COMAR TECHNICAL INFORMATION STATEMENT: EXPERT REVIEWS ON POTENTIAL HEALTH EFFECTS OF RADIOFREQUENCY ELECTROMAGNETIC FIELDS AND COMMENTS ON THE BIOINITIATIVE REPORT

The Committee on Man and Radiation (COMAR)*

Abstract—The Committee on Man and Radiation (COMAR) is a technical committee of the Engineering in Medicine and Biology Society (EMBS) of the Institute of Electrical and Electronics Engineers (IEEE). Its primary area of interest is biological effects of non-ionizing electromagnetic radiation, including radiofrequency (RF) energy. The public interest in possible health effects attributed to RF energy, such as emitted by mobile phones, wireless telephone base stations, TV and radio broadcasting facilities, Wi-Fi systems and many other sources, has been accompanied by commentary in the media that varies considerably in reliability and usefulness for their audience. The focus of this COMAR Technical Information Statement is to identify quality sources of scientific information on potential health risks from exposure to RF energy. This Statement provides readers with references to expert reports and other reliable sources of information about this topic, most of which are available on the Internet. This report summarizes the conclusions from several major reports and comments on the markedly different conclusions in the BioInitiative Report (abbreviated BIR below). Since appearing on the Internet in August 2007, the BIR has received much media attention but, more recently, has been criticized by several health organizations (see Section titled "Views of health agencies about BIR"). COMAR concludes that the weight of scientific evidence in the RF bioeffects literature does not support the safety limits recommended by the BioInitiative group. For this reason, COMAR recommends that public health officials continue to base their policies on RF safety limits recommended by established and sanctioned international organizations such as the Institute of Electrical and Electronics Engineers International Committee on Electromagnetic Safety and the International Commission on Non-Ionizing Radiation Protection, which is formally related to the World Health Organization.

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INTRODUCTION

MANY STUDIES have been undertaken on biological effects and potential health and safety issues related to radiofrequency (RF) energy, dating back to the World War II era. This has resulted in an extensive scientific literature that contains several thousand scientific papers, including over 600 studies using mobile phone signals. The World Health Organization (WHO) database of this literature is freely available to the public (http://www.who.int/peh-emf/ research/database/en/index.html).

Review of this large body of scientific literature on RF bioeffects requires special effort and expertise. The literature is highly variable in relevance to health, scientific quality, and the success (or failure) of independent investigators to confirm results reported by others. Evaluating potential health risks requires analyses of a variety of different lines of scientific evidence including studies of humans, animals, cells, mechanisms, dosimetry, etc. Consequently, a careful review of the scientific literature related to biological effects of RF fields (as well as other potentially toxic agents) requires examination of many studies, and considerable expert judgment must be used in arriving at final conclusions. The most reliable reviews are carried out by panels of experts with a broad range of expertise and operating under well-defined procedures for selecting and evaluating data.

As an example of this approach, WHO has a series of well-regarded Environmental Health Criteria (EHC) documents that are designed to provide expert scientific advice to policy makers in member states. The EHC for extremely low frequency (ELF) fields (WHO 2007), such as produced by power lines, states in its Preamble: "All studies, with either positive or negative effects, need to be evaluated and judged on their own merit, and then

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all together 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 and laboratory) point to the same conclusion."

The EHC on ELF fields was written by a Task Group of 25 members who were approved by the Assistant Director General of WHO, with additional input by as many as 150 individuals around the world who were sent drafts of the ELF-EHC to review (van Deventer and Foster 2008). WHO has started work on the preparation of the draft EHC document for RF fields and the final document is estimated to be published in 2011. One can be assured that the preparation of the RF document will use a similar approach as that used in the ELF-EHC document including a weight-of-evidence approach in evaluating the scientific literature.

This approach contrasts with the tendency of the media to write about individual studies or reports deemed news worthy and to speculate about their significance, or of advocacy groups to focus on selected evidence to press a particular case.

