STATE OF CONNECTICUT

SITING COUNCIL

Re:	The Connecticut Light and Power Company and The United Illuminating Company Application for a Certificate of Environmental Compatibility and Public Need for the Construction of a New 345-kV Electric Transmission Line and Associated Facilities Between Scovill Rock Switching Station in Middletown and Norwalk Substation in Norwalk, Connecticut Including the Reconstruction of Portions of Existing 115-kV and 345-kV Electric Transmission Lines, the Construction of the Beseck Switching Station in Wallingford, East Devon Substation in Milford, and Singer Substation in Bridgeport, Modifications at Scovill Rock Switching Station and Norwalk Substation and the Reconfiguration of Certain Interconnections	)	Docket 272
		)	January 24, 2005

SUPPLEMENTAL TESTIMONY V
OF DRS. WILLIAM H. BAILEY & PHILIP COLE

Comment on January 2005 Testimony of Drs. Bell and Rabinowitz

Q. Dr. Bailey and Dr. Cole, please comment on the January 2005 testimony of Drs. Bell and Rabinowitz.

A. In response to one of the Council's questions at the January 20 hearing, Dr.Bell said that they had been unable to find a risk below 2 mG, although they had "tortured" the data in attempting to do so. This approach was also used to extract a 'confession' from the data in Greenland et al. (2000) regarding exposures above

2 mG. Their claim that the Greenland et al. data shows an increasing risk with increasing exposure between 2 mG and 5 mG is an example of *post hoc* analysis and "data dredging."[1] The authors of the Greenland study specifically did not claim that their data were compatible with a particular dose-response relationship.

Our testimony deals more extensively with three aspects of the recent pre-filed testimony of Drs. Bell and Rabinowitz:

- their failure to address an issue that Greenland et al. raised about possible alternative explanations for the association reported at exposures above 3 mG;
- their claim that the laboratory studies of breast cancer cells and tissues that they attached as an Appendix to their January pre-filed testimony represent "an evolving and strong line of scientific investigations and laboratory work" with the implication that these studies are directly relevant to the question whether magnetic field exposure constitutes a cancer risk or contributes to childhood leukemia; and
- their assertion that published data contradict Dr. Cole's testimony that there has not been an increase in childhood leukemia.

Q. What was the issue that Dr. Greenland and his co-authors raised about possible alternative explanations for the associations above 3 mG?

A. Geeenland et al. (2000) recognize that the potential effects of bias and confounding have not been fully eliminated from EMF studies. They state:

> One can of course raise many criticisms of the individual studies, which would increase the already large uncertainty in our results. For example, confounding effects of socioeconomic status, residential mobility, residential type, viral contacts, and traffic density have been raised as possible explanations for the observed associations. (p. 632)

[1] Data dredging is "a jargon term meaning analyses done on a post hoc basis without benefit of prestated hypotheses as a means of identifying noteworthy differences. Such analyses are sometimes done when data have been collected on a large number of variable and hypotheses are suggested by the data; **the scientific validity of data dredging is at best dubious, usually unacceptable**" (Last, 2001, p. 46) [emphasis added]

Q. Are the studies of associations between magnetic fields and childhood leukemia potentially confounded by exposures to recognized carcinogens or other confounders that were not measured by the investigators?

A. Yes. For example, there are studies that have reported far stronger associations between childhood leukemia and exposures to carcinogenic air pollutants than those discussed in this docket for magnetic fields. One cannot know what influence these exposures may have had on the results of the studies in the EMF meta-analyses, but such exposures should be considered as potential confounders in any future epidemiology studies of childhood leukemia and magnetic fields.

Q. Did Greenland et al. (2000) consider traffic density as a potential confounding factor?

A. Greenland et al. could not fully evaluate its potential role because traffic density[2] near residences, a surrogate for exposures to vehicle emissions, was only measured in three of the 12 studies in their pooled-analysis. They state:

> Some results suggest that traffic-density effects may be large enough to partly explain the associations seen here. We thus recommend that future studies obtain data on traffic density and ambient pollution levels, as well as details of socioeconomic status and residential history. (p. 632)

Q. Could the effects of potential confounders be taken into account in any epidemiology study, or meta-analysis of multiple studies, if they were not measured?

A. No, they could not.

[2] Traffic density is thought to represent a potential confounder largely because of vehicle emissions of hydrocarbons, including benzene.

Q. Does an estimate of the likelihood that an association is due to "chance" take into account alternative causes of the disease, for example air pollution in this case?

