterates that the findings of these studies should be interpreted with caution, given that distance appears to be a poor surrogate of EMF exposure.

Mezei et al. (2008a) assessed the likelihood that control selection bias could be causing the observed association in a previously published study of childhood leukemia in Canada (McBride et al., 1999). Mezei et al. (2008a) evaluated whether there were differences between the controls that participated and the controls that did not participate in the 1999 study. The goal of the study was to assess whether the non-participating controls had a higher prevalence of some factor that made them more likely to have a higher magnetic field exposure than the participating controls and, thus, resulted in an under-representation of exposure prevalence in the control group and an overestimation of the risk estimate. The study suggested that control selection bias was operating to some extent, although the authors noted the inherent problems associated with estimating magnetic field exposure and, therefore, concluded, "the role of selection bias cannot entirely be dismissed on the basis of these results alone" (p. 1).

Most childhood leukemias are characterized by a genetic anomaly that can be identified prenatally, but not all children with these anomalies go on to develop childhood leukemia (Buffler et al., 2005). It has been suggested that other postnatal events (e.g., environmental or viral exposures) are necessary for childhood leukemia to occur, although little research has been done in this area. This hypothesis suggests that the association may be concentrated in subgroups of the population that have both the genetic anomaly and the promotional exposure. The first study to examine a magnetic field-gene interaction in relation to childhood leukemia was published recently in China (Yang et al., 2008). They evaluated residential distance from power lines and the genetic variation of five genes associated with DNA repair in a group of children with childhood leukemia. The authors reported that a variation of one of the genes was more likely to be measured in children with leukemia living within 100 meters from a power line or transformer, compared to children with leukemia living at a farther distance. The significance of this finding is unknown and, as with all genetic epidemiology studies, the results cannot be deemed reliable until they are replicated. Several major limitations of the study are important to consider: (1) since this study enrolled only cases of childhood leukemia and no control group, the authors do not provide any information about the distribution of this DNA repair variation in children without leukemia and, as a result, no conclusions can be drawn about the relationship of this gene to childhood leukemia risk or etiology, (2) it is unknown what role (if any) DNA repair genes play in the development of childhood leukemia, and (3) distance is a poor proxy for magnetic field exposure. Although a positive association between distance and

one specific gene was observed in this study, the results do not provide information to draw any conclusions about gene-magnetic field interactions in the etiology of childhood leukemia at this time. A study that could provide a more reliable estimate of magnetic field-gene interactions has been proposed for the Danish National Birth Cohort (Greenland and Kheifets, 2009).

In response to the WHO recommendations to "focus on new aspects of exposure, potential interaction with other factors or on high exposure groups" (p. 17), recent research continues to be innovative in the area of childhood leukemia and magnetic field exposure. Recent data suggest that control selection bias may play some role in this observed association and distance from power lines is a poor proxy of exposure.

The results of these studies do not change the classification of the epidemiologic data as limited. In fact, they provide further evidence that the role of bias and confounding cannot be ruled out with reasonable confidence. This conclusion is supported by recent reviews (Kheifets and Oksuzyan, 2008; Schüz and Ahlbom, 2008; Schüz et al., 2009) and the recent conclusions of scientific organizations (SSI, 2007; SSI, 2008; HCN, 2009; SCENIHR, 2009).

Researchers will continue to investigate the magnetic field-childhood leukemia association. Magnetic fields, however, are just one area of study in the large body of research on the possible causes of childhood leukemia. There are many other hypotheses that are under investigation that point to possible genetic, environmental, and infectious explanations for childhood leukemia. There are other hypotheses with similar or stronger support in epidemiology studies; magnetic fields are one among many research priorities in the field of childhood leukemia (Ries et al., 1999; McNally and Parker, 2006; Belson et al., 2007; Rossig and Juergens, 2008).

Table 5. Studies of childhood leukemia published after Exponent 2007

Authors	Year	Study
Kavet and Hooper	2009	Residential magnetic fields and measures of neutral-to-earth voltage: variability within and between residences
Maslanyj, et al.	2009	Power frequency magnetic fields and risk of childhood leukaemia: Misclassification of exposure from the use of the distance from power line' exposure surrogate.
Mezei, et al.	2008a	Assessment of selection bias in the Canadian case-control study of residential magnetic field exposure and childhood leukemia.
Yang, et al.	2008	Case-only of interactions between DNA repair genes (hMLH1, APEX1, MGMT, XRCC1 and XPD) and low-frequency electromagnetic fields in childhood acute leukemia

4.1.2 Childhood brain cancer

What was previously known about childhood brain cancer?

The research related to magnetic fields and childhood brain cancer has been less consistent than that observed for childhood leukemia. The WHO report recommended the following:

> As with childhood leukaemia, a pooled analysis of childhood brain cancer studies should be very informative and is therefore recommended. A pooled analysis of this kind can inexpensively provide a greater and improved insight into the existing data, including the possibility of selection bias and, if the studies are sufficiently homogeneous, can offer the best estimate of risk (WHO, 2007a, p. 18).

What relevant studies have been published since Exponent 2007?

The four relevant studies of childhood brain cancer and magnetic field exposure are listed in Table 6 below.

In response to the WHO recommendation, Mezei et al. (2008b) performed a meta-analysis of studies on childhood brain tumors and residential magnetic field exposure. Thirteen epidemiology studies were identified that used various proxies of magnetic field exposure (distance, wire codes, calculated magnetic fields, and measured magnetic fields). For all of the exposure proxies considered, the combined effect estimate was close to 1.0 and not statistically significant, indicating no association between magnetic field exposure and childhood brain tumors. A sub-group of five studies, however, with information on childhood brain tumors and calculated or measured magnetic fields greater than 3-4 mG reported a combined OR that was elevated but not statistically significant (OR=1.68, 95% CI=0.83-3.43). The authors suggested two explanations for this elevated OR. First, they stated that an increased risk of childhood brain tumors could not be excluded at high exposure levels (i.e., >3-4 mG). Second, they stated that the similarity of this result to the findings of the pooled analyses of childhood leukemia suggests that control selection bias is operating in both analyses. Overall, the authors concluded that the analysis did not find a significant increase in childhood brain cancer risk using various proxies of residential exposure to magnetic fields.

Saito et al. (2010) published findings on brain cancer from a larger case-control study of childhood cancer in Japan; an earlier publication by Kabuto et al. (2005) reported the results for

childhood leukemia. The average weekly magnetic field level in the bedrooms of 55 children with brain cancer and 99 children without brain cancer was estimated. The investigators reported that children with brain cancer were more likely to have average magnetic field levels greater than 4 mG, compared to children without brain cancer (OR=10.9, 95% CI=1.05-113). This study's strength is its exposure assessment, in that measurements were taken continuously over a weeklong period in the child's bedroom approximately one year after a diagnosis of brain cancer. Similar to Kabuto et al. (2005), there are important methodological limitations of this study, however, that limit its overall weight in this assessment. The intent of the study was to include all brain cancer cases identified between 1999 and 2002 from five urban regions in Japan; however, nearly half of the diagnosed brain cancer cases in the population were not asked to join and, among the 72 remaining cases, only 55 met all the inclusion criteria. Thus, only 55 of 167 possible cases (33%) were included. The same situation was observed for the control group – only 99 out of 692 originally identified controls (14%) participated. Low participation is a significant source of bias because the association may be distorted if there are important differences between the children who participated in the study and those that did not (i.e., selection bias). Another limitation of this study was its small sample size in the highest exposure category (only three cases and one control had an average exposure >4 mG). A small sample size makes the statistical association unstable –i.e., if a few children are classified in the wrong exposure category, the results can easily change.

Studies of parental occupational magnetic field exposure and childhood brain tumors have been inconsistent (WHO, 2007). In a recent pooled analysis of two Canadian case-control studies, Li et al. (2009) calculated individual maternal occupational magnetic field exposure pre- and post-conception and analyzed average, cumulative, and maximum exposure estimates in relation to brain cancer in their offspring. Associations were reported between childhood brain cancer and average magnetic-field exposures greater than approximately 3 mG for exposure in the two years prior to conception and during conception; the association was weak and restricted to astroglial tumors. This is the first study to evaluate estimates of *maternal* magnetic-field exposure and the risk of brain cancer in their offspring. The methods for exposure assessment in this study, based on exposure duration, work tasks, and work environment, are more

advanced than previous work. Additional research, with even more advanced methods for estimating maternal exposure, is required.

