Introduction

While for substances that may be detrimental to health if incorporated through the skin, or by inhalation or ingestion precautionary procedures have been developed in the past decades that are applied in a transparent and standardised way by health authorities, public health agencies and international organisations in order to protect the public from a potential health hazard, no such procedures have been applied so far on a broader scale for electric, magnetic, and electromagnetic fields (EMF). In some countries (e.g. Italy and Switzerland) aspects of precaution have been entered into decisions about guideline levels limiting exposure to EMFs, however, these approaches have not been appreciated as major steps towards a change of paradigm in the derivation of exposure standards. “A cautionary policy for EMF should be adopted only with great care and deliberation. A principal requirement is that such policies be adopted in such a way not to undermine scientific assessment of risk and science-based exposure limits.” (WHO International EMF Project, Geneva, Oct 2003). This statements neglects a number of essential problems inherent in the process of the derivation of exposure limits that have since long been considered by other WHO bodies. An example are the introductory remarks to the WHO Air Quality Guidelines for Europe: “To produce a guideline with a high probability of offering absolute safety, one would need a detailed knowledge of dose–response relationships in individuals in relation to all sources of exposure, the types of toxic effect elicited by specific pollutants or their mixtures, the existence or nonexistence of ‘thresholds’ for specified toxic effects, the significance of interactions, and the variation in sensitivity and exposure levels within the human population. Such comprehensive and conclusive data on environmental contaminants are generally unavailable. Very often the relevant data are scarce and the quantitative relationships uncertain. Scientific judgement and consensus therefore play an important role in establishing guidance that can be used to indicate acceptable levels of population exposure. Value judgements are needed and the use of subjective terms such as ‘adverse effects’ and ‘sufficient evidence’ is unavoidable.” (WHO 2000).

It must be emphasised that neither risk assessment nor derivation of exposure limits can be based purely on scientific evidence. As underlined by the statement above value judgements are unavoidable as are decisions about how to deal with scientific uncertainties and which margin of safety is acceptable. In order to make the process transparent it is necessary to differentiate between statements that are based on a scientific evaluation (i.e. that are based on a thorough and balanced consideration of scientific evidence) and statements that are based on value judgements (e.g. introduction of safety factors).

The precautionary principle

There are a number of different procedures that could be adopted to effectively reduce exposure to environmental factors that could deteriorate human health. The precautionary principle demands that such measures should be taken before health impairments have been established beyond reasonable doubt. However, there are still a number of rules that must be observed, as has been pointed out in the EU Commission paper on the Precautionary
Principle: “Recourse to the precautionary principle presupposes that potentially dangerous effects deriving from a phenomenon, product or process have been identified, and that scientific evaluation does not allow the risk to be determined with sufficient certainty...The implementation of an approach based on the precautionary principle should start with a scientific evaluation, as complete as possible, and where possible, identifying at each stage the degree of scientific uncertainty.” (EC Commission, 2000, p.4).

In its document the EC Commission points out that where action is deemed necessary, measures should be:

- “proportional to the chosen level of protection,
- non-discriminatory in their application,
- consistent with similar measures already taken,
- based on an examination of the potential benefits and costs of action or lack of action (including, where appropriate and feasible, an economic cost/benefit analysis),
- subject to review, in the light of new scientific data, and
- capable of assigning responsibility for producing the scientific evidence necessary for a more comprehensive risk assessment.” (EC Commission, 2000, p.4)

It is pointed out that risk can rarely be reduced to zero. The measures should aim at reaching the chosen level of protection and not more (although a procedure that continuously reduces exposure to a possible hazard, like ‘Prudent Avoidance’, might be adopted). Also of great importance is the statement on ‘Non-discrimination’. At present chemical hazards are addressed more rigorously as compared to EMFs, and guidelines provide a much greater margin of safety for exposure to chemicals and particulates as for EMFs. It could be argued that under the non-discrimination principle this is exactly what is warranted, because it is said that “different situations should not be treated in the same way, unless there are objective grounds for doing so” (EC Commission 2000, p.4). However, there is no argument that has been brought forward so far, why the principles for the derivation of measures (e.g. guideline levels) should differ between chemicals and EMFs. The argument that these principles apply only to effects of long-term exposure and for EMFs such effects are not established and hence these principles cannot be applied, is invalid because the very fundament of the precautionary principle is that the risk has not been determined to sufficient certainty.

There are different types of precautionary measures that could be chosen in response to a possible health hazard:

- the total ban of the source of exposure (although this reaction might not be proportional, the EC Commission points out that this might in some cases be the only reaction possible)
- reduction of the exposure to as low a level as is technically or reasonably achievable (ALATA and ALARA principle)
- an avoidance strategy that aims at a stepwise reduction of the exposure by reducing exposures higher than a certain percentile of all exposures
• a minimising strategy that demands to choose from possible scenarios in a given context one that leads to the lowest exposure

• if the emission cannot be reduced, measures to reduce exposure either by obstructing the propagation or by shielding of subjects may be successful (especially in occupational settings)

• exposure levels can be derived that introduce high margins of safety thereby giving impulses to technical developments that effectively reduce exposure.