A. No, it does not.

Q. Please comment on the studies claimed by Drs. Bell and Rabinowitz to represent "an evolving and strong line of scientific investigations and laboratory work that has tied *in vivo* cancer susceptibility with EMF to variations in genetic background." (pre-filed testimony p. 9)

A. Their characterization of laboratory research in relation to cancer susceptibility is incomplete and misleading. The development of any form of cancer is influenced by genetic factors to a greater or lesser degree but it would be incorrect to conclude that the studies they have cited yield any new insight into, or support for, the hypothesis that magnetic fields cause leukemia or other cancers in humans:

1) The three *in vitro* studies of MCF-7 cells cited by Bell and Rabinowitz (Blackman et al., 2001; Ishido et al., 2001; Harland and Liburdy, 1997[3]) have not been shown to have direct relevance to human breast tumors (or childhood leukemia) *in vivo* or to the assessment of potential carcinogenic risks.

2) The three *in vivo* studies, all from one laboratory in Germany (Thun-Battersby et al., 1999; Fedrowitz et al., 2004; Fedrowitz et al., 2002[4]), are

[3] Bell and Rabinowitz references 31, 32 and 33.
[4] Bell and Rabinowitz references 34, 35 and 36.

a selection of the published studies from the literature on the DMBA breast cancer model. None report that magnetic field exposure causes breast tumors in animals that are not treated with the carcinogen DMBA. As noted in the review article also cited (Anderson et al., 2000[5]), other laboratories, including the laboratory that performed studies of magnetic fields for the NIEHS National Toxicology Program, have failed to confirm the claims of the German laboratory that magnetic fields promote the development of DMBA-induced tumors. While differences in the results obtained by different laboratories may in part reflect genetic differences in the strain of rats tested, this fails to explain why the German laboratory has had trouble replicating their own findings using the same strain of rat.

3) The model used to study the promotion of DMBA-induced mammary cancers does not provide data as relevant as to the question of childhood leukemia as do other models. The results of tests designed specifically to assess effects on development of leukemia and lymphoma are quite consistent—magnetic field exposures do not promote the development of leukemias or lymphomas initiated by chemicals or ionizing radiation in a variety of rat and mouse strains.

4) Reports of magnetic field effects on MCF-7 cells *in vitro* as well as tests for the promotion of DMBA-initiated tumors *in vivo*, including those from the German laboratory cited by Drs. Bell and Rabinowitz have already

[5] Bell and Rabinowitz reference 37.

been considered in the multidisciplinary evaluations of laboratory research performed for IARC, NIEHS, and NRPB.

Q. Dr. Cole, please respond to the claim in the January testimony of Drs. Bell and Rabinowitz on page 7 that childhood leukemia rates have increased.

A. They cite two references, Ries et al. (1999)[6] for the incidence of childhood leukemia in the U.S. Surveillance, Epidemiology, and End Results (SEER) program, and other to Steliarova-Foucher et al. (2004)[7] for their incidence of childhood leukemia in Europe. However, my comment on March 25th related to the trends of leukemia incidence in Connecticut, which I described in my March testimony as the finest cancer registry in the world. They do not refute the Connecticut data. Trends in the incidence of childhood leukemia have been the subject of study for the past decade. It has been observed that incidence may not be reported consistently across databases. Lieberson et al. (2000) investigated the trend in the SEER data and found that when coding differences in one of the SEER regions (Detroit) in 1973-1975 were accounted for, there was no significant increase in the incidence of childhood leukemia between 1973 and 1995 for any age or histological classification.

Drs. Martha Linet, Lynn A.G. Reis, et al. (1999) evaluated trends in childhood leukemia rates reported by SEER and concluded that:

> There were no consistent large increases or decreases in incidence for the major categories of cancer among children ages 0-14 years during 1975-1995... The modest increases for childhood...leukemia...were confined to short intervals in the mid-1980s. This pattern suggests that the

[6] Bell reference 13.
[7] Bell reference 12.

increases likely reflected reporting or diagnostic changes rather than effects of environmental influences." (p. 1057)

Buffer Zones

Q. Dr. Bailey, what is your understanding of a "buffer zone" in the context of this Docket?

A. It is my understanding that the Council must find that any overhead line it approves is contained within "a buffer zone that protects the public health and safety, as determined by the council" (P.A. 04-246, §3). The Council's EMF Best Management Practices provide that such a buffer zone is "minimally [to] be the distance between the proposed transmission line and the edge of the utility right-of-way;" and that the Council will consider a buffer zone "based on magnetic field levels at the edge of the right of way." (EMF Best Management Practices 12/21/04). Dr. Ginsberg of the Connecticut Department of Public Health states that *long-term average exposures* to less than 6 mG are "[n]ot a defined public health risk (10/14/04 Tr. at p. 164), and that no prudent avoidance policy is necessary for long term average exposures to less than 3 mG (10/14/04 Tr. at p. 166).