Another analysis of parental occupational magnetic-field exposure pre-conception was published by Hug et al. in 2010. The large case-control study enrolled all cases of childhood cancer (leukemia [N=846], NHL [N=159], central nervous tumors [N=444], and other solid tumors [N=600]) reported to the German Childhood Cancer Registry. Parental occupations pre-conception were broadly categorized based on expert opinion; no individualized measurements were taken, nor was the duration of employment, tasks completed, or sources encountered taken into account. No evidence was found of a relationship between any type of childhood cancer and parental employment in higher-exposure jobs pre-conception. While this study is large and generally well-conducted, the crude nature of its job exposure matrix (JEM) limits the strength of any conclusions.

These four studies do not change the classification of the epidemiologic evidence as inadequate in relation to childhood brain cancer. Although the meta-analysis of brain cancer observed an association, it could not be distinguished from a chance finding.

Table 6. Studies of childhood brain cancer published after Exponent 2007

Authors	Year	Study
Hug et al.	2010	Parental occupational exposure to extremely low frequency magnetic fields and childhood cancer: a German case-control study
Li et al.	2009	Maternal occupational exposure to extremely low frequency magnetic fields and the risk of brain cancer in the offspring.
Mezei et al.	2008b	Residential magnetic field exposure and childhood brain cancer: a meta-analysis.
Saito et al.	2010	Power-frequency magnetic fields and childhood brain tumors: a case-control study in Japan

4.1.3 Breast cancer

What was previously known about breast cancer?

Studies have been conducted of breast cancer and electric blanket use, as well as residential and occupational magnetic field exposure. These studies have not reported consistent associations between magnetic field exposure and breast cancer. The WHO concluded that, since the recent body of research was higher in quality compared with previous studies, it provided strong support to previous consensus statements that magnetic field exposure does not influence the risk of breast cancer;[22] studies published after the WHO review and included in Exponent 2007 supported this conclusion. The WHO recommended no further research with respect to breast cancer and magnetic field exposure.

What relevant studies have been published since Exponent 2007?

A large cohort study of utility workers in Denmark recently reported that women exposed to higher occupational magnetic field levels did not have higher rates of breast cancer (Johansen et al., 2007). This study adds to the growing support against a role for magnetic fields in breast cancer. This is consistent with the recent conclusion by the SCENIHR, which stated that the association is "unlikely" (p. 43, SCENIHR 2009).

[22] The WHO concluded, "Subsequent to the IARC monograph a number of reports have been published concerning the risk of female breast cancer in adults associated with ELF magnetic field exposure. These studies are larger than the previous ones and less susceptible to bias, and overall are negative. With these studies, the evidence for an association between ELF exposure and the risk of breast cancer is weakened considerably and does not support an association of this kind" (p. 307, WHO 2007a).

Table 7. Studies of breast cancer published after Exponent 2007

Authors	Year	Study
Johansen et al.	2007	Risk for leukaemia and brain and breast cancer among Danish utility workers: a second follow-up.

4.1.4 Other adult cancers

What was previously known about other adult cancers?

In general, scientific panels have concluded that there is not a strong or consistent relationship between other adult cancers (leukemia, lymphoma, or brain cancers) and exposure to magnetic fields; however, the possibility cannot be entirely ruled out because the findings have been inconsistent (IARC, 2002; WHO 2007). The fact that stronger findings have not been observed in studies with better exposure assessment methods has led the scientific panels to conclude that the evidence for an association is weak and the observed inconsistency is probably due to chance or bias. The IARC classified the epidemiologic data with regard to adult leukemia, lymphoma and brain cancer as "inadequate" in 2002, and the WHO confirmed this classification in 2007, with the remaining uncertainty attributed mainly to limitations in exposure assessment methods.

Much of the research on EMF and adult cancers is related to occupational exposures, given the higher range of exposures encountered in the occupational environment. The main limitation of these studies, however, has been the methods used to assess exposure, with early studies relying simply on a person's occupational title (often taken from a death certificate) and later studies linking a person's full or partial occupational history to representative average exposures for each occupation (i.e., a job exposure matrix). The latter method, while advanced, still has some important limitations. These limitations, as already mentioned in Section 2.3.4, were highlighted recently in a review summarizing an expert panel's findings by Kheifets et al. (2009). While a person's occupation may provide some indication of the overall magnitude of their occupational magnetic field exposure, it does not take into account the possible variation in exposure due to different job tasks within occupational titles, the frequency and intensity of contact to relevant exposure sources, or variation by calendar time. Furthermore, since scientists do not know any mechanism by which magnetic fields could lead to cancer, an appropriate exposure metric is unknown.

Therefore, in order to reduce the remaining uncertainty about whether there is an association between magnetic fields and these cancers, researchers have recommended (1) meta-analyses to clarify the likely reasons for inconsistencies in the data and (2) better exposure assessment methods that incorporate a greater level of detail on tasks and exposure characteristics such as spark discharge, contact current, harmonics, etc. (WHO, 2007; Kheifets et al., 2009).

4.1.4.1. Adult brain cancer

What was previously known about adult brain cancer?

As described above, the WHO classified the epidemiologic data on adult brain cancer as inadequate[23] and recommended (1) updating the existing cohorts of occupationally-exposed individuals in Europe and (2) pooling the epidemiologic data on brain cancer and adult leukemia to confirm the absence of an association. Studies reviewed in Exponent 2007 added support to the previous conclusions that the data does not indicate a cause-and-effect relationship between magnetic fields and brain cancer.

What relevant studies have been published since Exponent 2007?

Epidemiology studies published after Exponent 2007 on adult brain cancer and EMF exposure are listed in Table 8 and include one case-control study, one cohort study, and a meta-analysis, all of which are related to occupational magnetic field exposure.

In response to the WHO recommendation, a cohort of utility workers in Denmark was updated (Johansen et al., 2007), and brain cancer rates were similar between jobs with high magnetic field exposure and jobs with lower exposures.

Coble et al. (2009) published a large case-control study of gliomas and meningiomas in the United States. For the first time, the exposure metric in this study incorporated the frequency of exposure to EMF sources, as well as the distance people worked from these sources, on an individual basis. The authors also evaluated exposure metrics aside from TWA exposure (maximum exposed job, total years of exposure above 1.5 mG, cumulative lifetime exposure,

[23] The WHO concluded, "In the case of adult brain cancer and leukaemia, the new studies published after the IARC monograph do not change the conclusion that the overall evidence for an association between ELF [EMF] and the risk of these disease remains inadequate" (p. 307, WHO 2007a).

and average lifetime exposure). No association was reported between any of these exposure metrics and brain cancer.

As recommended in the WHO report, a meta-analysis of occupationally-exposed cohorts was performed by Khefeits et al. (2008) which updated an earlier meta-analysis on this topic. All relevant publications of occupational EMF exposure and adult leukemia or brain cancer were collected and summary risk estimates were calculated using various schemes to weight and categorize the study data. The authors reported a small and statistically significant increase of leukemia and brain cancer in relation to the highest estimate of magnetic field exposure in the individual studies. Several findings, however, led the authors to conclude that magnetic field exposure is not responsible for the observed associations, including the lack of a consistent pattern among leukemia subtypes when the previous and new meta-analyses were compared. In addition, for brain cancer, the recent meta-analysis reported a weaker estimated association than the previous meta-analysis, whereas a stronger association would be expected if there is a true relationship since the quality of the studies has increased over time. The authors concluded, "the lack of a clear pattern of EMF exposure and outcome risk does not support a hypothesis that these exposures are responsible for the observed excess risk" (p. 677).

A relevant dosimetric study has also recently been published. Mee et al. (2009) measured the personal magnetic-field exposures of a proportion of their study participants in an ongoing case-control study of brain cancer in the UK (the UK Adult Brain Tumour Study). Personal magnetic-field measurements were taken for a minimum of 3 days in 317 persons (cases, controls, or proxies of either), and statistical analyses were performed to establish whether crude occupational classifications, which are traditionally employed in JEMs, accounted for the observed variation in measured occupational magnetic-field exposures. The analysis confirmed that JEMs could be improved by linking occupational classifications with industry or information on participation in certain tasks of interest (e.g., use of welding equipment or work near power lines).

Thus, recent studies reduced possible exposure misclassification by improving exposure assessment methods (i.e., the expanded JEM in Coble et al., 2009) and attempted to clarify inconsistencies by updating studies and meta-analyzing data (Johansen et al., 2007; Kheifets et

al., 2008); no association has been observed despite these advances. While an association still cannot be *entirely* ruled out because of the remaining deficiencies in exposure assessment methods, the current database of studies provides weak evidence of an association between magnetic fields and brain cancer.[24] The recent report by the SCENIHR described the data on brain cancers as "uncertain" (p. 43, SCENIHR 2009).

