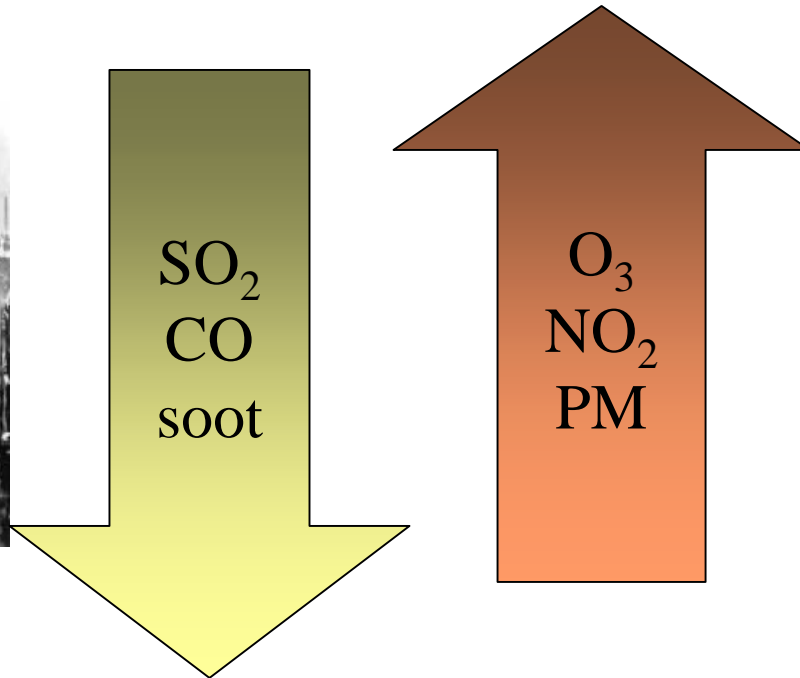


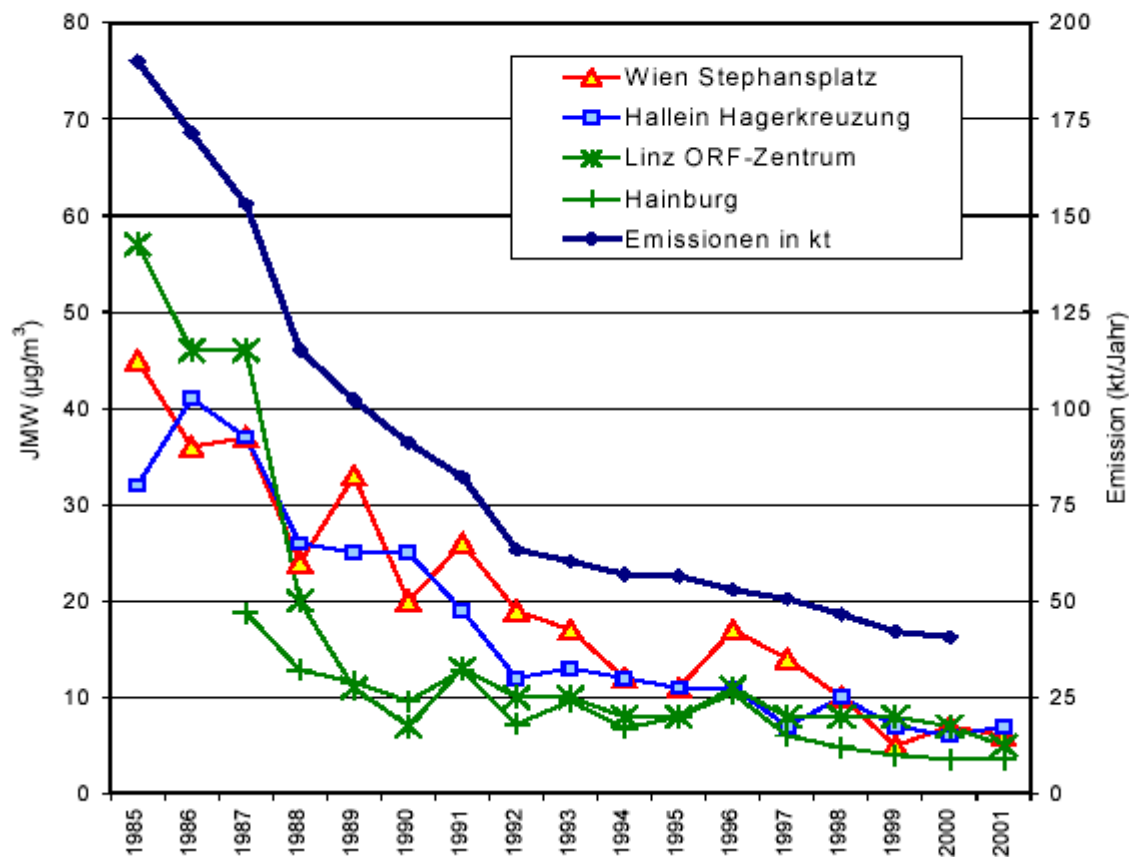
Precaution: Comparing Air and EMF Pollution