Q. Have you submitted previous testimony that is relevant to setting a buffer zone on a "prudent avoidance" basis?

A. Yes. My *Supplemental Testimony Concerning Passive Regulatory Responses with Respect to 60-Hz Electric and Magnetic Fields*, dated May 3, 2004 (Companies' Exhibit 75) explains the doctrine of "prudent avoidance" and

provides examples of its recommended application by agencies such as the World Health Organization (WHO). In particular, the WHO explains that "Prudent Avoidance...does not imply setting exposure limits at an arbitrarily low level, and requiring that they be achieved regardless of cost, but rather adopting measures to reduce public exposure to EMF at modest cost." (WHO, 2000, p. 4). Moreover, the WHO cautions that "scientific assessments of risk and science-based exposure limits should not be undermined by the adoption of arbitrary cautionary approaches. That would occur, for example, if limit values were lowered to levels that bear no relationship to the established hazards or have inappropriate arbitrary adjustments to the limit values to account for the extent of scientific uncertainty." (WHO, 2000, p. 5). Moreover, WHO recommends against adoption of an ALARA (as low as reasonably achievable) policy for powerline magnetic fields as inappropriate "in the absence of any expectation of risk at low exposure levels and given the ubiquity of exposure" (WHO, 2000, p. 5).[8]

Q. What are the "science-based exposure limits" to which WHO refers?

A. These are exposure limits recommended by the International Commission on Non-Ionizing Radiation Protection (ICNIRP) that are based on known effects of electric and magnetic fields, and these limits are much higher than any of the field values that have been discussed in this Docket. The ICNIRP guidelines (Companies' Exhibit 75, Attachment 5) recommend limiting the magnetic field exposure of the general public to 100μT (=1000 mG at 50 Hz; 833 mG at 60 Hz).

[8] WHO is now in the process of completing a recommended *Framework to Develop Precautionary Measures in Areas of Scientific Uncertainty* (WHO, 2004). The discussion draft of this document, published on the WHO website in October, 2004, includes extensive recommendations for EMF policy, which contrast sharply with the analyses and proposals offered by Drs. Bell and Rabinowitz. The WHO requested comments on the draft to be submitted by January 30, 2005.

The National Radiological Protection Board of the United Kingdom (NRPB) recently described these guidelines as a "cautious approach to the interpretation of the scientific data" (NRPB, 2004a).

Q. Dr. Bailey, have any governmental authorities adopted the ICNIRP guidelines?

A. Yes. The United Kingdom of Great Britain and 30 other countries have adopted these guidelines or are in the process of doing so (NRPB, 2004a; NRPB, 2004b). NRPB (2004a) summarizes the process it followed in addressing public concerns about EMF, the public comments it received, and its response to them, and is attached in an Appendix to this testimony.

Q. Dr. Bailey, what options would you suggest that the Council consider in its application of PA 04-246 to the Applicants' proposed design?

A. First, the Council should find that the design and location of the proposed transmission line will not pose an "undue hazard" to people, and that it is appropriate for the overhead sections of the line to be contained within a buffer zone defined as the existing right-of-way. This is supported by policies of the NRPB and WHO, as well as the testimony of the Council's consultant, Dr. Ginsberg, and the Applicants' consultants.

Second, in order to respond to public concern (as opposed to the scientific data), the Council could direct the Applicants to construct overhead sections of the line with low magnetic field designs in order to lower fields at the edge of the right-of-way and beyond, as a form of "prudent avoidance." In considering low magnetic field designs, the Council should recognize that the designs that achieve the

lowest fields may not be compatible with reasonable economic and environmental costs. For example, incurring extraordinary costs or visual impacts in order to obtain small decreases in expected magnetic field exposures would not seem a prudent trade off and could be interpreted as inconsistent with the requirement that the Council balance a variety of potential impacts. To be consistent with a policy of "prudent avoidance" and not exceed reasonable economic and environmental costs, such low field designs might be considered just at locations where large numbers of children might spend significant amounts of time.

Third, the Council should conclude that there is there is no sound scientific basis to create a buffer zone defined by a specific exposure limit at the edge of the right-of-way or beyond.