Table 8. Studies of adult brain cancer published after Exponent 2007

Authors	Year	Study
Coble et al.	2009	Occupational exposure to magnetic fields and the risk of brain tumors.
Johansen et al.	2007	Risk for leukaemia and brain and breast cancer among Danish utility workers: A second follow-up.
Kheifets et al.	2008	Occupational electromagnetic fields and leukemia and brain cancer: An update to two meta-analyses.

4.2.4.2 Adult leukemia and lymphoma

What was previously known about adult leukemia/lymphoma?

The same issues discussed above with regard to adult brain cancer are relevant to research on adult leukemia/lymphoma. The WHO classified the epidemiologic evidence as "inadequate" and recommended updating the existing occupationally exposed cohorts in Europe and the meta-analysis on occupational magnetic field exposure[25] (p. 307, WHO 2007a). The data published subsequent to WHO (2007) and reviewed in Exponent 2007 was consistent with WHO conclusions.

What relevant studies have been published since Exponent 2007?

As discussed above, recent studies of adult leukemia include an updated meta-analysis of occupationally-exposed cohorts (Kheifets et al., 2008) and cohort of Danish utility workers (Johansen et al., 2007). Neither study provided strong evidence in support of an association. While the possibility still cannot be *entirely* ruled out because of the remaining deficiencies in exposure assessment methods, the current database of studies provides weak evidence of an association between magnetic fields and leukemia.

[24] A recent consensus statement by the National Cancer Institute's Brain Tumor Epidemiology Consortium confirms this statement. They classified residential power frequency EMF in the category "probably not risk factors" and described the epidemiologic data as "unresolved" (p. 1958, Bondy et al., 2008).

[25] No specific conclusions were provided by the WHO with regard to lymphoma.

Table 9. Studies of adult leukemia/lymphoma published after Exponent 2007

Authors	Year	Study
Johansen et al.	2007	Risk for leukaemia and brain and breast cancer among Danish utility workers: A second follow-up.
Kheifets et al.	2008	Occupational electromagnetic fields and leukemia and brain cancer: An update to two meta-analyses.

4.1.5 *In vivo* studies of carcinogenesis

What was previously known from *in vivo* studies of carcinogenesis?

It is standard procedure to conduct studies on laboratory animals to determine whether exposure to a specific agent leads to the development of cancer (USEPA, 2005). This approach is used because all known human carcinogens cause cancer in laboratory animals. In the field of ELF-EMF research, a number of research laboratories have exposed rodents, including those with a particular genetic susceptibility to cancer, to high levels of magnetic fields over the course of their lifetime and performed tissue evaluations to assess the incidence of cancer in many organs. In these studies, magnetic field exposure has been administered alone (to test for the ability of magnetic fields to act as a complete carcinogen), in combination with a known carcinogen (to test for a promotional or co-carcinogenetic effect), or in combination with a known carcinogen and a known promoter (to test for a co-promotional effect).

The WHO described four large-scale, long-term studies of rodents exposed to magnetic fields over the course of their lifetime that did not report increases in any type of cancer (Mandeville et al., 1997; Yasui et al., 1997; Boorman et al., 1999a,b; McCormick et al., 1999). No directly relevant animal model for childhood ALL existed at the time of the WHO report. Some animals, however, develop a type of lymphoma similar to childhood ALL and studies exposing transgenic mice predisposed to this lymphoma to ELF magnetic fields did not report an increased incidence of lymphoma (Harris et al., 1998; McCormick et al., 1998; Sommer and Lerchel, 2004).

Studies investigating whether exposure to magnetic fields can promote cancer or act as a co-carcinogen used known cancer-causing agents, such as ionizing radiation, UV radiation or other chemicals. No effects were observed for studies on chemically-induced preneoplastic liver lesions, leukemia/lymphoma, skin tumors, or brain tumors; however, the incidence of 7,12-dimethylbenz[a]anthracene (DMBA)-induced mammary tumors was increased with magnetic

field exposure in a series of experiments in Germany (Löscher et al., 1993, 1994, 1997; Baum et al., 1995; Löscher and Mevissen, 1995; Mevissen et al., 1993a,b, 1996a,b, 1998), suggesting that magnetic field exposure increased the proliferation of mammary tumor cells. These results were not replicated in subsequent series of experiments in a laboratory in the United States (Anderson et al., 1999; Boorman et al.1999a, b; NTP, 1999), possibly due to differences in experimental protocol and the species strain. In Fedrowitz et al. (2004), exposure enhanced mammary tumor development in one sub-strain (Fischer 344 rats), but not in another sub-strain that was obtained from the same breeder, which argues against a promotional effect of magnetic fields.[26]

Some studies have reported an increase in genotoxic effects among exposed animals (e.g., DNA strand breaks in the brains of mice [Lai and Singh, 2004]), although the results have not been replicated.

The WHO concluded the following with respect to *in vivo* research: "There is no evidence that ELF exposure alone causes tumours. The evidence that ELF field exposure can enhance tumour development in combination with carcinogens is inadequate" (p. 322, WHO 2007a). Recommendations for future research included the development of a rodent model for childhood ALL and the continued investigation of whether magnetic fields can act as a promoter or co-carcinogen. Research reviewed in Exponent 2007 was consistent with the conclusion that exposure to magnetic fields does not increase the incidence of cancer, even in animals predisposed to cancer.

What relevant studies have been published since Exponent 2007?

Five recent experimental studies exposed animals *in vivo* to high levels of magnetic fields for substantial portions of their lifespan (see Table 10). In view of the available evidence that exposure to magnetic fields *alone* does not increase the occurrence of cancer, recent studies first treated animals with the initiators ethylnitrosourea (ENU) (Bernard et al., 2008; Chung et al., 2008) and DMBA (Fedrowitz and Löscher, 2008; Negishi et al., 2008).

[26] The WHO concluded with respect to the German studies of mammary carcinogenesis, "Inconsistent results were obtained that may be due in whole or in part to differences in experimental protocols, such as the use of specific substrains" (p. 321, WHO 2007a).

Chung et al. (2008) exposed rats *in utero* to ENU, followed by exposure to magnetic fields up to 5,000 mG from the age of 4 weeks to the age of 32 or 42 weeks. Rats exposed to ENU developed brain tumors, but rats exposed to both ENU and magnetic fields did not develop more brain tumors than the rats that were exposed to ENU only. The size of the comparison groups was adequate. The authors reported that they followed guidelines for good laboratory practice, but did not specifically mention whether the analysis was blinded.

Negishi et al. (2008) used a strain of mice known to develop lymphoma/lymphatic leukemia when treated with DMBA. The mice were exposed to DMBA as newborns and then exposed to magnetic fields up to 3,500 mG. After magnetic-field exposure of 22 hours per day for 30 weeks, the percentage of mice with lymphoma/lymphatic leukemia was not higher in the magnetic-field exposed groups, compared to the sham-exposed groups. This study also did not report that they followed any guidelines for good laboratory practice or that the analysis was blinded.

Bernard et al. (2008) used a newly developed rat model for lymphoblastic leukemia, which the authors maintain is closer to ALL (the most common type of childhood leukemia) than previous experimental models. Leukemia was induced by a chemical similar to ENU (n-butylnitrosourea, BNU). Animals were then exposed to 50-Hz magnetic fields at 1,000 mG for 52 weeks. To serve as a control, an equal number of BNU-initiated animals were not exposed to magnetic fields. A third group was not initiated with BNU or exposed to magnetic fields, to serve as a no treatment group, or negative control.[27] The incidence of leukemia was not higher in the BNU-treated rats exposed to magnetic fields, compared to the BNU-treated rats not exposed to magnetic fields. Experience with this rat strain is limited, however, so the significance of the results is unknown.

Chung et al (2009) exposed AKR mice, a strain prone to lymphoma, to test whether magnetic fields promote lymphoma/leukemia, or reduce survival in these cancer prone animals. The

[27] An additional experiment was conducted in this study by the authors to compare BNU-induced rats to rats exposed to both BNU and ionizing radiation. Since exposure to ionizing radiation is expected to increase the risk of cancer, this part of the experiment is called a positive control and is used to verify that the animal model is a valid test for the promotion of leukemia. The overall incidence of leukemia was not elevated in the group induced by BNU and irradiated compared to the BNU-induced group that was not irradiated, although the type of leukemia in the irradiated group differed from that in the BNU-only group.

study was long term and included three exposure levels, the highest 500 uT (5000 mG). No adverse effects were seen on any of the clinical signs, including body weight and composition of the blood. Although most of these AKR mice eventually developed this cancer, there was no evidence of higher cancer incidence or decreased survival time in higher exposed groups. Similar to the results of other studies, exposure to magnetic fields did not cause adverse effects on the health endpoints studied, or promote lymphoma/leukemia in these genetically prone mice.