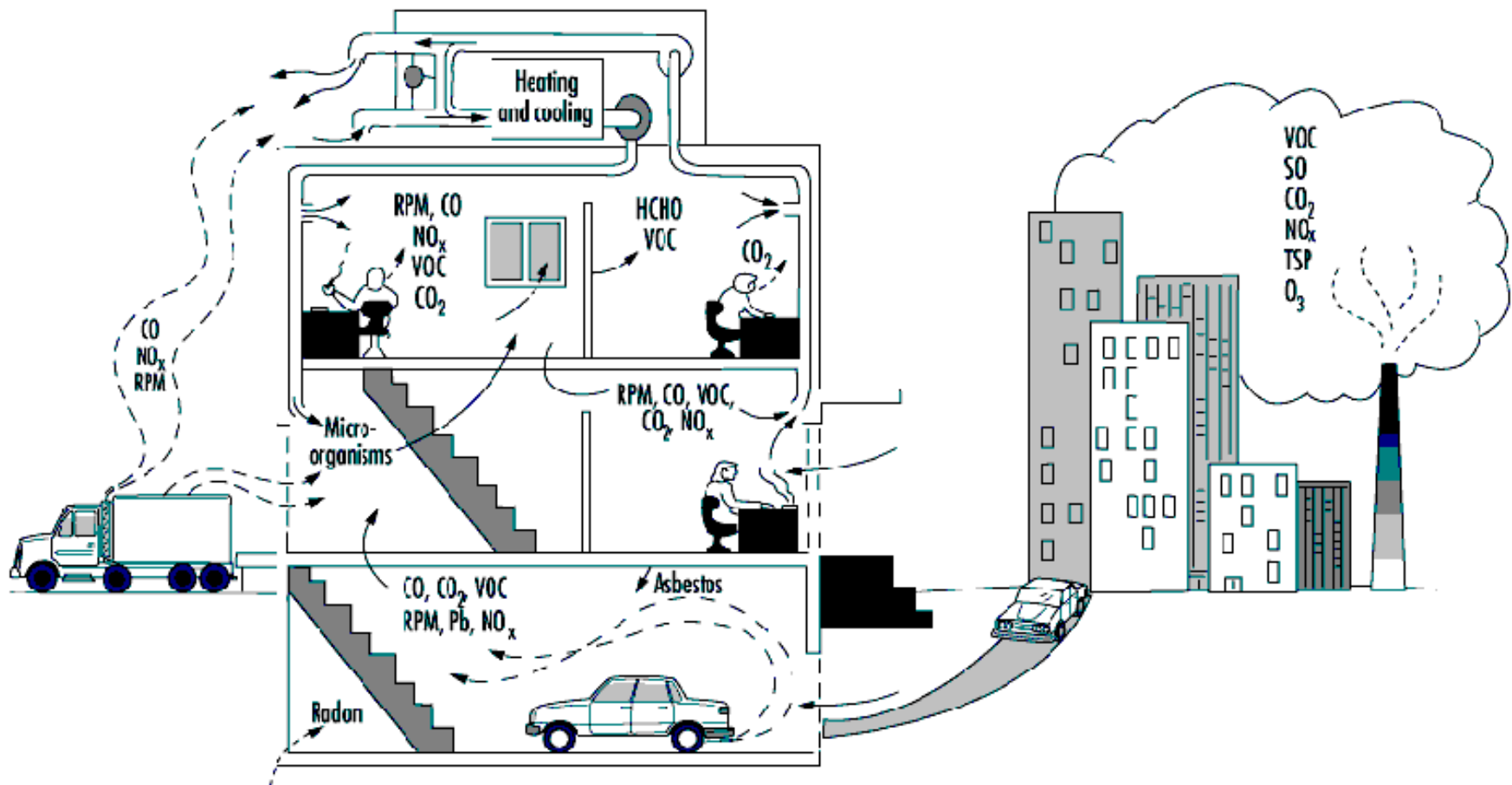
Michael Kundi

Air Pollution



Reduction of Sulphur Dioxide Emission and Exposure in Austria





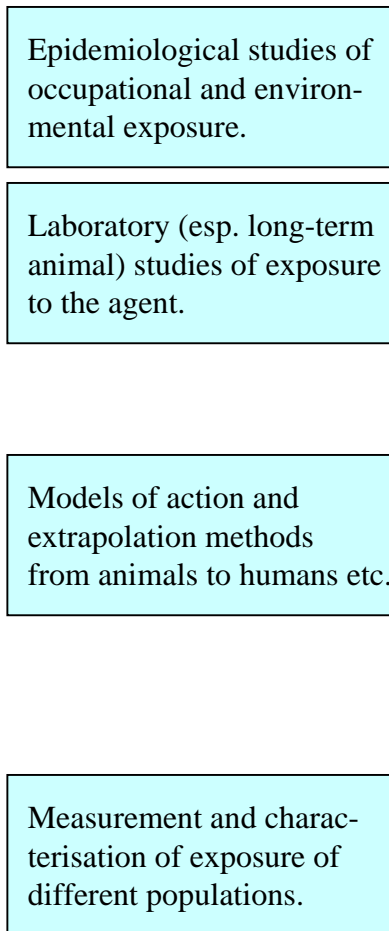
CO = carbon monoxide; CO₂ = carbon dioxide; HCHO = formaldehyde; NO_x = nitrogen oxides; Pb = lead; RPM = respirable particulate matter; VOC = volatile organic compounds.