However, if the Council concluded that it desired to limit magnetic fields, then the Council could consider the following options:

1) Adopt a health-based limit on the exposure of the general public to magnetic fields such as the 833 mG proposed by ICNIRP (at 60 Hz), and followed by 30 countries (NRPB 2004a, Appendix, p. 19). This was recently recognized by the state of Vermont (Applicants' Administrative Notice Item 16, at 6).

2) If the Council decides to act in a more "precautionary" manner, the Council could seek to preserve the *status quo*. New York followed such a course, and restricts the magnetic field at the edge of new transmission line rights-of-way to 200 mG at maximum loading (Applicants' Exhibit #75, Attachment 4).

Conclusions

Q. Dr. Bailey and Dr. Cole, please summarize your views on the potential health effects of transmission line magnetic fields.

A. After decades of research at costs of hundreds of millions of dollars or more, no causal relationship between magnetic fields and any health outcome has been established. Suggestions that magnetic fields may cause a wide range of adverse health effects that arose many years ago have been narrowed to a single question—does EMF contribute to childhood leukemia? There is an overwhelming consensus in the scientific community, as expressed in multidisciplinary reviews, that the evidence is insufficient to demonstrate a causal relationship between this exposure and this disease; however, neither has such a relationship been deemed to be totally impossible. If there is a real risk, it is a small one.

Based upon all of the research:

1) No scientific or governmental body has concluded that magnetic fields from transmission lines cause any adverse health outcome, including leukemia in children; and

2) No scientific or public health organization has ever recommended imposing limits on magnetic fields at the edges of transmission line rights-of-way to protect public health. The two states that that have adopted edge of right-of-way magnetic field limits have done so to preserve the *status quo*.

Q. Does this conclude your testimony?

A. Yes, it does.

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Appendix

Proposals for Limiting Exposure to Electromagnetic Fields (0 to 300 GHz)

Summary of Comments Received on the May 2003 Consultation Document and Responses from NRPB

Proposals for Limiting Exposure to Electromagnetic Fields (0 to 300 GHz)

Summary of comments received on the May 2003 Consultation Document and responses from NRPB

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Chilton
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Approval: June 2004
Publication: July 2004
£13.00
ISBN 0 85951 540 0

This NRPB report reflects understanding and evaluation of the current scientific evidence as presented and referenced in this document.

CONTENTS

1 INTRODUCTION

The National Radiological Protection Board (NRPB) has recently issued *Advice on Limiting Exposure to Electromagnetic Fields (0–300 GHz)* (NRPB, 2004a). Guidance is provided for people who are occupationally exposed and for members of the public.

NRPB recommends the adoption in the UK of the exposure guidelines of the International Commission on Non-Ionizing Radiation Protection (ICNIRP, 1998). This recommendation takes into account the need to adopt a cautious approach to the interpretation of the scientific data and recognises the benefits of international harmonisation on exposure guidelines. A detailed review of the relevant scientific data supports the recommendation by ICNIRP that exposure guidelines for members of the public should be more restrictive than exposure guidelines for people occupationally exposed (NRPB, 2004b).

As part of the development of the advice, a consultation document was published on the NRPB website in May 2003. This detailed the scientific evidence providing the basis for exposure guidelines and made proposals for revising previous advice (NRPB, 1993, 1999).

Around 50 responses were received to the consultation document and these made a valuable contribution to the development of the advice from NRPB. Specific public concerns were raised at an open meeting on power lines held in Birmingham in December 2002 and attended by over 100 people. This and other issues of public concern are discussed in Section 2.

This report provides a summary of the issues raised in the consultation comments and how these were addressed by NRPB in its science review (NRPB, 2004b) and in developing its advice (NRPB, 2004a).

From the diversity of comments received, it is clear that no single answer to any issue will be acceptable to everyone and, inevitably, some respondents will remain unsatisfied. Section 3 of this document considers questions raised in relation to epidemiological (human health) studies, in particular the criteria for study selection and how judgements are made when assessing the evidence available. A number of respondents referred to the California Health Department report, which has achieved wide publicity and is now explicitly addressed in the science review (NRPB, 2004b).

Several respondents sent information and expressed views about individual sensitivity to electromagnetic fields (EMFs). Section 2.2 reviews the wide range of symptoms attributed to exposure to EMFs, which can be a cause for concern for some people. Whilst the range of responses discussed makes it difficult to generalise, it is the view of NRPB that there is a need for further investigation into this area. NRPB has commissioned work to examine whether there are any public health implications.

