

12 HEALTH RISK ASSESSMENT

12.1 Introduction

The control of health risks from the exposure to any physical, chemical or biological agent is informed by a scientific, ideally quantitative, assessment of potential effects at given exposure levels (risk assessment). Based upon the results of the risk assessment and taking into consideration other factors, a decision-making process aimed at eliminating or, if this is not possible, reducing to a minimum the risk from the agent (risk management) can be started. The discussion below is based on the WHO Environmental Health Criteria 210 which describes the principles for the assessment of risks to human health from exposure to chemicals (WHO, 1999). These principles are generally applicable and have been used here for ELF electric and magnetic fields.

Risk assessment is a conceptual framework that provides the mechanism for a structured review of information relevant to estimating health or the environmental effects of exposure. The risk assessment process is divided into four distinct steps: hazard identification, exposure assessment, exposure-response assessment and risk characterization.

- The purpose of *hazard identification* is to evaluate qualitatively the weight of evidence for adverse effects in humans based on the assessment of all the available data on toxicity and modes of action. Primarily two questions are addressed: (1) whether ELF fields may pose a health hazard to human beings and (2) under what circumstances an identified hazard may occur. Hazard identification is based on analyses of a variety of data that may range from observations in humans to studies conducted in laboratories, as well as possible mechanisms of action.
- *Exposure assessment* is the determination of the nature and extent of exposure to EMF under different conditions. Multiple approaches can be used to conduct exposure assessments. These include direct techniques, such as the measurement of ambient and personal exposures, and indirect methods, for example questionnaires and computational techniques.
- *Exposure-response assessment* is the process of quantitatively characterizing the relationship between the exposure received and the occurrence of an effect. For most types of possible adverse effects (i.e. neurological, behavioural, immunological, reproductive or developmental effects), it is generally considered that there is an EMF exposure level below which adverse effects will not occur (i.e. a threshold). However, for other effects such as cancer, there may not be a threshold.
- *Risk characterization* is the final step in the risk assessment process. Its purpose is to support risk managers by providing the essential scientific evidence and rationale about risk that they need

for decision-making. In risk characterization, estimates of the risk to human health under relevant exposure scenarios are provided. Thus, a risk characterization is an evaluation and integration of the available scientific evidence and is used to estimate the nature, importance and often the magnitude of human risk, including a recognition and characterization of uncertainty that can reasonably be estimated to result from exposure to EMF under specific circumstances.

The health risk assessment can be used as an input to risk management, which encompasses (1) all the activities needed to reach decisions on whether an exposure requires any specific action(s), (2) which actions are appropriate and (3) the undertaking of these actions. Such risk management activities are further discussed in Chapter 13.

12.2 Hazard identification

12.2.1 *Biological versus adverse health effects*

According to the WHO Constitution, health is a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity. Before identifying any actual health hazards, it is useful to clarify the difference between a biological effect and an adverse health effect. A biological effect is any physiological response to, in this case, exposure to ELF fields. Some biological effects may have no influence on health, some may have beneficial consequences, while others may result in pathological conditions, i.e. adverse health effects. Annoyance or discomfort caused by ELF exposure may not be pathological per se but, if substantiated, can affect the physical and mental well-being of a person and the resultant effect may be considered to be an adverse health effect.

12.2.2 *Acute effects*

ELF electric and magnetic fields can affect the nervous systems of people exposed to them, resulting in adverse health consequences such as nerve stimulation, at very high exposure levels. Exposure at lower levels induces changes in the excitability of nervous tissue in the central nervous system which may affect memory, cognition and other brain functions. These acute effects on the nervous system form the basis of international guidelines. However, they are unlikely to occur at the low exposure levels in the general environment and most working environments.

Exposure to ELF electric fields also induces a surface electric charge which can lead to perceptible, but non-hazardous effects, including microshocks.