Fighting Air Pollution

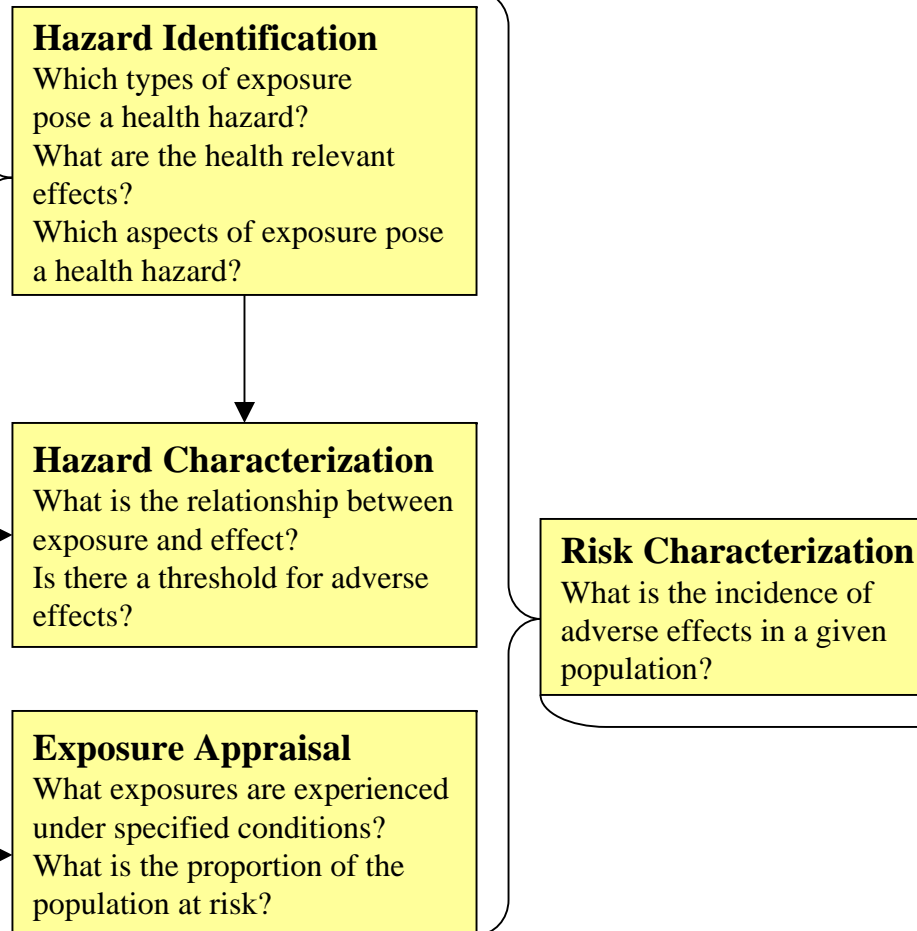
- Reduction of exposure at the workplace
- Improvement of filter technique and other measures to reduce industrial emission
- Reduction of emissions from vehicles
- Strict legislation ('Clean Air Act') concerning air pollution and introduction of target values for future improvements