REVIEWS

This Technical Information Statement (TIS) considers several kinds of reviews:

- ! Reviews by a standards-setting organization, notably the Institute of Electrical and Electronics Engineers International Committee on Electromagnetic Safety (IEEE/ICES), which works under the auspices of the IEEE Standards Association and develops IEEE standards C95.1 (IEEE 2005) and C95.6 (IEEE 2002), and by an organization that develops guidelines, i.e., the International Commission on Non-Ionizing Radiation Protection (ICNIRP 1998), which is formally related with WHO (see "Reviews by standards-setting organizations" below);
- ! Major reviews by expert panels under the auspices of health agencies or other branches of government, which evaluate the primary scientific literature related to possible health effects of RF fields (see "Reviews of the primary scientific literature by expert groups under government auspices" below); and
- ! The review called the BioInitiative Report (BIR 2007) that was written by an independent group. The differences in the BIR and the expert reviews considered here in regards to selection of committee members, the development of the report, and conclusions and recommendations are discussed below in "BioInitiative Report."

Reviews by standards-setting organizations

Comprehensive reviews of the scientific literature related to biological effects of RF fields are prepared by standards-setting organizations and organizations that develop international guidelines, of which the most influential around the world are IEEE/ICES and ICNIRP, respectively. The ICES subcommittee that developed the latest edition of the RF safety standard (IEEE 2005) had 132 participants from 24 countries from government, universities, industry, and the public. The variety of disciplines is listed below. ICES operates under the extensive rules, requirements, and audit procedures of the IEEE Standards Association to ensure openness, transparency and due process at every level.

The most recent revision of the IEEE C95.1 RF safety standard (IEEE 2005) was based on a review of more than 1,300 peer-reviewed research papers covering a 53-y span of the RF literature. The review included epidemiology and other human studies and animal, in vitro, mechanistic, dosimetric and engineering studies as well as other relevant papers. The studies addressed acute (short-term), intermittent and chronic (long-term) exposures, including lifetime exposure of animals, at a variety of exposure levels. Some of the exposures were at levels too low to produce significant heating ("non-thermal" exposures); others were at levels high enough to produce obvious RF heating ("thermal" exposures). The fields included continuous-wave RF energy, pulsed RF energy such as used in radar, and ELF-modulated RF energy such as used in communications systems. The scientific review was published in the IEEE standard (see IEEE C95.1-2005, Annex B, "Identification of levels of RF exposure responsible for adverse effects: summary of the literature," pages 34-77). To assist with the assessment of the extensive RF literature, ICES commissioned the series of review papers published in a special issue of the peer-reviewed journal Bioelectromagnetics (Supplement 6, 2003, 213 pages).

The other major international group, ICNIRP, develops guidelines (ICNIRP 1998) and consists of a Main Commission of 12 members plus a chairman and vice chairman; the Commission is assisted by a panel of 33 consulting experts from a variety of disciplines. Nearly all of these individuals are employees of government health agencies, with a few others employed by universities and none employed by industry. The ICNIRP guidelines, which are closely similar to the present IEEE standard, were published in 1998. It is to be noted that the IEEE standard and the ICNIRP guidelines are in agreement on the following major points with regards to RF safety: a) the dosimetric quantity *specific absorption rate* (SAR) as the basic restriction for frequencies from 100 kHz to a few GHz, b) the thresholdSAR for adverse health

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effects, c) whole-body and localized exposure limits, and d) safety factors for both occupational and public exposure limits. The ICES and ICNIRP limits are designed to protect against all proven hazards of RF energy.

Reviews of the primary scientific literature by expert groups under government auspices

Appendix A provides references and Internet links to recent expert reviews of the primary scientific literature recommended by COMAR.

To give the reader a sampling of current views of expert groups, the quotations below were taken from analyses completed in 2007–2008 by Ireland, WHO, a European Commission scientific committee and the United Kingdom. The consistent conclusion that there are no adverse effects from exposure to RF fields below internationally accepted limits is readily apparent.

Ireland Expert Group on Health Effects of Electromagnetic Fields (2007). "So far no adverse short or long-term health effects have been found from exposure to the RF signals produced by mobile phones and base station transmitters" (p. 3).

"The ICNIRP guidelinesprovides adequate protection for the public from any EMF sources" (p. 4). Available at: http://www.dcenr.gov.ie/NR/rdonlyres/9E29937F-1A27-4A16-A8C3-F403A623300C/0/ElectromagneticReport.pdf.