As described above, a series of experiments from a German laboratory had suggested that magnetic fields promote the development of mammary tumors but the results were not replicated in a subsequent series of experiments in a laboratory in the United States. Later findings suggested that the discrepancy was possibly due to differences in experimental protocol and the species strain (WHO, 2007). In the most recent study from the German laboratory, researchers treated rats from a specific inbred strain with DMBA, followed by either high levels of magnetic fields (1,000 mG) or no exposure for 26 weeks (Fedrowitz and Löscher, 2008). The analysis was blinded to the exposure status of the experimental animals. The incidence of breast cancer was significantly elevated in the group exposed to magnetic fields after initiation with DMBA. These results still remain wholly inconsistent with similar studies with other rat strains by authors in the United States.

Cakir et al. (2010) evaluated the effects of *in vivo* exposure to magnetic fields (50-Hz, 9,700 mG) on red and white blood cells, and liver and body weight in rats. Rats in the experimental groups were exposed for 3 hours per day for either 50 (short protocol) or 100 (long protocol) days. The results of the study showed no significant differences in total white or red blood cell counts between the exposed and control groups. Additionally, the exposure had no effect on body, or liver weight. The group did report a slight decrease in hemoglobin, eosinophils (a type of white blood cell commonly associated with asthma and allergy), and mean cell volume in the 50 day group, but these effects were not seen in the group treated for a longer period (100 days) and were not outside the normal physiological range. The findings of this study do not support any associations with signs of pre-leukemia or leukemia.

Overall, recent *in vivo* studies provide further support that there is no promotional effect of magnetic fields on the incidence of cancer, particularly leukemia, although questions still remain regarding the inconsistent findings on mammary carcinogenesis.

Table 10. Studies of carcinogenesis published after Exponent 2007

Authors	Year	Study
Bernard et al.	2008	Assessing the potential leukemogenic effects of 50 Hz and their harmonics using an animal leukemia model.
Cakir et al.	2010	Alterations of hematological variations in rats exposed to extremely low frequency magnetic fields (50 Hz)
Chung et al.	2008	Lack of a co-promotion effect of 60 Hz rotating magnetic fields on ethylnitrosourea induced neurogenic tumors in F344 rats.
Fedrowitz and Löscher	2008	Exposure of Fischer 344 rats to a weak power frequency magnetic field facilitates mammary tumorigenesis in the DMBA model of breast cancer.
Negishi et al.	2008	Lack of promotion effects of 50 Hz magnetic fields on 7,12-dimethylbenz(a)anthracene-induced malignant lymphoma/lymphatic leukemia in mice

4.1.6 *In vitro* studies of carcinogenesis

In vitro studies are supplementary to epidemiology and *in vivo* studies, and they are not directly used by health agencies to assess risk to human health. For that reason, Exponent reviews have relied largely on the discussions and the conclusions of scientific panels with regard to studies of mechanism (Exponent 2007).

What did the WHO and other scientific panels conclude with respect to *in vitro* studies of carcinogenesis?

The IARC and other scientific review panels that systematically evaluated *in vitro* studies concluded that there is no clear evidence indicating how ELF magnetic fields could adversely affect biological processes in cells (IARC, 2002; ICNIRP, 2003; NRPB, 2004). The WHO panel reviewed the *in vitro* research published since the time of these reviews and reached the same conclusion. The WHO noted that previous studies have not indicated a genotoxic effect of ELF magnetic fields on mammalian cells, however, a series of experiments reported DNA damage in human fibroblasts exposed intermittently to 50 Hz magnetic fields (Ivancsits et al., 2002a, 2002b; Ivancsits et al., 2003a, 2003b). These findings have not been replicated by other laboratories (Scarfi et al., 2005), and the WHO recommended continued research in this area.

Research on the promotional effects of magnetic fields *in vitro* was also recommended, following suggestive findings from several laboratories. As noted by the SSI, however, the levels at which these effects were observed are much higher than the levels we are exposed to in our everyday environments and, therefore, are not directly relevant to questions about low-level, chronic exposures (SSI, 2007). *In vitro* studies investigating other possible mechanisms, including gene activation, cell proliferation, apoptosis, calcium signaling, intercellular communication, heat shock protein expression and malignant transformation, have produced "inconsistent and inconclusive" results, according to the WHO (p. 347, WHO, 2007a).

What have scientific panels concluded about *in vitro* research since Exponent 2007?

The SSI (2008) reviewed eight *in vitro* studies of effects of EMF, which examined different endpoints primarily related to the assessment of potential genotoxicity or gene expression. The SSI noted that some of the studies reported effects on the exposed cells, however, they concluded that exposure levels were about 1,000 times above environmental levels and therefore the relevance for humans at environmental levels is not known. In 2009, the SCENIHR updated its review from 2007, and they also commented that the *in vitro* research was conducted at levels higher than the environmental levels in epidemiology studies. They concluded that no mechanistic information has been shown that is relevant to cancer or childhood leukemia, and that new information did not change its previous (2007) conclusion.

4.2 Reproductive and developmental effects

What was previously known about reproductive and developmental effects?

Two studies received considerable attention because of a reported association between peak magnetic field exposure greater than approximately 16 mG and miscarriage: a prospective cohort study of women in early pregnancy (Li et al., 2002) and a ***nested case-control*** study of women who miscarried compared to their late-pregnancy counterparts (Lee et al., 2002). The WHO concluded, "There is some evidence for increased risk of miscarriage associated with measured maternal magnetic field exposure, but this evidence is inadequate" (p. 254, WHO 2007a). As discussed in Exponent 2007, later studies supported the notation that the associations observed in Lee et al. (2002) and Li et al. (2002) were due to important biases in

the collection of the data. The scientific panels that have considered these two studies concluded that the possibility of this bias precludes making any conclusions about the effect of magnetic fields on miscarriage (NRPB, 2004; FPTRPC, 2005; WHO, 2007; ICNIRP, 2009).

What relevant studies have been published since Exponent 2007?

No new original epidemiology studies on magnetic-field exposure and reproductive or developmental effects have been conducted.

Five recent experimental studies have examined the effect of electric or magnetic fields on reproductive or developmental endpoints (see Table 11). One assessed results after exposure to magnetic fields and the other assessed results after exposure to electric and magnetic fields in a barn under a power line (Al-Akras et al., 2008; Aydin et al., 2009). The results of two of these studies, which examined female sex hormone levels and organ weights, showed no evidence of exposure-related adverse effects. The results of Aydin et al. (2009), however, are limited by its study design, where only one of the four study groups was exposed under controlled laboratory conditions, while the other groups may have had confounding exposures that impacted the study results.

The remaining three studies reported exposure-related effects in rats or mice during pregnancy or during sexual development, or both (Anselmo et al., 2008, 2009; Dundar et al., 2009). Anselmo et al. (2008) designed a study to test if magnetic fields in combination with a nutrition-deficient regional diet had any effect on developmental endpoints defined in the "somatic maturation indexes," in which growth milestones occur such as time of eye opening, auditory canal opening, and eruption of teeth. Pregnant rats were exposed to magnetic fields at 30 mG, one group with a normal diet and another with a diet found in regions of Brazil that is deficient in protein and other nutrients. For comparison, there were unexposed groups, one with a normal and the other with a deficient diet. A delay in some body development indices (e.g., tooth eruption, eye opening) was reported in the offspring of exposed rats, compared to unexposed animal controls. The difference was small, but was more pronounced in offspring of rats on the deficient diet. Magnetic-field exposure did not decrease body weight on the 21st day of life in either the normal or nutrient-deficient exposed group. In a similar study of rats on a deficient diet and exposed to magnetic fields, changes were reported in thyroid hormone levels, but not

on three other metabolic endpoints, among the maternal rats after giving birth (Anselmo et al., 2009).