Much of the supporting evidence described in the main report relates to experimental biology and this is covered in Section 4. Four main areas of concern were raised by respondents including the criteria for the selection of papers used to develop guidance, and the perception that guidance is overly restrictive for occupational exposure to static magnetic fields, particularly for work with magnetic resonance imaging (MRI) systems.

Such broad areas have implications for other aspects of the supporting evidence, including epidemiology, as covered in Section 3, and explanation is given in Section 4.1 of how NRPB develops guidance based on the totality of the scientific evidence available.

Dosimetry allows the development of measurable reference levels against which compliance with basic restrictions can be tested. Respondents questioned the basis for the calculation of reference levels and whether exposure of tissues could be potentially underestimated or overestimated. The areas of concern related mainly to induced electric fields and current density from power frequency fields. There was also concern over the need for clarification of thermal dosimetry in the head relating specific absorption rate (SAR) of energy from exposure to radiofrequency (RF) fields to temperature rise. These aspects are discussed in Section 5.

A particular aspect of the consultation document was the adoption of a cautious approach to the interpretation of scientific data in developing exposure guidelines. This attracted a range of comments and these are considered in Section 6 on scientific uncertainty.

A range of other issues was raised, including the implications resulting from the practical application of the advice, the perceived overly conservative nature of the recommendations, and the assessment of actual conditions of exposure of individuals. Section 7 provides comment on these issues, particularly in terms of the application of the NRPB advice across the UK.

2 PUBLIC CONCERNS

2.1 Listening to the public

NRPB receives thousands of enquiries each year on EMFs from members of the public. Public concerns are mostly expressed on possible risks to health and issues relating to property values.

NRPB staff frequently participate in public meetings about concerns relating to EMFs and health. These meetings provide a valuable forum for discussion of EMF

issues with, amongst others, the general public, local government officials and special interest groups.

NRPB was generally well aware of public concerns about the health effects associated with the transmission, distribution and use of electricity. NRPB decided that these concerns could be further addressed by holding a meeting to which members of the public, health professionals and others were invited. The Powerlines Open Meeting was held in Birmingham in December 2002. Similar meetings addressing mobile phones and health had been successfully held by the Independent Expert Group on Mobile Phones (IEGMP) in 1999/2000, and NRPB was aware of issues raised at these meetings.

The Birmingham meeting enabled NRPB to hear and consider public concerns and it provided input to the development of the revised advice on EMFs and health. It was chaired by Lord Winston, and the panel included representatives from NRPB, the independent Advisory Group on Non-ionising Radiation (AGNIR) and the World Health Organization (WHO).

The meeting was evaluated by the independent Radiation, Risk and Society Advisory Group (R,RSAG) using questionnaires completed by the participants as an input to the Group's qualitative analysis. Most participants found the meeting was useful and commented favourably. However, it was clear that NRPB could improve the ways in which it listens to the public. A minority of participants felt that the meeting had not helped them and did not believe that NRPB wanted to listen to their views.

R,RSAG concluded that the meeting had met its objectives and agreed that subsequent advice from NRPB had more explicitly addressed public concern.

One specific topic raised at the meeting was the reported hypersensitivity of certain individuals to EMFs and this was also frequently raised in the consultation responses.

2.2 Hypersensitivity

Several comments were received on the description of the scientific evidence relating to hypersensitivity to EMFs. The main points were a perceived trivialisation of the condition, the need for hypersensitivity to be recognised as a serious illness, multiple sensitivities and the need for more research in this area.

2.2.1 Perceived trivialisation of the condition

In the main, the respondents considered that the consultation document tended to trivialise the condition of hypersensitivity insofar as it did not reflect accurately their personal experiences or understanding. The respondents described a range of distressing symptoms including headaches, aches and pains and muscular fatigue, that they attributed to exposure to EMFs from various

sources, including power lines, domestic appliances, mobile phones and base stations.

It was clear from these descriptions that, although there was some commonality of symptoms among individuals, different people experienced differing symptom profiles, and similar sources of EMFs did not affect all people in the same way. However, a number of common features were also apparent. For example, several respondents suggested that the magnitude of any response and the ability to recover after exposure were dependent on the field strength and on cumulative exposure. In addition to the increased sensitivity to EMFs, there would most likely be a heightened sensitivity to chemicals and to physical stimuli. Several respondents mentioned a particular event, such as using a new piece of electrical equipment or a medical intervention, as having triggered or exacerbated their particular condition.