The Risk Analysis Framework (adapted after NRC 1983)

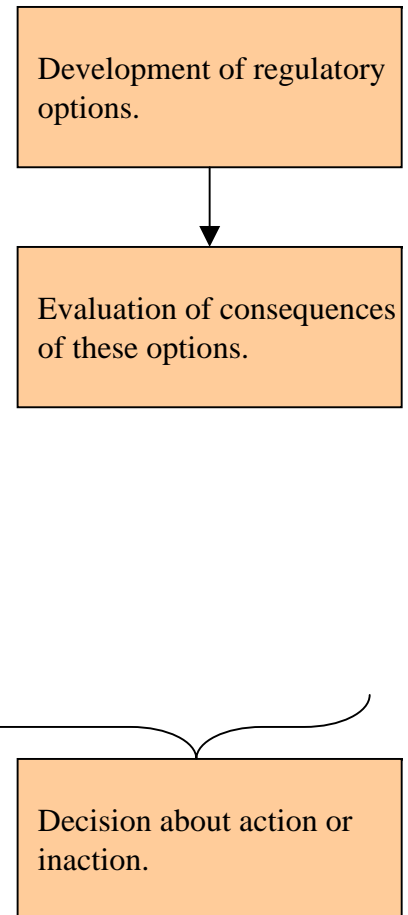
Research



Risk Assessment



Risk Management



The Precautionary Principle

...is a risk management concept that provides a flexible approach to identifying and managing possible adverse consequences to human health even when it has not been established that the activity or exposure constitutes harm to health.

The Precautionary Principle in the EC Communication from the Commission on the Precautionary Principle, Brussels 2.2.2000

Where action is deemed necessary, measures based on the precautionary principle should be, *inter alia*:

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

“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)

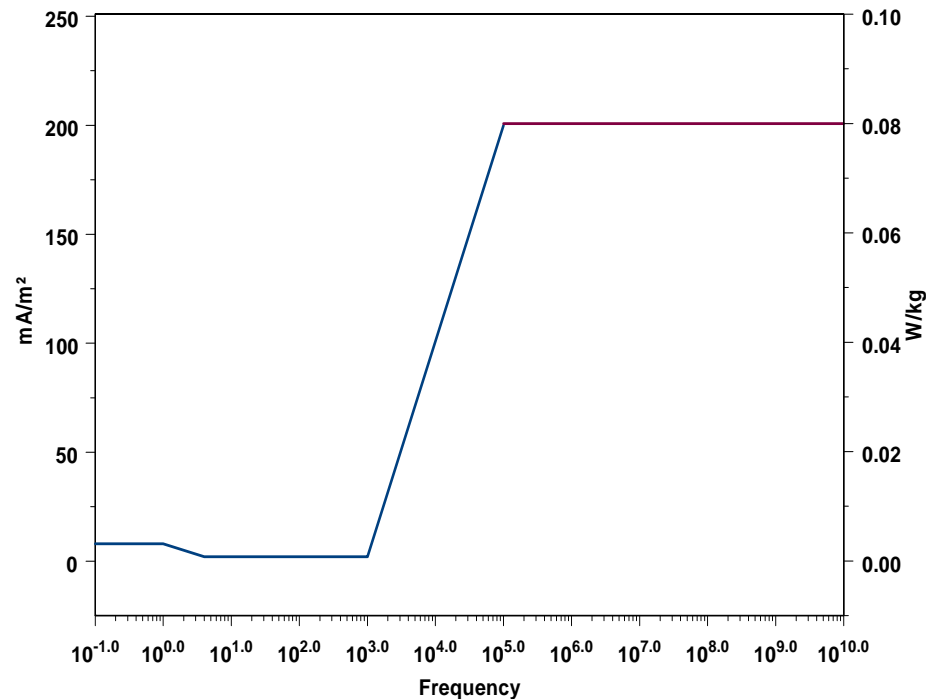
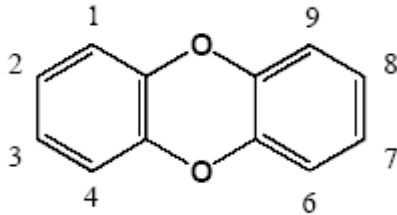
The ‘Framework for Developing EMF Standards‘ by the WHO EMF Project is based on a fundamental misunderstanding of the role and scope of science within the process of derivation of guidelines for limiting human exposure.