Dundar et al. (2009) investigated the effects of pre- or post-natal exposure, or both, to electric fields at 10 kV/m, 24-hour per day among female Wistar rats and their offspring until the offspring reached puberty. They evaluated pre- and post-natal growth, pubertal development, and levels of reproductive hormones and a growth hormone (i.e., serum insulin-like growth hormone-1[IGF-1]). They also examined effects on endocrine glands related to puberty, i.e., the hypothalamus, pituitary gland, and gonads. The researchers reported that the mean age at vaginal opening and estrous were significantly greater in the pre-natal exposure group than post-natal and sham-exposed groups. IGF-1 levels were reduced in the pre-natal group, compared with the other two groups. There was no difference in levels of reproductive hormones at puberty among the three groups. The histological results were interpreted as evidence of tissue damage on the hypothalamus, pituitary gland, and ovaries in the pre-natal and post-natal exposure groups. The authors concluded that exposure of rats to electric fields from conception until puberty resulted in growth restriction, delayed puberty and reduced IGF-1 levels. Delayed puberty, however, is inconsistent with the study's reported absence of an effect on the reproductive hormones that influence this process. Other serious limitations of this study include a small sample size, improper experimental methods, and an incomplete description of the experimental methods and statistical analyses. For example, there was no indication that the "scoring" of the tissues for damage was performed by someone blinded to the test status. For these reasons, results reported in this study are questionable, and the study does not in itself provide convincing evidence of effects of electric fields on the endpoints studied.

Given that the effects observed are not consistent with previous research and the absence of adverse health effects in larger studies at higher exposure levels, these results do not modify previous conclusions. Based on long-term and multi-generation studies, the evidence does not support adverse effects of EMF exposure on reproduction and development.

Table 11. Studies of reproductive and developmental effects published after Exponent 2007

Authors	Year	Study
Al-Akras et al.	2008	Influence of 50 Hz magnetic field on sex hormones and body, uterine, and ovarian weights of adult female rats.
Anselmo et al.	2008	Influence of 60 Hz, 3 mircroT, electromagnetic field on the somatic maturation of wistar rat offspring fed a regional basic diet during pregnancy.
Anselmo et al.	2009	Effects of the electromagnetic field, 60 Hz, 3 microT, on the hormonal and metabolic regulation of undernourished pregnant rats.
Aydin et al.	2009	Evaluation of hormonal change, biochemical parameters, and histopathological status of uterus in rats exposed to 50-Hz electromagnetic field.
Dundar et al.	2009	The effect of the prenatal and post-natal long-term exposure to 50 Hz electric field on growth, pubertal development and IGF-1 levels in Wistar rats.

4.3 Neurodegenerative disease

What was previously known about neurodegenerative disease?

Research into the possible effect of magnetic fields on the development of neurodegenerative diseases began in 1995, and the majority of research since then has focused on Alzheimer's disease and a specific type of motor neuron disease called amyotrophic lateral sclerosis (ALS), which is also known as Lou Gehrig's disease. The inconsistency of the Alzheimer's disease studies prompted the NRPB to conclude that there is "only weak evidence to suggest that it [ELF magnetic fields] could cause Alzheimer's disease" (p. 20, NRPB, 2001). Early studies on ALS, which had no obvious biases and were well conducted, reported an association between ALS mortality and estimated occupational magnetic field exposure. The review panels, however, were hesitant to conclude that the associations provided strong support for a causal relationship. Rather, they felt that an alternative explanation (i.e., electric shocks received at work) may be the source of the observed association.

The majority of the more recent studies discussed by the WHO reported statistically significant associations between occupational magnetic field exposure and mortality from Alzheimer's disease and ALS, although the design and methods of these studies were relatively weak (e.g., disease status was based on death certificate data, exposure was based on incomplete occupational information from census data, and there was no control for confounding factors). Furthermore, there was no biological data to support an association between magnetic fields and neurodegenerative diseases. The WHO panel concluded that there is "inadequate" data in

support of an association between magnetic fields and Alzheimer's disease or ALS.[28] The panel recommended more research in this area using better methods; in particular, studies that enrolled incident Alzheimer's disease cases (rather than ascertaining cases from death certificates) and studies that estimated electrical shock history in ALS cases were recommended. Studies reviewed in Exponent 2007 continued to report inconsistent associations between magnetic field exposure and Alzheimer's disease or ALS.

What relevant studies have been published since Exponent 2007?

Two epidemiology studies have recently been published (see Table 12), along with an *in vivo* study of an ALS mouse model. A meta-analysis was conducted of studies related to occupational magnetic field exposure and Alzheimer's disease (García et al., 2008), and the first study of non-occupational EMF exposure and neurodegenerative disease was published (Huss et al., 2009).

García et al. (2008) identified 14 epidemiology studies with information on Alzheimer's disease and occupational EMF exposure; the WHO considered the majority of these studies in their 2007 review. A statistically significant association between Alzheimer's disease and occupational EMF exposure was observed for both case-control and cohort studies (OR =2.03, 95% CI=1.38-3.00 and RR =1.62, 95% CI=1.16-2.27, respectively), although the results from the individual studies were so different that the authors cautioned against the validity of these combined results. While some subgroup analyses had statistically significant increased risks and were not significantly heterogeneous between studies, the findings were contradictory between study design types (e.g., elevated pooled risk estimates were reported for *men* in cohort studies and elevated pooled risk estimates were reported for *women* in case-control studies). The authors concluded that their results suggest an association between Alzheimer's disease and occupational magnetic field exposure, but noted the numerous limitations associated with these studies, including the difficulty of assessing EMF exposure during the appropriate time period,

[28] After considering the entire body of literature and its limitations, the WHO report concluded, "When evaluated across all the studies, there is only very limited evidence of an association between estimated ELF exposure and [Alzheimer's] disease risk" (p. 194, WHO 2007a).

case ascertainment issues due to diagnostic difficulties, and differences in control selection. They recommended further research that uses more advanced methods.

An earlier publication by the same group of investigators documented the relatively poor quality of the studies included in the meta-analysis. Santibáñez et al. (2007) evaluated studies related to occupational exposures and Alzheimer's disease, which included seven of the studies in the García et al. meta-analysis. Two epidemiologists blindly evaluated each of these studies using a questionnaire to assess the possibility of a number of biases, with a score assigned to each study that represents the percentage of possible points that the study obtained (range 0 – 100%). Only one of the seven studies obtained a score above 50%, and disease and exposure misclassifications were the most prevalent biases.

Huss et al. (2009) is a cohort study conducted in Switzerland that linked all persons older than 30 years of age at the 2000 census with a national database of death certificates from 2000 through 2005. Residential location was also extracted from 1990 and 2000 census data and the closest distance of a person's home in 2000 to nearby 220-380-kV transmission lines was calculated. The authors reported that persons living within 50 meters of these high-voltage transmission lines were more likely to have died from Alzheimer's disease, compared to those living farther than 600 meters, although chance could not be ruled out as an explanation (HR=1.24, 95% CI=0.80-1.92). The association was stronger for persons that lived at the residence for at least 15 years (HR=2.00, 95% CI=1.21-3.33). Associations of similar magnitude were reported for senile dementia and residence within 50 meters of a high-voltage line. No associations were reported beyond 50 meters for Alzheimer's disease or senile dementia, and no associations were reported at any distance for Parkinson's disease, ALS, or multiple sclerosis.

The study's main limitation is the use of residential distance from transmission lines as a proxy for magnetic-field exposure (Maslanyj et al, 2009). It is also limited by the use of death certificate data, which are known to under-report Alzheimer's disease, and the lack of a full residential and occupational history. Furthermore, while the underlying cohort was very large, relatively few cases of Alzheimer's disease lived within 50 meters of a high-voltage transmission line –20 cases total and 15 cases who lived at the residence for at least 15 years.

This means that misclassification of a small number of cases could have a large impact on the risk estimate. The HCN stated the following, "no conclusion can be drawn from this single study on the relationship between residing in the vicinity of power lines and Alzheimer's disease; it is not possible to pronounce upon the question of whether this elevated risk is also related to the exposure to the low-frequency magnetic fields generated by power lines" (HCN, 2009b).

The meta-analysis and supporting evaluation of study quality by García, Santibáñez and colleagues confirmed that the associations reported in previous occupational studies are highly inconsistent and the studies have many limitations (Santibáñez et al., 2007; García et al., 2008). The recent epidemiology studies do not alter the conclusion that there is "inadequate" data on Alzheimer's disease or ALS. While a good number of studies have been published since the WHO report, little progress has been made on clarifying these associations. Further research is still required, particularly on electrical occupations and ALS (Kheifets et al., 2008). There is currently no body of *in vivo* research to suggest an effect, and a recent study reported no effect of magnetic fields on ALS progression (Poulletier de Gannes et al., 2008). These conclusions are consistent with recent reviews by the SCENIHR and ICNIRP (ICNIRP, 2009; SCENIHR, 2009).

Table 12. Studies of neurodegenerative disease published after Exponent 2007

Authors	Year	Study
García, et al.	2008	Occupational exposure to extremely low frequency electric and magnetic fields and Alzheimer disease: a meta-analysis.
Huss, et al.	2009	Residence near power lines and mortality from neurodegenerative diseases: longitudinal study of the Swiss population.
Poulletier de Gannes et al.	2008	Amyotrophic lateral sclerosis (ALS) and extremely-low frequency (ELF) magnetic fields: a study in the SOD-1 transgenic mouse model.
Santibáñez, et al.	2007	Occupational risk factors in Alzheimer's disease: a review assessing the quality of published epidemiological studies.