The incidence and severity of these responses to EMFs appear at odds to those experienced by self-reported hypersensitive subjects in laboratory provocation tests. The consultation document indicated that, although two studies offered some evidence in support of hypersensitivity, most studies failed to confirm the existence of the condition. In these tests, subjects could not reliably distinguish the presence of the field, and similar symptoms were induced when there was no explicit exposure to EMFs. The inference is that since exposure to EMFs under these circumstances failed to elicit the expected responses, the reported symptoms may not be entirely related to EMF exposure. Similar views have been expressed by other scientific expert groups that have examined these particular data.

It was not the intention of the consultation document to deny the existence of symptoms or to suggest that the causes were not related to exposure to EMFs. Indeed, the possibility that a hypersensitive phenotype may exist was highlighted in the consultation document by reference to the studies performed by Johansson and colleagues in Sweden (Johannson et al, 1994, 1996, 2001). In these studies, morphological differences have been observed in the skin of people displaying hypersensitive reactions. Further research on this topic would be most useful and should be encouraged.

2.2.2 Recognition of hypersensitivity as a disease

Several respondents expressed the view that hypersensitivity to EMFs needs to be recognised as a physiological illness, for example, it was argued that hypersensitivity to EMFs was better considered as migraine variants caused by pulsed sensory input signals. The view was also expressed that treatment for this condition should be available from the National Health Service. However, the identification, recognition and treatment of potential diseases are not part of the remit of NRPB. Nevertheless the Department of Health has been made aware of these comments and concerns. The process of identification of new diseases is part of the responsibilities of WHO. In the UK, the National Institute for Clinical Excellence (NICE) develops guidance on appropriate clinical treatments.

Respondents mentioned the electromagnetic radiation and health complaints register launched by the Australian Radiation Protection and Nuclear Safety Agency (ARPANSA). This aims to collect reports of health problems possibly related to EMFs in order to assess their scope and scale. Statistical summaries of the data will be produced by ARPANSA and may be used to help identify future research needs.

2.2.3 Multiple sensitivities

As some respondents pointed out, hypersensitivity is a complex condition and EMF hypersensitivity may interact with a number of other conditions such as chemical sensitivity and migraine. The respondents realised that the condition can be difficult to study both because of the diversity of symptoms that may be engendered and because there are significant ethical and scientific problems in testing vulnerable and ill people.

Specific concerns were raised about the conduct of provocation tests. It was suggested that only those individuals who can lead a sufficiently normal life to enable them to travel to laboratories for testing could be investigated in such tests. It was also suggested that it might be unethical for the most sensitive individuals to participate in such tests. Hence, it was argued that only the less EMF-sensitive individuals might have participated in the provocation tests, and that these individuals would be less likely to show any significant field-dependent effects.

It was also suggested that other factors might have contributed towards the inability to observe any field-dependent effects. For example, if there had been simultaneous exposure to chemicals in the laboratory during testing, this may have masked any effect of the applied EMF. Another possibility was that subjects may have had insufficient time to recover from the effects of previous exposure to EMFs, perhaps experienced while travelling to the laboratory, so these responses continued to be observed during both sham exposure and field exposure.

While these concerns appear plausible, there is insufficient knowledge about the relationship between the magnitude of any response and the intensity of a particular stimulus, or about the speed of recovery following an EMF challenge, to draw any definite conclusions at this time. Nevertheless it would seem reasonable that studies conducted with sufficient power should be able to detect even a marginal effect. Overall, this tends to suggest that future studies should use subjects who exhibit the most consistent field-dependent symptoms that are compatible with levels in everyday situations. Also, experimental conditions should be designed to remove possible confounding stimuli. Similarly, given the subjective nature of many of the reported symptoms, the environment of a typical laboratory may be less than ideal to elicit responses observed under more familiar, everyday conditions, and testing should be performed in conditions that provide a reassuring and non-threatening environment.

2.2.4 Additional research

Most respondents called for additional research on hypersensitivity and it is clear that questions remain unanswered. However, according to the WHO International EMF Project database (http://www.who.int/peh-emf/research/database/en/), few studies appear to be investigating hypersensitivity at the moment. Key aspects to be addressed include a more detailed characterisation of the condition, how responses may alter with different frequencies and pulse modulations, and a possible synergy with other physical and chemical agents. Another aspect is that the development and manifestation of symptoms are affected by cultural, environmental and behavioural influences as has been suggested regarding emotional responses to pain. As part of the International EMF Project, WHO is organising a workshop on 'electrical hypersensitivity' in October 2004. Both epidemiological and experimental research will be considered, and aims of the workshop will include a better identification and characterisation of symptoms.