12.2.3 *Chronic effects*

Scientific evidence suggesting that everyday, chronic, low-intensity ELF magnetic field exposure poses a possible health risk is based on epidemiological studies demonstrating a consistent pattern of an increased risk of childhood leukaemia. Uncertainties in the hazard assessment include the role

of control selection bias and exposure misclassification. In addition, virtually all of the laboratory evidence and the mechanistic evidence fails to support a relationship between low-level ELF magnetic field exposure and changes in biological function or disease status. Thus, on balance, the evidence is not strong enough to be considered causal and therefore ELF magnetic fields remain classified as possibly carcinogenic.

A number of other diseases have been investigated for possible association with ELF magnetic field exposure. These include other types of cancers in both children and adults, depression, suicide, reproductive dysfunction, developmental disorders, immunological modifications, neurological disease and cardiovascular disease. The scientific evidence supporting a linkage between exposure to ELF magnetic fields and any of these diseases is weaker than for childhood leukaemia and in some cases (for example, for cardiovascular disease or breast cancer) the evidence is sufficient to give confidence that magnetic fields do not cause the disease.

12.3 Exposure assessment

Electric and magnetic field exposures can be expressed in terms of instantaneous or temporally averaged values. Either of these can be calculated from source parameters or measured.

12.3.1 Residential exposures

In the case of residential exposure, data from various countries show that the geometric means of ELF magnetic field strengths across homes do not vary dramatically. Mean values of ELF electric fields in the home can be up to several tens of volts per metre. In the vicinity of some appliances, the instantaneous magnetic field values can be as much as a few hundreds of microtesla. Close to power lines, magnetic fields reach as much as approximately 20 μT and electric fields can be between several hundreds and several thousands of volts per metre.

The epidemiological studies on childhood leukaemia have focused on average residential ELF magnetic fields above 0.3 to 0.4 μT as a risk factor for cancer. Results from several extensive surveys showed that approximately 0.5–7% of children had time-averaged exposures in excess of 0.3 μT and 0.4–3.3% were exposed to in excess of 0.4 μT . Calculations based on case-control studies of ELF magnetic field exposure and childhood leukaemia resulted in approximately similar ranges.

12.3.2 Occupational exposures

Occupational exposure is predominantly at power frequencies and their harmonics. Magnetic field exposure in the workplace can be up to approximately 10 mT and this is invariably associated with the presence of conductors carrying high currents. In the electrical supply industry, workers may be exposed to electric fields up to 30 kV m^{-1} , which induce electric fields in the body and lead to increased occurrence of contact currents and microshocks.

12.4 Exposure-response assessment

Exposure-response assessment is the process of characterizing the relationship between the exposure received by an individual and the occurrence of an effect. There are many ways in which exposure-response relationships can be evaluated and a number of assumptions must be used to conduct such assessments.

12.4.1 Threshold levels

For some effects there may be a continuous relation with exposure, for others a threshold may exist. There will be a certain amount of imprecision in determining these thresholds. The degree of uncertainty is reflected partly in the value of a safety factor that is incorporated in order to derive the exposure limit.

Frequency-dependent thresholds have been identified for acute effects on electrically excitable tissues, particularly those in the central nervous system. These effects result from electric fields and currents that are induced in body tissues by ELF electric or magnetic field exposure (see Chapter 5). The ICNIRP (1998a) identified a threshold current density of 100 mA m^{-2} for acute changes in functions of the central nervous system (CNS: brain and spinal cord, located in the head and trunk) and recommended basic restrictions on current density induced in these tissues of 10 mA m^{-2} for workers and 2 mA m^{-2} for members of the public. A general consideration of neural tissue physiology suggested that these restrictions should remain constant between 4 Hz and 1 kHz, rising above and below these frequencies. More recently, the IEEE (2002) identified a threshold induced electric field strength of 53 mV m^{-1} at 20 Hz for changes in brain function in 50% of healthy adults. Effects taken into account included phosphene induction and other effects on synaptic interactions. The IEEE recommended basic restrictions on induced electric field strength in the brain of 17.7 mV m^{-1} in “controlled” environments and 5.9 mV m^{-1} for members of the public. The phosphene threshold rises above 20 Hz and therefore the basic restrictions recommended by the IEEE follow a frequency-proportional law up to 760 Hz, above which restrictions are based on peripheral nerve stimulation up to 100 kHz (IEEE, 2002). The net effect is that the guidance recommended by the ICNIRP (1998a) is more restrictive than that recommended by the IEEE (2002) at power frequencies (50/60 Hz) and above (see Section 12.5.1 below). The major factor responsible for this is the difference in cut-off frequency (20 Hz for the IEEE and 1 kHz for the ICNIRP) at which thresholds for electric field strength and induced current density begin to rise (Reilly, 2005).