5 Possible Effects of ELF Electric and Magnetic Fields on Implanted Cardiac Devices

The sensing system of pacemakers and other implanted cardiac devices (ICD) is designed to be responsive to the heart's electrical signal. For this reason, other electrical signals can potentially interfere with the normal functioning of pacemakers and ICDs, a phenomenon called electromagnetic interference (EMI). Most sources of EMF are too weak to affect a pacemaker or ICD; however, EMF from certain sources, e.g., some appliances and industrial equipment, may cause interference. This section considers potential EMI with implanted cardiac devices such as pacemakers and defibrillators.

In the presence of electromagnetic fields, devices can respond in different ways, defined as modes. The likelihood of interference occurring, and the mode of the response depend on the strength of the interference signal, the patient's orientation in the electromagnetic field, the exact location of the device, and the variable parameters of the device that are specific to a patient. Experimental research has been conducted to assess whether interference may occur when currents are induced in the patient's body by environmental electric and magnetic fields.

5.1 Electromagnetic interference: pacemakers and implanted cardiac devices

What was previously known about electromagnetic interference?

Both the American Conference of Governmental Industrial Hygienists (ACGIH) and the Electric Power Research Institute (EPRI) have suggested that exposures be kept below 1.5-2 kV/m for electric fields, and the ACGIH recommends an exposure limit of 1 G for magnetic fields. These recommendations are general in nature, however, and do not address that classes of pacemakers and devices from some manufacturers are quite immune to interference even at levels much greater than their recommendations. These organizations recommend that the patient first consult their physician and the respective pacemaker manufacturer. When a manufacturer does not specify the limits, then the patient is referred to the specifications quoted in the guidelines.

What relevant studies have been published since Exponent 2007?

The literature search on PubMed included terms to locate literature on the effects of EMI at power line frequency on pacemakers and ICDs published since Exponent 2007. Two recent articles were identified that relate to the effects of power line frequency EMF on pacemakers (Andretzko et al., 2008; Joosten et al., 2009). No new publications were found on PubMed on the effects of power line frequency EMF on ICDs. Additionally, a query of the IEEE database returned no publications on pacemakers or ICDs and the interference effects of power line frequency EMF published since Exponent 2007.

The aim of the Joosten et al. (2009) study was to find out the anatomical and physiological conditions that yielded the lowest thresholds for effects on pacemaker performance for patients with an implanted pacemaker with unipolar sensing in external time-varying electric fields. The results of this study with 15 volunteer patients show that, in electric fields, the interference voltage at the input of a cardiac pacemaker can vary up to 200% because of individual factors such as state of respiration, systole and diastole of the heart, filling of the stomach and muscle activity.

Although the study identifies some key parameters to take into account when studying the effects of low frequency electric fields on the operation of pacemakers, the work does not suggest what the limits should be on electric fields to minimize potential interference with the function of these devices. The authors' analyses suggested an electric field between 4.3 kV/m and 6.2 kV/m would be required to affect the function of the most sensitive, single lead pacemakers and cited data that in Germany today only about 6% of the pacemakers have a single lead (unipolar) sensing system.

Andretzko et al. (2008) presents a method of calculating induced voltage, *in vitro*, at the terminals of a unipolar pacemaker subjected to a low frequency magnetic field. The mathematical model is compared to experimental measurements of actual pacemakers immersed in saline solution to simulate body conditions. Results are presented for various pacemaker models, with different loop areas for a unipolar device. The authors compare the calculated induced voltages to the detection limit of a variety of pacemaker models at 10 and 25 kHz incident magnetic fields. The study shows that the exposure guidelines set by the European

directive 2004/40/EC for workers are very conservative for the pacemaker models on which the study was conducted. Even at very sensitive settings of the pacemaker, the detection limits are above the thresholds set by the directive. The study, however, takes into account only a small sample of pacemakers and does not analyze or explicitly discuss 50/60 Hz frequencies.

These two articles, while adding to our information on this topic, do not provide a basis to lower the recommended exposure limits of the ACGIH or EPRI (ACGIH, 1998, 2001; EPRI, 2004).

Table 13. Studies of EMI published after Exponent 2007

Authors	Year	Study
Andretzko et al.	2008	A model for determining the induced voltage at the terminals of a pacemaker exposed to a low frequency magnetic field
Joosten et al.	2009	The influence of anatomical and physiological parameters on the interference voltage at the input of unipolar cardiac pacemakers in low frequency electric fields

6 Fauna and Flora Research

6.1 Fauna

What was previously known from fauna research?

Exponent 2007 concluded that the research to date did not suggest that electric or magnetic fields result in any adverse effects on the health, behavior or productivity of fauna, including livestock such as cows, sheep, and pigs, and a variety of small mammals, deer, elk, birds and bees.

What relevant studies have been published since Exponent 2007?

Subsequent to Exponent 2007, one study has been published on the possible effects of AC EMF on fauna (Burchard et al., 2007). This study is the most recent publication in a long series of controlled studies at McGill University on the possible effects of strong and continuous EMF exposure on the health, behavior and productivity of dairy cattle (e.g.; Rodriquez et al., 2002; Burchard et al., 2003; Rodriquez et al., 2003; Burchard et al., 2004; Rodriguez et al., 2004). The goal of the research program was to assess whether EMF exposure could mimic the effect of days with long periods of light and *increase* milk production and feed intake through a hormonal pathway involving melatonin. In previous studies, some differences were reported between EMF-exposed and unexposed cows; however, they were not reported consistently between studies, the changes were still within the range of what is considered normal, and it did not appear that the changes were adverse in nature. The study by Burchard et al. in 2007 differed from previous studies in that the exposure was restricted to magnetic fields; the outcomes evaluated included the hormones progesterone, melatonin, prolactin, and insulin-like growth factor 1 (IGF-1), as well as feed consumption. No significant differences in melatonin levels, progesterone levels, or feed intake were reported. Significant decreases in prolactin and IGF-1 levels were reported, which is inconsistent with the authors' theory that EMF exposure may increase these hormone levels.

Thus, similar to the previous studies by this group of investigators, Burchard et al. (2007) did not report findings that suggest magnetic fields cause changes in the melatonin pathway that

could result in effects on reproduction or production. The authors concluded the following: "The absence of abnormal clinical signs and the absolute magnitude of the significant changes detected during MF [magnetic field] exposure, make it plausible to preclude any major animal health hazard" (p. 471).

6.2 Flora

What was previously known from flora research?

Exponent 2007 described the body of research on the possible effects of EMF on forest species and agriculture crops, concluding that researchers have found no adverse effects on plant responses at the levels of EMF produced by high-voltage transmission lines, excluding some corona-related effects from high-voltage lines on the growth of nearby trees.

What relevant studies have been published since Exponent 2007?

A recent study by Huang and Wang (2008) evaluated the effects of magnetic fields induced by an inverter system on the early seed germination of mung beans. The exposures were applied at six different frequencies between 10-60 Hz, producing magnetic field levels from 6-20 mG. At 20 and 60 Hz, magnetic field exposure enhanced early growth of the mung beans, while magnetic fields induced by other frequencies had an inhibitory effect on early growth of the mung beans.

Table 14. Studies of flora and fauna published after Exponent 2007

Authors	Year	Study
Burchard et al.	2007	Exposure of pregnant dairy heifer to magnetic fields at 60 Hz and 30 uT
Huang and Wang	2009	The effects of inverter magnetic fields on early seed germination of mung beans.

Glossary

Association – An association is a measure of how things vary together. They are measured by odds ratios and relative risks. Associations are described as positive or negative. For example, a study may show that persons with coronary artery disease eat fewer vegetables than persons without the disease (i.e., a negative association). Or, persons with coronary artery disease may eat more vegetables than persons without the disease (i.e., a positive association).

Basic restriction – The basic restriction is the electric field level or current density inside the body that is recommended as a limit to protect exposed populations. The term is used in standards or guidelines that recommend exposure limits.

Bias – Bias refers to any error in the design, conduct or analysis of a study that results in a distorted estimate of an exposure's effect on the risk of disease. For example, the characteristics of persons selected by telephone calls to participate in a study may not accurately reflect those of the entire community and this can introduce error into the study's findings.

Carcinogenesis – Carcinogenesis describes the process of the progression of normal cells to cancerous cells.