”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 Air Quality Guidelines for Europe, 2000)

Science and Politics

Science	Overarching activities	Politics
Analysis of facts Systematically testing of hypotheses Explanation and prognosis based on theories and side conditions	Application of convention Deliberations to reach a consensus in the case of ambiguity Evaluation of facts	Interpretation of facts Examination of need for action or in-action Decisions and actions based on what-should-be (the political goal)

Precautionary Approach	Approach by ICNIRP, IEEE, NRPB,... for EMF
Differentiate between environmental contaminants even if they are quite similar	Extrapolate to all types of exposure and all frequencies for as broad a range as possible



<i>Precautionary Approach</i>	<i>Approach by ICNIRP, IEEE, NRPB,... for EMF</i>
Select the most sensitive endpoint from peer-reviewed scientific reports	Select established effects that allow for a generalised approach

”...only established effects were used as the basis for the proposed exposure restrictions.”
(ICNIRP 1998, p.496)

Tetrachloroethylene	Effects on kidneys in workers
Trichloroethylene	Carcinogenicity in rats and mice
Toluene	CNS effects in workers

Low-frequency EMF	Muscle and nerve stimulation from induced currents
High-frequency EMF	Tissue heating from absorption of EMF energy

<i>Precautionary Approach</i>	<i>Approach by ICNIRP, IEEE, NRPB,... for EMF</i>
Assume the worst: If there are alternative explanations for an observed effect assume the one that leads to the highest level of protection	If there are alternative interpretations assume that the effects have not been caused by exposure to EMF but are due to confounding

“From the available evidence, it cannot be conclusively established whether a threshold with regard to carcinogenicity in the action of TCE may be assumed. Therefore, linear extrapolation from the animal tumour data is used, providing a conservative approach for estimating human cancer risk.”
(WHO Air Quality Guidelines, 2000)

“In spite of the large number data base, some uncertainty remains as to whether magnetic field exposure or some other factor(s) might have accounted for the increased leukaemia incidence.”
(WHO International EMF Project, Fact Sheet 263, 2001)

AIR POLLUTION Example: Styrene WHO Air Quality Guidelines 1996	EMF POLLUTION Example: High frequency fields ICNIRP 1998
Most sensitive endpoint: Neurobehavioral effects	Endpoint: Tissue heating
Observed effects in occupational cohorts at 8 h/day exposure to an average of 108-217 mg/m ³	Observed increase of whole body temperature in young adults at 30 min exposure to 4 W/kg
Factor of 4.2 for conversion from occupational (40 h) to continuous (168 h) exposure → 26 mg/m ³	Factor of 10 considering thermal stress in occupational exposures → 0.4 W/kg
Factor of 10 considering variation in susceptibility → 2.6 mg/m ³	Factor of 5 considering compromised thermoregulation → 0.08 W/kg
Factor of 10 for choosing a LOAEL instead of NOAEL → 0.26 mg/m ³	
Considering odour threshold 0.07 mg/m ³	
Overall safety factor: 420 (1543)	Overall safety factor: 50

Uncertainty factors

Uncertainty Factor	Definition
U_{FH}	Use a 1-, 3-, or 10-fold factor when extrapolating from valid data in studies using long-term exposure to average healthy humans. This factor is intended to account for the variation in sensitivity (intraspecies variation) among the members of the human population.
U_{FA}	Use an additional 1-, 3-, or 10-fold factor when extrapolating from valid results of long-term studies on experimental animals when results of studies of human exposure are not available or are inadequate. This factor is intended to account for the uncertainty involved in extrapolating from animal data to humans (interspecies variation).
U_{FS}	Use an additional 1-, 3-, or 10-fold factor when extrapolating from less-than-chronic results on experimental animals when there are no useful long-term human data. This factor is intended to account for the uncertainty involved in extrapolating from less-than-chronic NOAELs to chronic NOAELs.
U_{FL}	Use an additional 1-, 3-, or 10-fold factor when deriving a guideline level from a LOAEL, instead of a NOAEL. This factor is intended to account for the uncertainty involved in extrapolating from LOAELs to NOAELs .
U_{FD}	Use an additional 1-, 3-, or 10-fold factor when deriving a guideline level from an "incomplete" data base . Missing studies, e.g., reproductive, are often encountered with chemicals. This factor is meant to account for the inability of any study to consider all toxic endpoints. The intermediate factor of 3 ($\frac{1}{2}$ log unit) is often used when there is a single data gap exclusive of chronic data.