No thresholds have not been identified for chronic effects.

12.4.2 Epidemiological methods

The most common means of characterizing an exposure-response relationship in epidemiology is through the derivation of estimates of relative risk or the odds ratio per unit of exposure or across exposure categories.

Most epidemiological studies have used the latter method. In summary, two recent pooled analyses of the studies on ELF magnetic fields and childhood leukaemia have presented dose-response analyses. These analyses have been conducted both on the basis of exposure categories and of continuous exposure data. All these analyses show that the risk increase becomes detectable around 0.3–0.4 μT . For exposure levels above these values, the data at present do not allow further analysis because of the small numbers of cases in the high exposure category.

12.5 Risk characterization

12.5.1 Acute effects

Exposure limits based on the acute effects on electrically excitable tissues, particularly those in the CNS, have been proposed by several international organizations. The current ICNIRP (1998a) guidelines for the general public at 50 Hz are 5 kV m^{-1} for electrical fields and 100 μT for magnetic fields, and at 60 Hz are 4.2 kV m^{-1} and 83 μT . For workers, the corresponding levels are 10 kV/m and 500 μT for 50 Hz and 8.3 kV m^{-1} and 420 μT for 60 Hz. The IEEE (2002) exposure levels are 5 kV m^{-1} and 904 μT for exposure to 60 Hz EMF for the general public. For occupational groups, the IEEE levels are 20 kV m^{-1} and 2710 μT at 60 Hz. The differences in the guidelines, derived independently by the IEEE and the ICNIRP, result from the use of different adverse reaction thresholds, different safety factors and different transition frequencies, i.e. those frequencies at which the standard function changes slope (see Section 12.4.1).

12.5.2 Chronic effects

The most common means of characterizing risks from epidemiological data for a single endpoint is to use the attributable fraction. The attributable fraction, based on an established exposure–disease relation, is the proportion of cases (of a disease) that are attributable to the exposure. The attributable fraction is based on the comparison between the number of cases in a population that occur when the population is exposed and the number that would occur in the same population if the population were not exposed, assuming that all the other population characteristics remain the same. The assumption of a causal relationship is critical to this evaluation. As noted in Chapter 11 and later in this chapter, an assumption of this kind is difficult to accept because of the numerous limitations on the epidemiological data on childhood leukaemia and ELF magnetic field exposure and a lack of supporting evidence from a large number of experimental studies. Nevertheless, a risk characterization has been performed in order to provide some insight into the possible public health impact assuming that the association is causal.

Attributable fractions for childhood leukaemia that may result from ELF magnetic field exposure have been calculated in a number of publications (Banks & Carpenter, 1988; Grandolfo, 1996; NBOSH - National Board of Occupational Safety and Health et al., 1996; NIEHS, 1999). Greenland & Kheifets (2006) have expanded on the analyses of two different sets of

pooled data on childhood leukaemia and ELF magnetic field exposure (Ahlbom et al., 2000; Greenland et al., 2000) to provide an updated evaluation covering estimates for attributable fractions in a larger number of countries than were included in the pooled analyses. In global terms, most of the information on exposure comes from industrialized countries. There are a number of regions of the world, such as Africa and Latin America, where no representative information on exposure is available. Although the odds ratios from the major study regions – North America, Europe, New Zealand and parts of Asia – are similar (and therefore estimates from a pooled analysis of data obtained in these regions could be used for the present calculation), there are substantial differences in the exposure distributions between these regions. Comparable or larger differences are expected to exist with and within other regions. Therefore, the estimates of attributable fractions calculated from the data of industrialized countries cannot be confidently generalized to cover developing countries.

