

# Environmental Health Criteria

## PREAMBLE

### *The WHO Environmental Health Criteria Programme*

In 1973 the WHO Environmental Health Criteria Programme was initiated, with the following objectives:

- (i) to assess information on the relationship between exposure to environmental pollutants and human health, and to provide guidelines for setting exposure limits;
- (ii) to identify new or potential pollutants;
- (iii) to identify gaps in knowledge concerning the health effects of pollutants;
- (iv) to promote the harmonization of toxicological and epidemiological methods to have internationally comparable results.

The first Environmental Health Criteria (EHC) monograph, on mercury, was published in 1976. Since that time, an ever-increasing number of assessments of chemical and physical agents have been produced. In addition, many EHC monographs have been devoted to evaluating toxicological methodology, e.g., for genetic, neurotoxic, teratogenic and nephrotoxic agents. Other publications have been concerned with epidemiological guidelines, evaluation of short-term tests for carcinogens, biomarkers, effects on the elderly and so forth.

The original impetus for the Programme came from World Health Assembly resolutions and the recommendations of the 1972 UN Conference on the Human Environment. The work subsequently became an integral part of the International Programme on Chemical Safety (IPCS), a cooperative programme of UNEP, ILO and WHO. With the strong support of the new partners, the importance of occupational health and environmental effects became fully recognized. The EHC monographs have become widely established, used and acknowledged throughout the world.

### *Electromagnetic Fields*

Three monographs on electromagnetic fields (EMF) have addressed possible health effects from exposure to extremely low frequency (ELF) fields, static and ELF magnetic fields, and radiofrequency (RF) fields (WHO, 1984; WHO, 1987; WHO, 1993). They were produced in collaboration with the United Nations

Environment Programme (UNEP), the International Labour Office (ILO) and the International Non-Ionizing Radiation Committee (INIRC) of the International Radiation Protection Association (IRPA), and from 1992 the International Commission on Non-Ionizing Radiation Protection (ICNIRP).

EHC monographs are usually revised if new data are available that would substantially change the evaluation, if there is public concern for health or environmental effects of the agent because of greater exposure, or if an appreciable time period has elapsed since the last evaluation. The EHCs on EMF are being revised and will be published as a set of three monographs spanning the relevant EMF frequency range (0 - 300 GHz); static fields (this volume), ELF fields (up to 100 kHz) and RF fields (100 kHz - 300 GHz).

WHO's assessment of any health risks produced by EMF emitting technologies falls within the responsibilities of the International EMF Project. This Project was established by WHO in 1996 in response to public concern over health effects of EMF exposure and is managed by the Radiation and Environmental Health Unit (RAD), which is coordinating the preparation of the EHC Monograph on static fields.

The WHO health risk assessment exercise includes the development of an extensive database comprising relevant scientific publications. Interpretation of these studies can be controversial, as there is a spectrum of opinion within the scientific community and elsewhere. To achieve as wide a degree of consensus as possible, the health risk assessment also draws on reviews already completed by other national and international expert review bodies. With regard to static fields in particular, these reviews include:

- the IARC Monograph on static and extremely low frequency (ELF) fields (IARC, 2002). In June 2001 IARC formally evaluated the evidence for carcinogenesis from exposure to static and ELF fields. The review concluded that static fields were not classifiable as to their carcinogenicity to humans because there was inadequate evidence in humans and no relevant data available in experimental animals,
- reviews on physics/engineering, biology and epidemiology commissioned by WHO to the International Commission on Non-Ionizing Radiation Protection (ICNIRP), a non-governmental organization in formal relations with WHO (ICNIRP, 2003), and
- the WHO workshop on 'Effects of Static Magnetic Fields relevant to Human Health', co-sponsored with ICNIRP and the UK National Radiological Protection Board (NRPB), and hosted by NRPB on 26-27 April 2004 (Noble et al., 2005).

### *Scope*

The EHC monographs are intended to provide critical reviews on the effect on human health and the environment of physical, chemical and biological agents. As such, they include and review studies that are of direct relevance for the evaluation. However, they do not describe *every* study that has been carried out. Worldwide data are used and are quoted from original studies, not from abstracts or reviews. Both published and unpublished reports are considered, but preference is always given to published data. Unpublished data are only used when relevant published data are absent or when the unpublished data are pivotal to the risk assessment. A detailed policy statement is available that describes the procedures used for unpublished proprietary data so that this information can be used in the evaluation without compromising its confidential nature (WHO, 1990).

In the evaluation of human health risks, sound human data, whenever available, are generally more informative than animal data. Animal and *in vitro* studies provide support and are used mainly to supply evidence that is missing from human studies. It is mandatory that research on human subjects be conducted in full accord with ethical principles, including the provisions of the Helsinki Declaration.