Basis for limiting exposure of power-frequency fields

Induced current density [mA/m ²]	Effects
> 1,000	Cardiac fibrillation
100 – 1,000	Induction of nerve/muscle excitations, changes in CNS reactions
10 – 100	Induction of phosphenes, reduction of heart rate, metabolic changes, effects on enzyme cycles, bone healing
1 - 10	Endocrine alterations, melatonin suppression, effects on calcium homeostasis
< 1	Long-term effects (cancer, degenerative CNS diseases)

Basis for limiting exposure of power-frequency fields

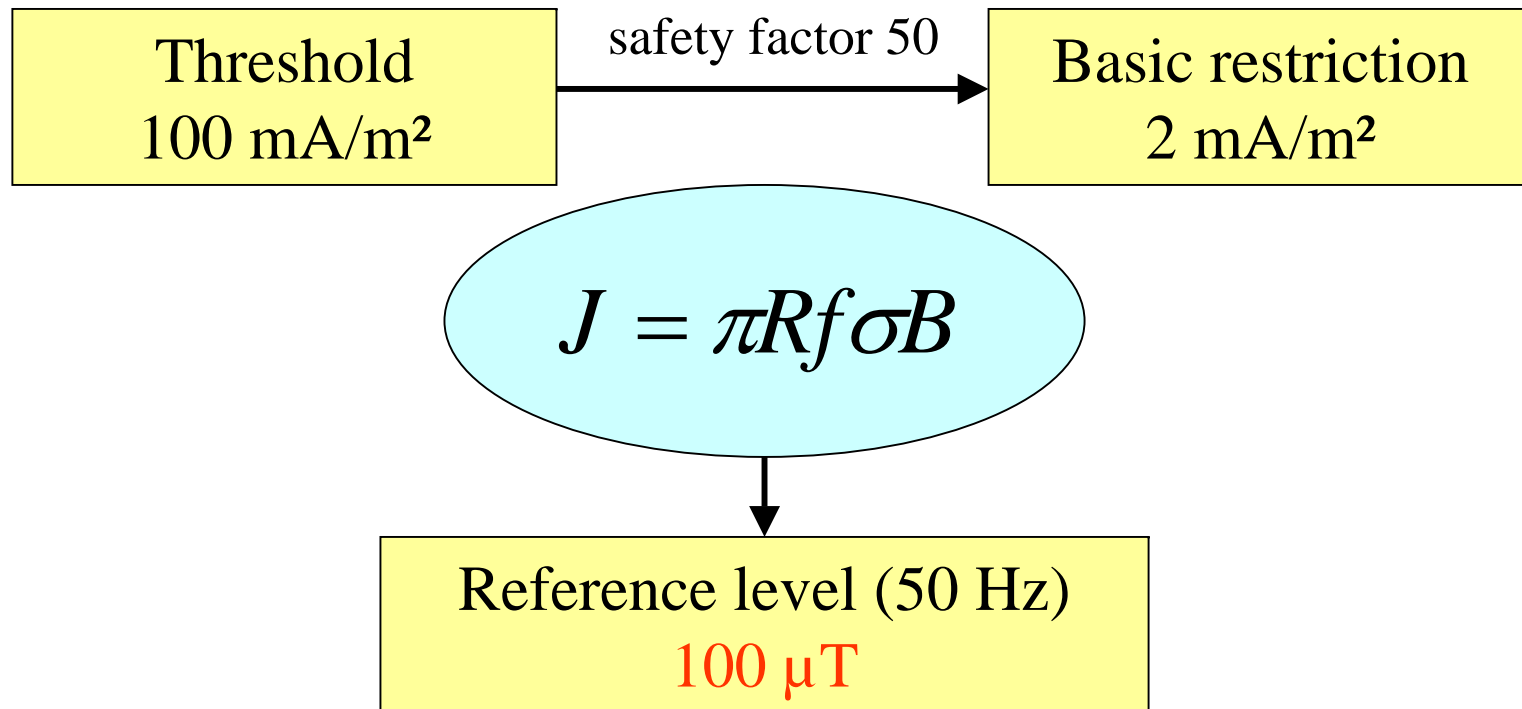
“It is the view of the ICNIRP that the results from the epidemiological research on EMF field exposure and cancer, including childhood leukemia, are not strong enough in the absence of support from experimental research to form a scientific basis for setting exposure guidelines.” (ICNIRP 1998, p.499)

“Neuroendocrine alterations (e.g., suppression of nocturnal melatonin synthesis) have been reported in response to ... induced current densities of approximately 2 mA m^{-2} or less... However, there is no clear evidence that these biological interactions of low-frequency fields lead to adverse health effects.” (ICNIRP 1998, p.501)