World Health Organization (2007). "Despite extensive research, to date there is no evidence to conclude that exposure to low level electromagnetic fields is harmful to human health" (Key Point #6). Available at: http://www.who.int/peh-emf/about/WhatisEMF/en/ index1.html.

"To date, all expert reviews on the health effects of exposure to RF fields have reached the same conclusion: There have been no adverse health consequences established from exposure to RF fields at levels below the international guidelines on exposure limits published by the International Commission on Non-Ionizing Radiation Protection (ICNIRP 1998)." Children and Mobile Phones: Clarification statement (second paragraph). Available at: http://www.who.int/peh-emf/meetings/ottawa_june05/ en/index4.html.

European Commission, Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) (2008). Possible Effects of Electromagnetic Fields (EMF) on Human Health. "Since the adoption of the 2001 opinion extensive research has been conducted regarding possible health effects of exposure to low intensity RF fields, including epidemiologic, in vivo, and in vitro research. In conclusion, no health effect has been consistently demonstrated at exposure levels below the limits of ICNIRP (International Committee on Non Ionising Radiation Protection) established in 1998. However, the data base for evaluation remains limited especially for long-termlow-level exposure" (p. 4). Availableat: http://ec.europa.eu/health/ph_risk/committees/ 04_scenihr/docs/scenihr_o_007.pdf See also Toxicol 246: 248–250; 2008.)

UK Government (2008). "The published evidence for health effects of radiofrequency (RF) electromagnetic fields in general is reviewed in Health Effects from Radiofrequency Electromagnetic Fields: Report of an Independent Advisory Group on Non-ionising Radiation. The report found that, as a whole, the research published since the report of the Independent Expert Group on Mobile Phones does not give cause for concern. The weight of evidence now available does not suggest that there are adverse health effects from exposures to RF fields below guideline levels." Available at: http://www.number10.gov.uk/output/Page14249.asp.

In addition, Appendix B lists statements by health agencies and expert panels from around the world on RF safety issues that summarize the scientific literature without providing extensive technical details. Some of these statements comment on the current scientific uncertainty and gaps in knowledge [see WHO (Appendix B), Canada (Appendix B), and UK Mobile Telecommunications and Health Research Programme (Appendix B)]. Also, WHO (http://www.who.int/peh-emf/research/ rf_research_agenda_2006.pdf) and the U.S. National Research Council (http://www.nap.edu/catalog.php?record_ id ! 12036#toc) have developed RF research agendas to address unresolved issues.

BioInitiative Report

In August 2007, an independent group issued a report called the "BioInitiative Report: A Rationale for a Biologically-based Public Exposure Standard for Electromagnetic Fields (ELF and RF)" (BIR 2007). This report offers conclusions and recommendations that are very different from those of IEEE/ICES, ICNIRP, and health agencies (e.g., WHO) around the world, both in its assessment of the scientific evidence and in its policy recommendations. A paper summarizing the BIR has been published recently (Hardell and Sage 2008). The BIR considers both ELF (e.g., electric power frequency) fields as well as RF fields. For conciseness, this TIS considers only the BIR text about RF fields.

The BIR was written by 14 individuals under the direction of a 4-person organizing committee. Most of its 21 sections are authored by single individuals or (in a few

cases) pairs or trios of authors; the section "Key Scientific Evidence and Public Health Policy Recommendations" was written by a pair of individuals and appears to reflect their views only. There is no indication of how the members of the committee were chosen or how balance was provided in the group of contributors, a majority of whom have public records of criticism of existing exposure standards and guidelines.

In Section 2, the BIR states that it was written "to document the reasons why current public exposure standards for non-ionizing electromagnetic radiation are no longer good enough to protect public health." Consequently, COMAR views the BIR as an advocacy document, rather than a balanced review of the scientific literature.