Causation or cause – A cause is an exposure or condition of the individual that has been proven through a sound weight-of-evidence review to increase risk of a disease.

Cause-and-effect relationship – A cause-and-effect relationship between an exposure and a disease is a statistically significant association that is determined through a weight-of-evidence review to be causal in nature.

Case-control study – A case-control study compares persons without a disease (controls) to persons with a disease (cases) to see if they differ on any factors or exposures of interest.

Chance – Chance refers to random sampling variation, like a coincidence. An association can be observed between an exposure and disease that is simply the result of a chance occurrence.

Cohort study – A cohort study follows a group of people over a long period of time to observe whether the occurrence of disease differs among exposed and unexposed persons in the group.

Confidence interval – A confidence interval is a range of values for an estimate of effect that has a specified probability (e.g., 95%) of including the "true" estimate of effect. A 95% confidence interval indicates that, if the study were conducted a very large number of times, 95% of the measured estimates would be within the upper and lower confidence limits.

Confounding – Confounding is a situation in which an association is distorted because the exposure is associated with other risk factors for the disease. For example, a link between coffee drinking in mothers and low birth weight babies has been reported in the past. However, some women who drink coffee also smoke cigarettes. It was found that when the smoking

habits of the mothers are taken into account, coffee drinking was not associated with low birth weight babies because of the confounding effect of smoking.

Dose-response assessment/relationship – Data from scientific research in which a change in amount, intensity, or duration of exposure is associated with a change in risk of a specified outcome. A pattern of a stronger association with increasing exposure, or dose.

Electric fields – The electric field is a property of a location or point in space and its electrical environment, and describes the forces that would be experienced by a charged body in that space by virtue of its charge. The electric field is expressed in measurement units of volts per meter (V/m) or kilovolts per meter (kV/m); a kilovolt per meter is equal to 1,000 V/m.

Electromagnetic spectrum – The range of wavelengths of electromagnetic energy, including visible light, arranged by frequency. Wavelength decreases with increasing frequency; the ELF range includes the power frequencies of 50/60-Hz.

Epidemiology – The study of the frequency and distribution of disease and health events in human populations and the factors that contribute to disease and health events.

Exposure assessment – The step in risk assessment that characterizes the exposure circumstances of the situation under analysis.

Extremely low frequency (ELF) fields – Extremely low frequency refers to electromagnetic fields in the range of 0-300 Hz.

Hazard identification – The identification of adverse effects on health from a specific exposure based on a weight-of-evidence review of the scientific research.

In vitro – Laboratory studies of isolated cells that are artificially maintained in test tubes or culture dishes are called *in vitro* studies, literally "in glass." Researchers expose isolated cells or groups of cells (tissues) to a specific agent under controlled conditions. These studies help explain the mechanisms by which exposures might affect biological processes.

In vivo – Studies in living animals or experimental studies of processes in whole living organisms are called *in vivo* studies. Scientists expose laboratory animals to a specific agent under controlled conditions and look for effects on body function, measures of health, or disease. Experience has shown that effects in laboratory animals can help to predict effects that occur in people.

Initiation – The first stage in the development of cancer, initiation typically results from exposure to an agent that can cause mutations in a cell. Initiation is believed to be irreversible, and increases the likelihood of cancer occurring.

Job-exposure matrix – A job-exposure matrix cross-classifies job titles and exposure estimates. Job-exposure matrices are used to estimate cumulative occupational exposure (e.g., magnetic field exposure) based on an individual's job history.

Magnetic fields – The magnetic field is a state of region in space, and describes the forces that

would be experienced by a moving charge (or magnetic material) in proportion to its charge and velocity. The strength of magnetic fields is expressed as magnetic flux density in units called gauss (G), or in milligauss (mG), where 1 G = 1,000 mG.

Meta-analysis – An analytic technique that combines the results of many studies into one summary estimate of the association between a particular exposure and disease.

Nested case-control study – A case-control study in which the cases and controls are drawn from a cohort study's population.

Odds ratio – An odds ratio is a measure of association that describes the ratio of the odds of exposure among persons with a disease to the odds of exposure among persons without a disease. For example, an odds ratio of two would suggest that persons with the disease are two times more likely to have had exposure than persons without the disease.

Pooled analysis – A pooled analysis combines individual-level data across many studies and analyzes the data together to get a summary estimate of the association between a particular exposure and disease.

Precautionary principle – The precautionary principle refers to the idea that, when evidence does not support the suggestion that an exposure is a cause of a particular disease but where a risk is perceived, precautionary measures may be taken that are proportional to the perceived level of risk, with science as the basis for measuring that risk.

Promotion – Promotion is a later stage in cancer development, following initiation. If there is sufficient exposure to the agent, promoters increase the frequency of tumor formation that occurs after initiation.

Reference level – The reference level is a measurable level of electric or magnetic field outside of the body that is used as a screening value. It is a practical measure to determine whether the internal level identified as the basic restriction is likely to be exceeded.

Relative risk – A relative risk is an estimate that compares the risk of disease among persons who are exposed to the risk of disease among persons who are unexposed. For example, a relative risk of two means that that exposed persons in the study are two times more likely to develop the disease than unexposed persons.

Risk characterization – A quantitative estimation of the likelihood of adverse effects that may result from exposure to a specific agent in a specific situation.

Safety factor – A multiplicative factor (usually less than 1.0) incorporated into risk assessments or safety standards to allow for unpredictable types of variation, such as variability in responses from test animals to humans or person-to-person variability.

Selection bias – Selection bias occurs when there are differences in the type of person who participates in the study compared to the type of person who doesn't participate in the study. Selection bias introduces systematic error into a study, and limits the conclusions and generalizations that can be drawn.

Spot measurement – A spot measurement is an instantaneous magnetic or electric field reading that is taken at one location as an estimate of exposure.

Statistically significant – An association is statistically significant if one can conclude (with an established level of confidence using standard statistical tests) that the association is not due to a chance occurrence.

Time-weighted average (TWA) - The average exposure over a given specified time period (i.e., an 8-hr workday or a 24-hr day) of a person's exposure to a chemical or physical agent. The average is determined by sampling the exposure of interest throughout the time period.

Voltage – Voltage is the difference in electric potential between any two conductors of a circuit. It is the electric 'pressure' that exists between two points and is capable of producing the flow of current through an electrical conductor.

Weight-of-evidence review – A weight-of-evidence review critically evaluates the strength of the evidence for causality for a particular exposure and disease. It entails a comprehensive assessment of *all* relevant scientific research, in which each of the studies is critically evaluated, and more weight is given to studies of better quality.

Wire code categories – Wire coding categories are based on a classification system of homes using characteristics of power lines outside the home (e.g., thickness of the wires) and their distances from the home. This information is used to code the homes into categories based on their predicted magnetic field level.

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Appendix 1. Additional Topics

This appendix is designed to provide concise responses to questions typically raised by members of the public when they are trying to understand the scientific research related to EMF and health. These questions typically focus on reports or studies singled out from the large research database or concerns about specific diseases. Several of these reports are addressed below, including the BioInitiative Report, the study by Draper et al., and a report summarizing an evaluation of EMF by the California Department of Health. In addition, this appendix addresses concerns about the label "possible carcinogen" and the comparison of the utility industry to the tobacco industry.

Underlying many of these specific questions is a fundamental misunderstanding of the importance of assessing the cumulative body of evidence, including both epidemiologic and experimental research studies. Section 2 of the report has described the major steps in interpreting research, including the careful analysis needed to distinguish a statistical association from a causal link (Section 2.3.1). In addition, Section 4 of this report can address concerns commonly expressed about specific diseases such as Alzheimer's disease, childhood leukemia, breast cancer, and miscarriage.

According to the BioInitiative Report, the existing standards and reviews fall short of protecting us from adverse health effects. Why have the conclusions of this report been largely ignored by scientific organizations, and why have the authors' conclusions not led to the lowering of exposure limits?

The BioInitiative Report's conclusions have not been persuasive because the authors did not utilize the major elements of a weight of evidence review – i.e., a systematic review of the literature, an evaluation of the quality and reliability of each study, and the consideration of information from ***all*** research approaches (epidemiology, *in vivo* studies, and *in vitro* studies). The individuals who comprised the *ad hoc* group that prepared the report did not represent any well-established regulatory agency, nor were they convened by a recognized scientific authority; the report was a compilation of chapters written by separate authors, rather than a weight of the evidence review. The authors of the report contended that the standard scientific procedure for developing exposure guidelines –i.e., to set limits below exposure levels where adverse health effects have been established by using a weight-of-evidence approach– is not appropriate and should be replaced by a process that limits exposures at levels where biological effects have

been reported in some studies. Based on this argument, the main conclusion of the BioInitiative report was that existing standards for exposure to ELF-EMF are insufficient because "effects are now widely reported to occur at exposure levels significantly below most current national and international limits." The current scientific consensus, however, is that these biological effects (or bioeffects) have not been substantiated in a rigorous review of the scientific research, nor have they been linked to adverse health effects. Furthermore, the scientific community does not agree that exposure limits should be set at levels where bioeffects occur; rather, exposure limits should reflect the level at which any adverse health effects have been established.