In the UK, the Mobile Telecommunications and Health Research (MTHR) programme is funding studies to investigate the biological and health effects associated with RF fields from mobile phones (http://www.mthr.org.uk). Such a programme of research was recommended by IEGMP. Several studies are investigating symptoms associated with phone use in self-reported hypersensitives. For example, a study is investigating the effects of RF fields on hearing and balance. If inner ear function was affected by exposure to RF fields, possible symptoms could include disorientation, headache and nausea. Another investigation in progress is on the incidence and severity of unpleasant symptoms caused by exposure to RF fields as well as physiological changes in neuroendocrine function. A further group is investigating if simulated exposures from base stations can influence health and feelings of well-being, particularly in self-reporting hypersensitive subjects.

NRPB has commissioned a public health review of hypersensitivity. The issues to be addressed will include:

- achieving a definition of hypersensitivity, and describing its cause and development,
- examining evidence for the effectiveness of treatment,
- exploring any similarities with other currently poorly defined illnesses,
- identifying relevant policy elsewhere.

NRPB will consider the results of this review, together with emerging evidence from new scientific studies, the register set up by ARPANSA and any additional information.

3 EPIDEMIOLOGY

A range of points concerning epidemiological studies was raised in the consultation process. Certain issues were commented on by several different respondents, and the response of NRPB to them forms the majority of this section. Responses made to points by specific individuals are also summarised below.

3.1 Assessment of epidemiological studies

A key paper that has been cited on many occasions when interpreting epidemiological findings – not solely those relating to EMFs – is that by Bradford Hill (1965). One respondent stated that Bradford Hill did not use the word *criteria* – as cited in the consultation document - when considering the evidence that would indicate whether an epidemiological association represents a causal effect. Consequently, the science review refers to Bradford Hill's *guidelines*. Some of the respondents were concerned about the caveats attached to some epidemiological results in the consultation document, based partly on Bradford Hill's guidelines. It is important to have some system of evaluating the strengths and limitations of various studies, and in this regard the Bradford Hill guidelines are valuable in trying to draw inferences. Furthermore, several of the reviews cited in both the consultation document and the science review have provided detailed evaluations of many of the relevant studies (see Section 3.2 below).

One respondent suggested that it should not be automatically assumed that positive associations can be 'explained away' by bias and confounding. Whilst bias and confounding may not always explain positive findings, the interpretation of results can be very difficult when bias or confounding are present to a notable degree.

Another suggestion was that uncertainties in the choice of exposure metrics, health outcomes, or susceptible groups under study might heighten the importance of weak results, since they could generally obscure or understate a genuine relation. However, a weak observed association does not necessarily mean that there is a stronger underlying link, if there is any link at all – a weak result is a weak result. Furthermore, whilst results arising from testing multiple hypotheses are not necessarily invalid, it can be very difficult to interpret them in the absence of a prior hypothesis.

3.2 Study selection

One respondent asked for explicit ground rules for the inclusion of studies in the review. In view of the size of the literature and because many of the relevant studies have previously been reviewed by various scientific committees, the

consultation document cited such reviews. However, individual studies published in the peer-review literature have been cited also

- in order to highlight specific issues (for example, concerning the strengths or limitations of certain types of study), or
- where such studies have been published after earlier reviews were conducted.

In the case of mobile phone use and cancer, recent studies have been cited in both the consultation document and the science review. Work on the science review was largely complete by the time of publication of a recent review of the health effects from radiofrequency electromagnetic fields by AGNIR (2003). The conclusions of AGNIR are similar to those of NRPB as set out in the science review.

3.3 California Health Department Report

Several respondents remarked on the lack of reference in the consultation document to the report by the California Department of Health Services (Neutra et al, 2002), and thought it should be considered. It should be emphasised that this report was not an epidemiological study *per se*, but rather an evaluation based on studies that had been considered in reviews cited in the consultation document. Recent studies of miscarriage and magnetic fields that had been conducted by some of the Californian authors and upon which they placed particular weight had been reviewed by AGNIR (2002). In the science review, the text concerning these miscarriage studies has been expanded, in order to explain these studies' limitations in more detail. The retrospective aspects of these studies raise concerns about the potential for bias.

Some respondents commented on the procedure used in the Californian report to assess the evidence for associations between EMF exposure and ill-health. In contrast to other reviews, the members of the Californian panel expressed their individual judgements that risks might be real using numerical scales of uncertainty. This approach is unlikely, in itself, to provide a more reliable assessment than a non-numerical approach. Of greater relevance to understanding the conclusions reached by the Californian panel is the lack of emphasis that its members placed on experimental findings and their belief that certain epidemiological results could not be attributed to chance, bias or confounding. As indicated by AGNIR (2002) and re-iterated in the NRPB science review, there are notable grounds for concern about potential bias or confounding in the key studies cited by the Californian panel.