In contrast to the expert reviews by ICES and health agencies cited above, the BIR states that adverse health effects *have* been demonstrated from exposure to RF fields at levels below current guidelines: "*The lower limit for reported human health effects has dropped 100-fold below the safety standard (for mobile phones and PDAs); 1000- to 10,000-fold for other wireless (cell towers at distance; WI-FI and WLAN devices). The entire basis for safety standards is called into question, and it is not unreasonable to question the safety of RF [energy] at any level" (BIR 2007, Section 17, p. 21). A careful reading of the BIR does not find supporting evidence for the conclusions in this quotation.*

As a scientific review, the BIR has a number of weaknesses including internal inconsistency. The statement that "A weight-of-evidence approach has been used to describe the body of evidence between health endpoints and exposure to electromagnetic fields (ELF and RF)" (BIR 2007, Section 17, p. 5) and the text in another section referring to the weight-of-evidence approach as "unscientific" (BIR 2007, Section 7, p. 15) are not consistent.

A major weakness of the BIR is a selective, rather than a comprehensive, review of the literature in various topical areas. Two examples discussed here are a) animal tumor studies and b) genotoxicity (DNA damage).

Animal tumor studies. The BIR comments on only two studies investigating tumor development in laboratory animals exposed to RF energy. One of these studies (Repacholi et al. 1997) reported increased tumor development in exposed mice. Because of the potential health significance of the effect, a follow-on study by Utteridge et al. (2002) was conducted, but no change in tumor development was found. The BIR rejected the Utteridge et al. results for the reasons given in Section 7 (p. 16) and stated "the results of the Repacholi study are still looked upon as showing a relation between RF and cancer in an animal model" (BIR 2007, Section 7, p. 16). As discussed below, a weight-of-evidence assessment of the animal tumor studies shows that the BIR conclusion to promote the result in Repacholi et al. and reject the Utteridge et al. study is wrong. Other expert groups and health agencies have also given little weight to the Repacholi et al. study in their review of the broader set of relevant evidence.

The results of a second follow-on study (Oberto et al. 2007) agreed with the results in Utteridge et al. that there was no relation between RF exposure and tumor development. Thus, two studies employing improved experimental protocols compared to those in the 1997 study failed to confirm the effect on tumor development. As mentioned, the BIR discussed only two animal studies investigating tumor development in RF-exposed animals. For comparison, the ICES review, which was published before the BIR was written, included 35 studies on this topic and the weight of evidence of these studies showed no association between RF exposure and tumor development (see IEEE C95.1-2005, Annex B, Clause B.7.1 "Animal cancer bioassays," pp. 66-68). More than ten additional studies on this topic (see WHO database at http://www.who.int/peh-emf/research/database/en/index. html) have been published since the ICES review and the results of the more recent studies have strengthened the weight of evidence showing no association between RF exposure and tumor developmentin laboratory animals. In the BIR, the absence of a review of the large number of long term animal tumor studies is a major omission and, as a result, the BIR presents an incomplete scientific assessment that led to unsupportable claims of adverse biological effects and mechanisms of interaction.

Genotoxicity. The BIR concluded that "... RF exposures can be considered genotoxic (will damage DNA) under certain conditions of exposure, including exposure levels that are lower than existing safety limits" (BIR 2007, Section 1, p. 17). This conclusion is inconsistent with the conclusions from weight-of-evidence assessments by the UK Independent Expert Group on Mobile Phones (IEGMP 2000), called the Stewart Report, and the U.S. National Research Council Expert Panel (NRC 2008). Some of the evidence for the BIR conclusion was based on the results of Lai and Singh (1995, 1996), who reported DNA breaks in the brain cells of rats exposed to RF energy (BIR 2007, Section 6), and on the results from Rudiger's lab showing DNA breaks in cells cultured in vitro (Diem et al. 2005; Schwarz et al. 2008; BIR, Section 1, p. 17). Follow-on research to the Lai and Singh reports at another university included an extensive study comparing different DNA damage methods and included an attempt at exact replication of the original studies; the results failed to demonstrate an increase in DNA damage due to RF exposure (Lagroye et al. 2004). Other research (Malyapa et al. 1997) also failed to confirm DNA damage. The Stewart Report concluded that the evidence of Lai and Singh for DNA damage "is contradicted by a number of other studies in vivo and is not supported by in vitro work" (IEGMP 2000, Paragraph 5.134, page 70).