The Derivation of Guideline Levels

For hazardous conditions for which a total ban is not possible or feasible exposure might be reduced to a certain level that complies with a political decision about an acceptable risk. For exposures that are thought to have a threshold for the adverse effect usually a level is recommended that guarantees absence of these effects even in sensitive subjects (however, it should be noted that theoretically there are always subjects that have lower thresholds than any given limit), while for exposures that are associated with non-threshold effects (especially cancer) usually a limit is derived that is compliant with an accepted fraction of the population that will suffer from an adverse effect. In the case that both threshold and non-threshold effects occur, derivations are done for both types of effects and then the lower of the derived levels is chosen as guideline level.

Analysis starts with hazard characterisation based on a thorough examination of the evidence and also includes theoretical considerations of possible mechanisms of action. It is sought to describe in qualitative and/or quantitative terms the nature and severity of the effects. Furthermore, the relationship between the dose, intensity or amount of the agent and the magnitude, intensity or probability of the effect has to be explored. However, it is sometimes difficult or impossible to prove this relationship (e.g. because the causative component has not yet been established).

In the next step it is decided whether or not there are indications of non-threshold effects, especially if exposure may be carcinogenic. Although, according to modern theory, there are different types of carcinogens some of which may indeed have a threshold, usually for precautionary reasons it is assumed that there is no threshold. For this decision several procedures have been used. The International Agency for Research on Cancer (IARC), a WHO organisation, applies a procedure that includes consideration of possible mechanisms of action, evidence from epidemiology and animal experiments. These informations are used to classify the agent into one of four categories: The agent is carcinogenic in humans (class 1), it is probably (class 2A) or possibly (class 2B) carcinogenic, or it is probably not carcinogenic (class 4), or it is not classifiable as to its carcinogenicity (class 3). The process of classification is one of scientific discussion, because there is no unique procedure for the evaluation of evidence. It is a complex and subtle task that heavily relies on the subjects participating in the process. Despite the many critical comments it is still no distinctly better procedure at hand.

If an agent is classified into classes 1 or 2 all available information should be utilised to estimate the lifetime unit-risk, which is defined as the upper-bound excess lifetime cancer risk estimated to result from continuous exposure to one unit dose of the agent (e.g. 1 µg/m³). The upper bound is usually estimated by meta-analyses of existing epidemiological and other data. Typically a guideline level is derived from unit-risk by extrapolation to the acceptable risk, which is, according to regulations of the EC, set to $1 \times 10^{-6}$. Of course, as stated above, this rationale presupposes that there is no threshold for the endpoint in question.
**Childhood leukaemia and electromagnetic fields**

Thorough examinations of epidemiological evidence on power-frequency fields with respect to childhood leukaemia presented by a working group of the California Department of Health Services, by NIOSH, IARC and other groups provide some indication of a low threshold of about 0.2 to 0.3 µT for this endpoint. However, there is a severe methodological problem that is associated with the skewed distribution of exposure levels in the population. If in the case-control studies controls were selected randomly from the population at risk, distribution of exposure in controls is expected to be equal to that of the general population. It can be shown that the data accumulated up to now do not allow a distinction between models with and without assumption of a threshold.

Applying the derivation procedure outlined above a guideline value for power frequency fields below 0.2 µT would result. This value would be a factor of more than 500 below the guideline levels proposed by ICNIRP and recommended by the EC.

Considering the available evidence compiled in epidemiological studies about childhood leukaemia and high-frequency fields there is also weak support for the hypothesis of an association. Unfortunately there are too few studies that included some measurements and therefore these data can only be used for hazard identification. Based on the scarce data source no far reaching conclusions can be drawn. However, the precautionary approach demands to respond to the existing uncertainties by reducing the guideline levels. Based on this approach a reduction of exposure standards by a factor of 1000 or more would be recommended.

**Conclusions**

Derivation of exposure standards for electric, magnetic and electromagnetic fields have traditionally been based on a common denominator of established effects. In other areas of public health much less evidence has caused considerable reduction of exposure guidelines (e.g. particulate matter) and sometimes even a ban of usage of the respective factor (e.g. certain phthalate esters in toys).

There is coherent evidence that EMFs (especially power frequency fields but also low-frequency modulated high-frequency fields) are a risk factor for childhood leukaemia. However, considerations on the distribution of exposure in the population indicates that only a small proportion of these diseases may be associated with EMF exposure. The majority of leukaemias cannot be attributed to any known environmental or other factor and pose still a great challenge to the scientific community.