The BioInitiative Report has been reviewed and evaluated by scientists and scientific organizations around the world, including HCN (2008), the Australian Centre for Radiofrequency Bioeffects Research (2008), and the EMF-NET Consortium that is funded by the European Commission.[29] After reviewing the BioInitiative report, these agencies have not changed their opinion regarding EMF and health because the conclusions of the report were not rooted in a valid scientific process.

Should we be worried by the term "*possible carcinogen*" that has been used to describe power frequency magnetic fields?

The term is actually a specific category used by the IARC to classify exposures based on the evidence for carcinogenicity following a weight-of-evidence review. To interpret its meaning under ordinary circumstances can be misleading because it is a label that is generated in the context of describing scientific evidence.

The IARC weight-of-evidence review evaluates and rates the studies from each research type (epidemiology, *in vivo,* and *in vitro*) to determine the strength of the evidence for the ability of the exposure to cause cancer. After all of the epidemiologic studies are reviewed, the weight of evidence is summarized as *sufficient evidence, limited evidence*, or *inadequate evidence*. The same overall categories apply for *in vivo* research. *In vitro* research is used to a lesser degree in evaluating carcinogenicity and is classified as *strong*, *moderate,* or *weak*.

[29] This is a group of 41 participants that "aims to provide a framework for the coordination of the results of the research activities related to the biological effects of [EMF]…" (http://emf-net.isib.cnr.it).

Agents are then classified into the following categories using the combined categories from epidemiology, *in vivo* and *in vitro* research: *carcinogenic to humans, probably carcinogenic to humans, possibly carcinogenic to humans, unclassifiable*, and *probably not carcinogenic to humans* (from highest to lowest risk). The category "*possibly carcinogenic to humans*" typically denotes exposures for which there is limited evidence of carcinogenicity in epidemiology studies and less than sufficient evidence of carcinogenicity in *in vivo* studies. This category was applied to power frequency magnetic fields, based primarily on the research regarding childhood leukemia (IARC, 2002).[30]

The IARC has reviewed over 900 substances and exposure circumstances to evaluate their potential carcinogenicity. Over 80% of exposures fall in the categories *possible carcinogen* (27%) or *unclassifiable* (55%). This occurs because it is nearly impossible to prove that something is completely safe, and few exposures have shown a clear-cut or probable risk, so most agents will end up in either of these two categories. Note that throughout the entire history of the IARC only one agent has been classified in the category *probably not carcinogenic*, which illustrates the conservative nature of the evaluations and the difficulty in proving the absence of an effect beyond all doubt.

As an example, common exposures identified by IARC as *possible carcinogens* include occupation as a firefighter, coffee, and pickled vegetables, in addition to magnetic fields. Exposures identified as *probable carcinogens* include high temperature frying of food and occupation as a hairdresser. Finally, *known carcinogens* include benzene, asbestos, solar radiation, use of tanning beds, and tobacco smoke.

[30] The WHO reviewed more recent evidence and in 2007, wrote "Consistent epidemiological evidence suggests that chronic low intensity ELF magnetic field exposure is associated with an increased risk of childhood leukaemia. However, the evidence for a causal relationship is limited, therefore exposure limits based upon epidemiological evidence are not recommended, but some precautionary measures are warranted."

Does the epidemiology study from the United Kingdom by Draper et al. (2005) prove a link between power lines and leukemia?

The statistical association reported by Draper et al. (2005) between childhood leukemia and living within 600 meters of a power line suggests a cause-and-effect relationship to some individuals. In the Draper et al. study, the researchers used distance of the home from a transmission line as a surrogate for exposure to magnetic fields. Unreliable measurements of any exposure in epidemiology studies, including magnetic fields, cause the participants' exposures to be misclassified and, as a result, can cause serious bias (i.e., error) in the results. Distance from power lines has been shown to be an unreliable predictor of actual magnetic field levels in the home (Maslanyj et al., 2009). As a result, any observed association with a distance, even in a study otherwise well-designed, could be interpreted as a bias, or a relationship confused by another factor linked to distance (e.g., traffic density or socioeconomic status). For this reason, no scientific organization has placed weight on the findings by Draper et al.

A report summarizing an evaluation by the California Department of Health (CDHS) appears to support concerns that exposure to EMF can cause an increased risk of several diseases.[31] Why has this report been omitted from reviews that BCTC submitted to the BCUC?

The report from the state of California, published in 2002, was not included in the first review submitted to the BCUC because that report included reviews published December 2005 –August 2007 (Exponent, 2007). In order to reflect the current status of research, the report included weight-of-evidence reviews by national and international agencies that formed multidisciplinary scientific panels (SCENIHR, 2007; SSI, 2007; WHO, 2007).

The CDHS report reached conclusions regarding childhood leukemia and other diseases that differed from the conclusions of other organizations at that time, and from subsequent reviews. The disparity in conclusions stems from differences in several characteristics of the CDHS approach; these differences detract from the value of the CDHS's conclusions. First, the evaluation by the CDHS was conducted by a review committee of only three scientists who

[31] The report concludes: "To one degree or another, all three of the DHS scientists are inclined to believe that EMFs can cause some degree of increased risk of childhood leukemia, adult brain cancer, Lou Gehrig's disease, and miscarriage."

worked together at the CDHS. In contrast, each of the other contemporary expert review groups, such as the U.S. National Institute of Environmental Health Sciences (NIEHS, 1998) and IARC (2002), was convened by a scientific agency and included a large panel of independent scientists from various organizations and academic institutions. Second, the CDHS committee represented a narrow spectrum of professional expertise, mainly epidemiology, in contrast to other groups whose expertise included a broad spectrum of scientific disciplines including laboratory sciences (such as cytogenetics, biophysics, and toxicology), epidemiology, and engineering. Finally, the CDHS scientists gave undue importance to the results of epidemiologic studies and much less to results in experimental studies of animals, ignoring an important component of any weight-of-evidence health risk evaluation.

Section 3 of this report summarizes subsequent national and international reviews conducted by various international and national agencies (WHO, 2007; SCENIHR, 2009, etc.). None of these viewed the data as a basis to conclude that EMF causes or contributes to childhood leukemia, or any other disease.

Members of the public have suggested that exposure to EMF is just like cigarette smoking, implying that serious health effects of EMF exist, but are being denied by industry.

This analogy is not correct. The results of the epidemiologic and experimental research on the hazards of cigarette smoking are strikingly different from that on EMF, and the utility industry accepts the conclusions about health effects from scientific and health agencies, as opposed to the alleged misconduct of the tobacco industry.

The research differences can be illustrated by comparing the epidemiology data on cigarette smoking and the epidemiologic research on EMF. The associations between smoking and lung cancer reported in epidemiologic case-control studies were high, and an important study of a large cohort showed a 10-fold relative risk in smokers compared to non-smokers (Doll and Hill, 1956). These results contrast sharply with the weak, 2-fold or less associations reported for childhood leukemia and magnetic field exposure. A strong association is important in determining risk because the stronger the association, the less room for concern that the association is due to biases, confounding, difficulties in assessing exposure, or other potential errors that can occur into epidemiologic studies. In contrast with EMF, the research on smoking

shows clear evidence that the association was stronger with greater amounts of smoking (packs per day or number of cigarettes per day), that is, a dose-response relationship. Research prior to the 1950s also provided biological and medical evidence of health risks consistent with the epidemiologic observations, such as changes in cells lining the lung and bronchus. Neither a dose-response relationship nor consistency with experimental results has been reported for EMF research. One of the early formal health conclusions about cigarette smoking by a scientific agency was prepared in 1964, called the U.S. Surgeon General's Report on Smoking (USHEW, 1964). The Surgeon General used the Hill Criteria as a guide for assessing causation, evaluating the strength, consistency, dose response, and biological plausibility of the research data, just as BCTC's reports have done in the assessment of EMF research (See Section 2.3).

The role of the tobacco industry in denying the scientific consensus that smoking was harmful has no bearing in the matter of EMF. No scientific agency has concluded that there is a cause-and-effect relationship, and the utility industry relies on the conclusions of these scientific agencies.