The in vitro results published by Rudiger's lab could not be confirmed by an independent lab that attempted an exact replication (Speit et al. 2007). More recently, Rudiger's results have been the subject of a scientificmisconduct investigation that revealed that some of the data used in at least one publication by the group had been fabricated (Vogel 2008).

The recent U.S. National Research Council report (NRC 2008), developed by an international expert group, concluded that "... most investigators in the field agree that no compelling body of evidence exists to support the hypothesis that RF fields are genotoxic" (page 39). These and other expert groups clearly gave little weight to the studies by Lai and Singh and Rudiger's group in the face of a large body of other related evidence. By failing to conduct a comprehensive review of the many animal tumor studies and focusing on isolated and disputed results from a few studies, the BIR arrived at unsupported conclusions regarding the genotoxic potential of RF exposure.

The BIR mixes discussion of social and scientific issues. For example, the scientific review of effects of RF fields on stress proteins has a long editorial section headed with "*The troubling context of today's science*" with speculation about the "*mind set*" of scientists working in the field, and other *ad hominem* comments which greatly detracts from the overall objectivity of the BIR review.

Exposure limits

Without providing a rationale in support of their recommendations, the BIR recommends "precautionary" limits for human exposure to electromagnetic fields that are very much lower than limits in effect in more than 40 countries. For example, the BIR recommends a general public exposure limit of 0.614 volts per meter for exposure to RF energy, which is a factor of about 100 (in terms of field strength) or 10,000 (measured in terms of incident power density) below present limits that are in effect in the U.S. and most other countries around the world. A major weakness of the BIR is the absence of a rationale to support reduction of internationally accepted RF exposure limits.

The BIR repeatedly states that current safety standards are inadequate and that the standards-setting processes are flawed because they "have little, if any, input from other stakeholders outside professional engineering and closely-related commercial interests" (BIR 2007, p. 5). This is incorrect. The ICES Technical Committee 95 Subcommittee (SC4) that developed the RF safety standard (C95.1-2005) is open to anyone with a direct and material interest in the activities of the subcommittee. During the development of IEEE C95.1-2005, SC4 had 132 participants from government, universities, industry, and the public; they represented 24 countries and 14 disciplines including medicine, epidemiology, biology, biophysics, physics, risk assessment, risk communications, and engineering. It is noteworthy that the participants included representatives from the U.S. Federal Communications Commission, Food and Drug Administration, National Institute of Occupational Safety and Health, and Occupational Safety and Health Administration. The unlimited access, transparency, and broad multi-discipline expertise of the international participants in the IEEE/ICES Committee stand in contrast to the small ad hoc group of 14 authors of the BIR.

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COMAR notes that if the limits in the BIR were applied consistently, such limits would prevent, or at least greatly complicate, the installation and use of traditional radio and TV broadcasting services, airport radar systems, police and other emergency communications systems, wireless telephone and wireless Internet systems, and many other applications of the radiofrequency spectrum—all of which have important benefits to public health and safety. Therefore, the BIR recommendations would in effect potentially increase risks by degrading effectiveness of many safety systems employing RF energy.

Views of health agencies about BIR

Additional concerns about the BIR have been identified by the following scientific groups from Europe and Australia.

EMF-NET, a coordinating committee of the European Commission 6th FrameWork Programme (30 October 2007). The BIR is "not a consensus report of a working group, but rather an assembly of chapters written by various scientists and consultants." The "Summary for the public" is "written in an alarmist and emotive language and the arguments have no scientific support from well-conducted EMF research." "There is a lack of balance in the report; no mention is made in fact of reports that do not concur with authors' statements and conclusions. The results and conclusions are very different from those of recent national and international reviews on this topic . . . If this report were to be believed, EMF would be the cause of a variety of diseases and subjective effects . . . None of these health effects has been classified as established in any national or international reviews that assessed biological and health effects from exposures below internationally accepted EMF limits when the whole database of scientific literature is reviewed according to well-accepted international risk assessment methods and criteria."