All studies, with either positive or negative effects, need to be evaluated and judged on their own merit, and then collectively evaluated and judged in a weight of evidence approach. It is important to determine how much a set of evidence changes the probability that exposure causes an outcome. Generally, studies must be replicated or be in agreement with similar studies. The evidence for an effect is further strengthened if the results from different types of studies (epidemiology or laboratory) point to the same conclusion.

The EHC monographs are intended to assist national and international authorities in making risk assessments and subsequent risk management decisions. They represent a thorough evaluation of risks and are not, in any sense, recommendations for regulation or standard setting. These latter are the exclusive purview of national and regional governments. However, the EMF EHCs do provide bodies such as ICNIRP with the scientific basis for reviewing their international exposure guidelines.

### *Procedures*

The general procedures that result in the publication of this EHC monograph are discussed below (for more information, see van Deventer et al., 2005).

A first draft, prepared by consultants or staff from a RAD Collaborating Centre, is initially based on data provided from reference

databases, such as Medline and PubMed. The draft document, when received by RAD, may require an initial review by a small panel of experts to determine its scientific quality and objectivity. Once the document is acceptable as a first draft, it is distributed, in its unedited form, to well over 150 EHC contact points throughout the world who are asked to comment on its completeness and accuracy and, where necessary, provide additional material. The contact points, usually designated by governments, may be Collaborating Centres, or individual scientists known for their particular expertise. Generally, some months are allowed before the comments are considered by the author(s). A second draft incorporating comments received and approved by the Coordinator (RAD) is then distributed to Task Group members, who carry out the peer review at least six weeks before their meeting.

The Task Group members serve as individual scientists, not as representatives of their organization. Their function is to evaluate the accuracy, significance and relevance of the information in the document and to assess the health and environmental risks from exposure to the part of the electromagnetic spectrum being addressed. A summary and recommendations for further research and improved safety aspects are also required. The composition of the Task Group is dictated by the range of expertise required for the subject of the meeting (epidemiology, biological and physical sciences, medicine and public health) and by the need for a balance in gender, geographical distribution and the range of opinions on the science.

The membership of the WHO Task Groups is approved by the Assistant Director General of the Cluster on Sustainable Development and Healthy Environments. These Task Groups are the highest level committees within WHO for conducting health risk assessments. They are similar to the Working Groups established by the International Agency for Research on Cancer (IARC) that conduct 'carcinogen identification and classification' of various physical, chemical and biological agents.

Task Groups conduct a critical and thorough review of the scientific literature and assess any risks to health from exposure to both static electric and magnetic fields, reach agreements by consensus, and make final conclusions and recommendations that cannot be altered after the Task Group meeting.

The World Health Organization recognizes the important role played by non-governmental organizations (NGOs). Representatives from relevant national and international agencies may be invited to join the Task Group as observers. While observers may provide a valuable contribution to the process, they can only speak at the invitation of the Chairperson. Observers do not participate in the final evaluation, since this is the sole responsibility of the Task Group members. When the Task Group considers it to be appropriate, it may meet *in camera*.

All individuals who participate as authors, consultants or advisers in the preparation of the EHC monograph must, in addition to serving in their personal capacity as scientists, inform WHO if at any time a conflict of interest, whether actual or potential, could be perceived in their work. They are required to sign a conflict of interest statement. Such a procedure ensures the transparency and probity of the process.

When the Task Group has completed its review and the Coordinator (RAD) is satisfied as to the scientific consistency and completeness of the document, it is then subjected to language editing, reference checking, and a camera-ready copy is then prepared. After approval by the Director, the monograph is submitted to the WHO Office of Publications for printing. A copy of the final draft is then sent to the Chairperson and Rapporteur of the Task Group to check the proofs.

#### *Static Fields Environmental Health Criteria*

This EHC addresses the possible health effects of exposure to static electric fields and exposure to static magnetic fields. However, only a few animal and human laboratory studies have investigated the effects of exposure to static electric fields. The majority of studies reviewed here concern the effects of exposure to static magnetic fields. For completeness, studies of the effects of exposure to magnetic resonance imaging (MRI) fields have also been reviewed. In this case, however, the effects of static magnetic fields may well be confounded by possible effects of the pulsed gradient and radiofrequency (RF) magnetic fields. Other possible confounding variables, such as noise and vibration, may not have been adequately controlled in many experiments. These studies therefore contribute little to the static magnetic field health risk assessment.