Greenland & Kheifets (2006) also performed an analysis of the uncertainty in the estimates of attributable fractions, by varying the assumptions made (more details on this analysis can be found in the appendix). Using the exposure distribution from case-control studies, the calculated attributable fractions are generally below 1% for the European and Japanese studies and between 1.5 and 3% for the North American studies. Based upon the exposure surveys, the attributable fraction values vary between 1 and 5% for all areas. The confidence bounds on these numbers are relatively large. Moreover, since these calculations are highly dependent on assumptions about the exposure prevalence and distribution and on the effect of exposure on the disease, they are very imprecise. Thus, assuming that the association is causal, on a worldwide scale, the best point estimates of the calculated attributable numbers (rounded to the nearest hundred) range from 100 to 2400 childhood leukaemia cases per year that might be attributable to ELF magnetic field exposure (these numbers are derived from Figures A3 and A4 in the appendix; Kheifets, Afifi & Shimkhada, 2006), representing 0.2 to 4.9% of the total annual number of leukaemia cases, which was calculated to be around 49 000 worldwide in 2000 (IARC, 2000).

12.5.3 Uncertainties in the risk characterization

12.5.3.1 Biophysical mechanisms

The biophysical plausibility of various proposed direct and indirect interaction mechanisms for ELF electric and magnetic fields depends in particular on whether a “signal” generated in a biological process or entity by exposure to such a field can be discriminated from inherent random noise. There is considerable uncertainty as to which mechanism(s) might be relevant. Three mechanisms related to the direct interaction of fields with the human body stand out as potentially operating at lower field levels than the others: induced electric fields in networks of neural tissues, the prolongation of the lifetime of radical pairs and effects on magnetite.

12.5.3.2 *Exposure metric*

At present it is unknown which, if any, aspect of exposure might be harmful. Certain actions, while reducing one aspect of exposure, might inadvertently increase another aspect that, if it were a causal factor, would lead to increased risk. However, the assumptions are usually that less exposure is preferable and that reducing one aspect of exposure will also reduce any aspect that might be harmful. Neither of these assumptions is certain. In fact, some laboratory research has suggested that biological effects caused by EMF vary within windows of frequency and intensity of the fields. While such a complex and unusual pattern would go against some of the accepted tenets of toxicology and epidemiology, the possibility that it may be real cannot be ignored.

12.5.3.3 *Epidemiology*

The consistently observed association between average magnetic field exposure above 0.3–0.4 μT and childhood leukaemia can be due to chance, selection bias, misclassification and other factors which can potentially confound the association or a true causal relationship. Given that the pooled analyses were based on large numbers, chance as a possible explanation seems unlikely. Taking into account potential confounding factors has not changed the risk estimates and substantial confounding from factors that do not represent an aspect of the electric or magnetic fields is unlikely. Selection bias, particularly for the controls in case-control studies, may be partially responsible for the consistently observed association between ELF magnetic field exposure and childhood leukaemia. Difficulties with exposure assessment are likely to have led to substantial non-differential exposure misclassification, but this is unlikely to provide an explanation for the observed association and may in fact lead to an underestimation of the magnitude of risk. Exposure misclassification may also introduce uncertainty into the potential dose-response relation. Because the estimates of the attributable fraction are calculated from the relative risks and exposure prevalence, and since both are affected by exposure misclassification, the attributable fraction may also be affected by exposure misclassification. However, the effect on the relative risk and on the exposure misclassification tends to work in opposite directions.

12.6 **Conclusions**

Acute biological effects have been established for exposure to ELF electric and magnetic fields in the frequency range up to 100 kHz that may have adverse consequences on health. Therefore, exposure limits are needed. International guidelines exist that have addressed this issue. Compliance with these guidelines provides adequate protection.

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 lim-

ited, therefore exposure limits based upon epidemiological evidence are not recommended, but some precautionary measures are warranted.