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 (ARPANS, 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.

**Participants in the working group and Task Group meetings on static electric and magnetic fields**

**Members**

Dr Igor Y. Belyaev, Department of Genetics Microbiology, and Toxicology, Stockholm University, Stockholm, Sweden "

Professor Donald Chakere, College of Medicine and Public Health, The Ohio State University Medical Center, Columbus, Ohio, USA 

Professor Stuart Crozier, The School of Information Technology and Electrical Engineering, The University of Queensland, Brisbane, Australia 

Dr Stefan Engstrom, Vanderbilt University Medical Center, Neurology Department, USA 

Dr Maria Feychtting, Institute of Environmental Medicine, Division of Epidemiology, Karolinska Institute, Stockholm, Sweden "

Dr Lawrence Goldstein, private consultant, California, USA 

Professor Leeka Kheifets, Department of Epidemiology, UCLA School of Public Health, Los Angeles, California, USA "

Dr Isabelle Lagroye, Laboratoire de Bioélectromagnétisme EPHE, Bordeaux, France 

Mr Rüdiger Matthes, Federal Office for Radiation Protection, Bundesamt für Strahlenschutz, Oberschleissheim, Germany 

Dr Alastair McKinlay, National Radiological Protection Board, Chilton, Didcot, Oxfordshire, United Kingdom 

Dr Chiyoji Ohkubo, National Institute of Public Health, Department of Environmental Health, Tokyo, Japan "

Dr Eric van Rongen, Health Council of the Netherlands, The Hague, The Netherlands "
Dr Martin Röösli, Department of Social & Preventive Medicine, University of Bern, Switzerland\textsuperscript{b,c}

Dr Colin Roy, Australian Radiation Protection and Nuclear Safety Agency, Victoria, Australia\textsuperscript{a,b,c}

Dr Paolo Vecchia, Department of Technology and Health, National Institute of Health, Rome, Italy \textsuperscript{c}

Professor Barney de Villiers, University of Stellenbosch, Faculty of Health Sciences, Cape Town, South Africa \textsuperscript{c}

Dr Jakub Wiskirchen, University Hospital Tübingen, Germany \textsuperscript{a}

Professor Zhengping Xu, Zhejiang University School of Medicine, Hangzhou, People's Republic of China \textsuperscript{a}

\textit{Observers}

Dr Hans Engels, Philips Medical Systems, The Netherlands \textsuperscript{a}

Dr Daniel J. (Joe) Schaefer, GE Healthcare, Milwaukee, Wisconsin, USA\textsuperscript{c}

\textit{Secretariat}

Dr Michael Repacholi, Radiation & Environmental Health, World Health Organization, Geneva, Switzerland \textsuperscript{c}

Dr Rick Saunders, Radiation & Environmental Health, World Health Organization, Geneva, Switzerland \textsuperscript{b,c}

Dr Emilie van Deventer, Radiation & Environmental Health, World Health Organization, Geneva, Switzerland \textsuperscript{c}

Dr Elisabeth Cardis, International Agency for Research on Cancer (IARC), Lyon, France \textsuperscript{c}

\textsuperscript{a} Participated in the working group meeting on the initial draft of the Static Fields EHC (Vlaardingen, the Netherlands, November 2002).

\textsuperscript{b} Met in Geneva in September 2004 to review the draft monograph in preparation for the WHO Task Group meeting.

\textsuperscript{c} Participated in the WHO Task Group meeting on static fields (World Health Organization, Geneva, Switzerland, 6 - 10 December 2004).

\textbf{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.

Dr Michael Repacholi
Coordinator, Radiation and Environmental Health
World Health Organization
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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
<table>
<thead>
<tr>
<th>MAG</th>
<th>Metal Active Gas</th>
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<tr>
<td>MagLev</td>
<td>Magnetic Levitation</td>
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<td>MEPP</td>
<td>Miniature End-plate Potential</td>
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<td>MIG</td>
<td>Metal Inert Gas</td>
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<td>MN</td>
<td>Micronuclei</td>
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<td>MRI</td>
<td>Magnetic Resonance Imaging</td>
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<td>MRS</td>
<td>Magnetic Resonance Spectroscopy</td>
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<td>NAT</td>
<td>Serotonin-N-acetyltransferase</td>
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<td>NGO</td>
<td>Non-governmental Organization</td>
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<td>NIR</td>
<td>Non-ionizing Radiation</td>
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<td>NMR</td>
<td>Nuclear Magnetic Resonance</td>
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<td>NRPB</td>
<td>National Radiological Protection Board (United Kingdom)</td>
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<td>PAF</td>
<td>Platelet Activating Factor</td>
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<td>PBMC</td>
<td>Peripheral Blood Mononuclear Cells</td>
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<td>PHA</td>
<td>Phytohaemagglutinin</td>
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<td>PMNL</td>
<td>Polymorphonuclear Leucocytes</td>
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<td>RNA</td>
<td>Ribonucleic Acid</td>
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<td>RF</td>
<td>Radiofrequency</td>
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<td>SCE</td>
<td>Sister Chromatid Exchange</td>
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<td>System International</td>
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<td>SMF</td>
<td>Static Magnetic Fields</td>
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<td>Tumour Necrosis Factor</td>
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<td>Visual Display Unit</td>
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