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Basis for limiting exposure of power-frequency fields



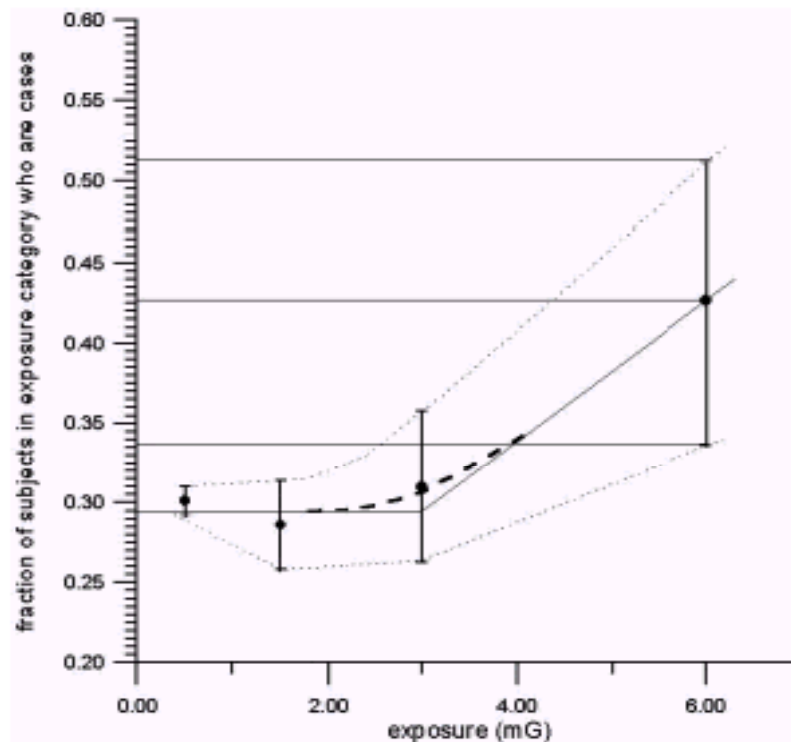
Alternative derivation based on a precautionary approach

IARC (International Agency for Research on Cancer, WHO) concluded that low-frequency magnetic fields are possibly carcinogenic to humans, based on limited evidence of an association with leukaemia in children and inadequate evidence for carcinogenicity in experimental animals.

Alternative derivation based on a precautionary approach

- Evaluation of the epidemiological evidence
- Evaluation of evidence from long-term animal studies
- Evaluation of in vitro studies and mechanistic interpretation

Alternative derivation based on a precautionary approach



Is there a threshold for the
increase of leukaemia risk?

California EMF Program, 2001

Alternative derivation based on a precautionary approach

Both, the model assuming a threshold as the one assuming no threshold, describe the data equally well.

The precautionary approach demands to choose the model leading to the higher margin of safety. In this case this is the model without threshold.

Alternative derivation based on a precautionary approach

Based on the analyses published by Ahlbom et al. (2000) and Greenland et al. (2000) the excess cumulative risk (below age 20) was estimated as a function of TWA magnetic field exposure. Background cumulative incidence was assumed to be approximately $60 \cdot 10^{-5}$.

Lower 95% CL for the TWA of magnetic field exposure associated with a relative risk of 1.017:

Proposed guideline level

0.21 μT

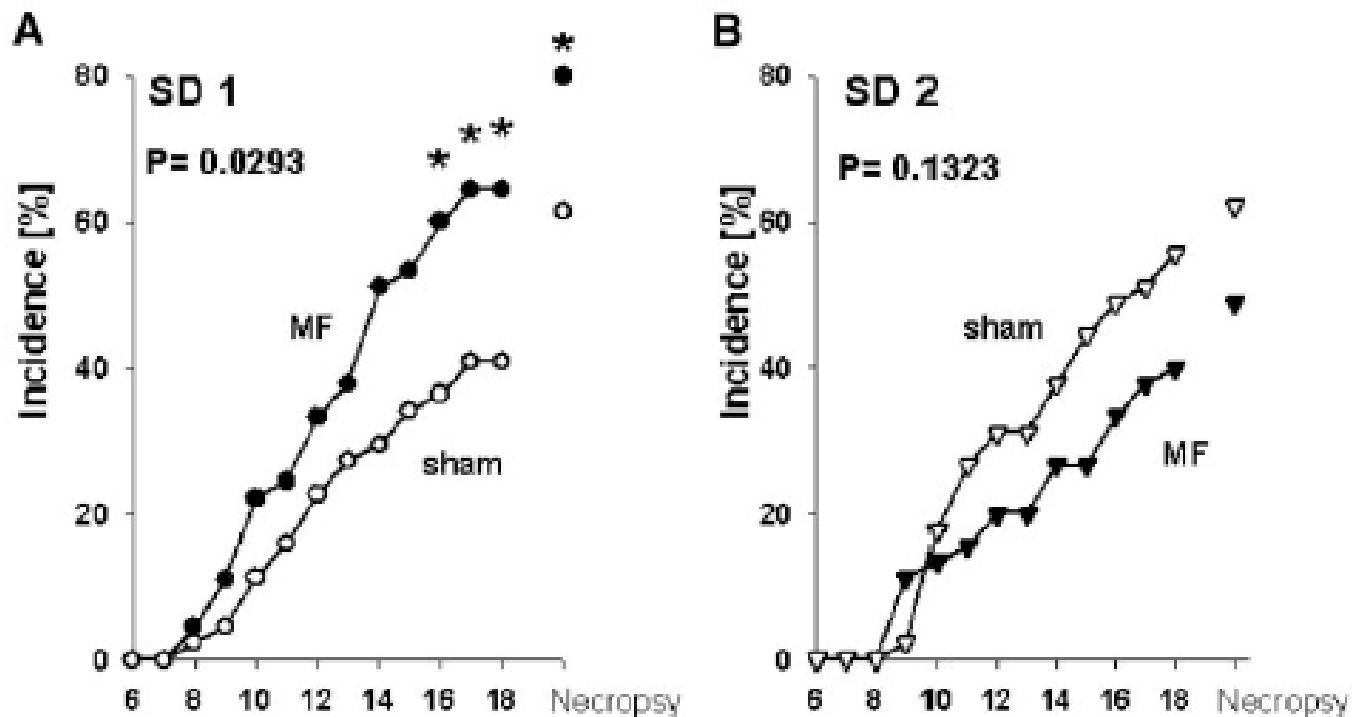
Alternative derivation based on a precautionary approach

Are epidemiological results consistent with animal experimentation?

IARC concluded that evidence from long-term animal studies is insufficient. The lack of consistency of results was addressed.

Alternative derivation based on a precautionary approach

Fedrowitz, Kamino & Löscher 2004 (Cancer Research 64:243-51)



Alternative derivation based on a precautionary approach

Is there supporting evidence from in vitro studies and a mechanistic interpretation?

IARC has concluded that the evidence from cellular studies and from animal experiments with genetic end-points are inconsistent.

The Melatonin Hypothesis

Original Formulation

Light at night and magnetic field exposure leads to reduced levels of circulating melatonin thereby reducing the anti-carcinogenic potential of melatonin and increasing the likelihood of cancer.

Alternative Formulation

Exposure to low levels of power-frequency fields inhibits anti-mitogenic pathways, in particular the action of melatonin, leading to increased turnover rates in either stem cells or pre-cancerous lesions thereby increasing the probability cancer.

The Melatonin Hypothesis

- It has been shown in three independent investigations that exposure to magnetic fields at low levels inhibits the action of melatonin in sensitive cell lines
 - Liburdy RP, Sloma TS, Sokolic R et al. ELF magnetic fields, breast cancer, and melatonin: 60 Hz fields block melatonin's oncostatic action on ER+ breast cancer cell proliferation. *J Pineal Res.* 1993;14:89-97
 - Blackman CF, Benane SG, House DE. The influence of 1.2 μ T, 60 Hz magnetic fields on melatonin- and tamocifen-induced inhibition of MCF-7 cell growth. *Bioelectromagnetics.* 2001;22:122-128
 - Ishido M, Nitta H, Kabuto M. Magnetic fields (MF) of 50 Hz at 1.2 μ T as well as 100 μ T cause uncoupling of inhibitory pathways of adenylyl cyclase mediated by melatonin 1a receptor in MF-sensitive MCF-7 cells. *Carcinogenesis,* 2001;22:1043-1048

Summary

- Understanding of basic interaction mechanisms of low-frequency magnetic fields at low exposure levels is poor
- There is some evidence that effects relevant to carcinogenesis occur only in individuals that have a specific disposition
- The type of disposition has not been clearly defined but it may be related to cell-cycle control

Summary

- There is evidence of an increased leukaemia risk in children
- There is some support from long-term animal studies
- There is some support from in vitro studies and a plausible and testable mechanistic hypothesis
- A precautionary procedure as applied for air pollutants would result in a recommended exposure standard of $0.2 \mu\text{T}$