The first draft of the EHC was written by a working group that met in Vlaardingen in the Netherlands (November 18-19, 2002). At this meeting, hosted by the Health Council of the Netherlands, it was decided that papers identified through literature searches performed in PubMed and other databases, including the reference lists and personal databases of working group members, would be reviewed by two reviewers and, on the basis of predefined criteria, considered informative or uninformative in the context of the EHC. These criteria included publication in a peer-reviewed journal, adequate description of the exposure, adequate description of the tests performed and of the biological system and materials used, appropriate statistical analysis of the data, and inclusion of adequate controls. Papers in languages other than English have been included as far as they could be read by at least one reviewer. All reviewed papers have been included in tables. Relevant information and comments from the reviewers are shown in the tables of those papers considered informative for health risk assessment. These have also been described in the text and form the basis of the health risk assessment and

the recommendations. Any papers considered inadequate for health risk assessment requirements have been listed at the end of each table.

The final draft EHC was subsequently distributed for external review. The comments received were processed by Dr Colin Roy (ARPANSA, Australia), Dr Rick Saunders (WHO, Switzerland) and Dr Eric van Rongen (Health Council of the Netherlands). The resulting modified draft EHC was then sent to the Task Group members.

The Task Group met from December 6-10, 2004, at WHO headquarters in Geneva, Switzerland. A full review of the draft EHC was made and changes incorporated into the text. The Task Group carried out a static field health risk assessment, summarized the EHC and formulated recommendations for further research.

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<sup>b</sup> Met in Geneva in September 2004 to review the draft monograph in preparation for the WHO Task Group meeting.

<sup>c</sup> Participated in the WHO Task Group meeting on static fields (World Health Organization, Geneva, Switzerland, 6 - 10 December 2004).

#### **Acknowledgements**

This monograph represents the most thorough health risk assessment ever undertaken for the static magnetic fields that are being increasingly used in medicine, industry and commerce. WHO acknowledges and thanks all contributors to this important monograph. Particular thanks go to Dr Eric van Rongen, Dr Colin Roy and Dr Richard Saunders for their continuing work throughout the development of this monograph. WHO also acknowledges the generous support from the

Health Council of the Netherlands in providing the time of Dr van Rongen, and for providing the scientific and language editing.

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23 August 2005

#### Abbreviations

AC	Alternating Current
ADPR	ADP Ribosylation
AGNIR	Independent Advisory Group on Non-ionising Radiation (United Kingdom)
AP	Action Potential
ARPANSA	Australian Radiation Protection and Nuclear Safety Agency
ASTM	American Society for Testing and Materials
BMD	Bone Mineral Density
CA	Chromosomal Aberrations
CERN	European Organization for Nuclear Research (Switzerland)
CGS	Centimetre – Gram – Second-based system of units (obsolete)
DC	Direct Current
DNA	Deoxyribonucleic Acid
DSV	Diameter Spherical Volume
EC	European Commission
ECG	Electrocardiogram
HVDC	High Voltage Direct Current
IARC	International Agency for Research on Cancer
ICNIRP	International Commission on Non-Ionizing Radiation Protection
INIRC	International Non-Ionizing Radiation Committee
IRPA	International Radiation Protection Association
ILO	International Labour Office
IPCS	International Programme on Chemical Safety
EHC	Environmental Health Criteria
ELF	Extremely Low Frequency
EMF	Electromagnetic Fields
EPSP	Excitatory Postsynaptic Potentials
GOT	Glutamic Oxalacetic Transaminase
GTP	Glutamic Pyruvic Transaminase
HIAA	Hydroxyindoleacetic Acid
HT	Serotonin
IFN	Interferon
LDH	Lactate Dehydrogenase
LEP	Large Electron Positron Collider

MAG	Metal Active Gas
MagLev	Magnetic Levitation
MEPP	Miniature End-plate Potential
MIG	Metal Inert Gas
MN	Micronuclei
MRI	Magnetic Resonance Imaging
MRS	Magnetic Resonance Spectroscopy
NAT	Serotonin- <i>N</i> -acetyltransferase
NGO	Non-governmental Organization
NIR	Non-ionizing Radiation
NMR	Nuclear Magnetic Resonance
NRPB	National Radiological Protection Board (United Kingdom)
PAF	Platelet Activating Factor
PBMC	Peripheral Blood Mononuclear Cells
PHA	Phytohaemagglutinin
PMNL	Polymorphonuclear Leucocytes
RNA	Ribonucleic Acid
RF	Radiofrequency
SCE	Sister Chromatid Exchange
SI	System International
SMF	Static Magnetic Fields
TNF	Tumour Necrosis Factor
US FDA	US Food and Drug Agency
UN	United Nations
UNEP	United Nations Environmental Program
UV	Ultraviolet
VDU	Visual Display Unit
WHO	World Health Organization