Available at: http://web.jrc.ec.europa.eu/emf-net/ doc/EFRTDocuments/EMF-NET%20Comments%20 on%20the%20BioInitiative%20Report%2030OCT2007pdf. [See EMF-NET 6th Framework Program Coordination Action, Effects of the Exposure to Electromagnetic Fields: From Science to Public Health and Safer Workplace, Comments on the BioInitiative Working Group Report (BioInitiative Report), October 30, 2007.]

The Netherlands Health Council (2 September 2008). In its opinion as to the scientific value of the BIR, the Health Council concluded "that the BioInitiative report is not an objective and balanced reflection of the current state of scientific knowledge. Therefore, the report does not provide any grounds for revising the current views as to the risks of exposure to electromagnetic fields."

Available at: http://www.gezondheidsraad.nl/sites/ default/files/200817E.pdf. Accessed 4 August 2009.

Australian Centre for Radiofrequency Bioeffects Research (ACRBR) (18 December 2008). "Overall we think the BioInitiative Report does not progress science, and would agree with the Health Council of the Netherlands that the BioInitiative Report is 'not an objective and balanced reflection of the current state of scientific knowledge.' As it stands it merely provides a set of views that are not consistent with the consensus of science, and it does not provide an analysis that is rigorous enough to raise doubts about scientific consensus."

Available at: http://www.acrbr.org.au/FAQ/ACRBR% 20Bioinitiative%20Report%2018%20Dec%202008.pdf.

CONCLUSION

COMAR, in agreement with the three comments above, concludes that the weight of scientific evidence in the current RF bioeffects literature does not support the safety limits recommended by the BioInitiative group. For this reason, COMAR recommends that government authorities and public health officials continue to base their policies on RF safety limits recommended by established and sanctioned international organizations such as IEEE/ICES and ICNIRP, which are formally recommended by WHO.

Acknowledgments—This TIS was reviewed and approved by the members of COMAR, all of whom have expertise in the general areas of the interactions of electromagnetic fields with humans. Although it represents a consensus of the opinions of COMAR Members, it does not necessarily reflect the opinion of the IEEE in general. At the time of the vote, the membership of COMAR consisted of:

Eleanor R. Adair, PhD Rajeev Bansal, PhD Howard Bassen, MS David Black, MBChB Ralf Bodemann, PhD Aviva Brecher, PhD Jerrold T. Bushberg, PhD Philip Chadwick, PhD Jules Cohen, PE John D'Andrea, PhD Richard L. Doyle, MS Joe Elder, PhD Linda S. Erdreich, PhD Kenneth R. Foster, PhD, PE Riadh Habash, PhD, PE James Hatfield, PE Daniel D. Hoolihan Veronica Ivans James Jauchem, PhD Sheila Johnston, PhD Rob Kavet, ScD B. Jon Klauenberg, PhD James H. Lambert, PhD, PE Gregory D. Lapin, PhD, PE Martin L. Meltz, PhD Joseph Morrissey, PhD John Moulder, PhD Michael R. Murphy, PhD John M. Osepchuk, PhD Ronald C. Petersen, MS Peter Polson, PhD Kenneth R. Proctor Pere J. Riu, PhD Mays Swicord, PhD Paul A. Testagrossa Art Thansandote, PhD Mohammad-Reza Tofighi, PhD Eric van Rongen, PhD David D. Royston W. James Sarjeant, PhD Richard A. Tell, MS, CHAIR Arthur Varanelli, MS Robert D. Weller, PE John Ziriax, PhD Donald W. Zipse, PE Marvin C. Ziskin, MD

Most recognized of COMAR products are the TIS on areas of technical interest or safety concerns and recommendations concerning electromagnetic fields. A list of COMAR Statements and Internet links are available to the public at http://ewh.ieee.org/soc/embs/comar/.

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APPENDIX A

COMAR Recommended Scientific Reviews by Government Agencies and Expert Panels Concerning Health Effects and Safe Levels of Radiofrequency Exposure (2003–2008). [Additional reviews are listed on the GSM Association Web site at http://www.gsmworld. com/health/links/independent.shtml and listed with a summary at http://www.hpa.org.uk/web/HPAwebFile/ HPAweb C/1194947376017 (see 2 below).]

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