3.4 Findings from recent studies

Various recent studies have been added to the science review. Further to the points made in Section 3.2 above, most of these studies had not been covered in

earlier reviews. These recent studies cover, for example, childhood leukaemia and maternal occupational exposure to extremely low frequency (ELF) magnetic fields during pregnancy; occupational EMF exposure in relation to adult leukaemia, brain cancer, prostate cancer and neurodegenerative disease; residential EMF exposure in relation to breast cancer and birth defects in offspring.

Some additional review articles have also been cited in the science review, concerning, for example, exposure to ELF EMFs with respect to breast cancer and amyotrophic lateral sclerosis. These reviews have often highlighted inconsistencies in the epidemiological literature and the difficulties in making inferences.

3.5 Studies of suicide and depressive illness

Some respondents referred to specific studies of suicide and depressive illness in relation to exposure to ELF EMFs. This topic had been considered in the consultation document, with particular reference to a review by ICNIRP (Ahlbom et al, 2001) that had examined many studies including those cited by the respondents. In line with the approach described in Section 3.2, the individual studies were not all listed in the consultation document. ICNIRP concluded that the literature was difficult to interpret, owing in part to inconsistency in findings (Ahlbom et al, 2001). The science review cites a more recent paper (van Wijngaarden, 2003), based on job titles recorded on death certificates. This study suggested a weak association with suicide, although the exposure assessment here was not as detailed as that in earlier studies, whose findings were variable.

3.6 Other points

Further to a query from one respondent, it has been pointed out in the science review that the raised risk of childhood leukaemia reported in epidemiological studies of prolonged exposure to ELF magnetic fields of time-weighted average exposure above 0.4 μT corresponds to a doubling in relative risk. This is small in absolute terms because the disease is rare, with a baseline annual incidence in the UK of about 1 in 20000.

One respondent drew attention to studies of melatonin in relation to suggested effects of EMF exposure and reports of cancer risk among people with suppressed melatonin levels due to light exposure. The interpretation of these cancer studies is not straightforward, owing to the possibility of confounding; for example, blind people or shift workers may not be directly comparable with the reference populations. AGNIR is examining the issue of melatonin, as regards implications for the assessment of EMFs and health.

4 BIOLOGY

About half of the respondents commented on the biological issues discussed in the consultation document. These comments comprised a broad mixture of both praise and criticism. Most respondents expressed the opinion that the major scientific issues had been well covered, and that the biological rationale for the basic restrictions for ELF and RF fields had been more thoroughly explained than in previous NRPB guidance.

The four main areas of concern with the review of biological studies were:

- doubts over the selection of papers discussed and the criteria on which the selection was based,
- an overly restrictive guidance for occupational exposure in certain situations,
- a lack of convincing evidence for the need to reduce exposure levels for the general public,
- a range of options for ELF basic restrictions could be identified based on different types of experimental data.

Some of these broad issues have implications for epidemiology and other areas supporting guidance. A number of comments concerning specific biological aspects were also made; these are also considered here. The specific comments concerning hypersensitivity to EMFs are discussed in Section 2.2.

4.1 Study selection

Several respondents made critical comments or requested further clarification of the way biological studies were selected for inclusion in the consultation document, the criteria used for assessing the scientific strength of evidence, and the cautious approach.

4.1.1 Scientific papers

A major difficulty in the development of a rational basis for EMF guidance is that the interpretation of studies of potential health effects is controversial; there exists a spectrum of opinion within the scientific community and elsewhere. Recognising this, various national and international expert bodies have undertaken reviews of the science, which have achieved a wide degree of consensus. The reviews of the various biological studies presented in the consultation document reflected this consensus. In addition, more recently published papers have been summarised. Generally, however, detailed comments and assessments remain in the original reviews.

Guidance concerning human exposure to EMFs has been largely developed from other bodies of scientific literature, notably electrophysiology and thermo-physiology, about which there is a greater degree of consensus with regard to the quantification of health risks, although there still remain considerable uncertainties. Here, views have been sought from experts within these disciplines and the EMF biological effects research field. In particular, the consequences of whole-body and localised RF heating were discussed at a WHO Workshop (WHO, 2003). The consequences of exposure to weak induced electric fields and currents in the body were examined by an *ad hoc* expert group (NRPB, 2004b), and later discussed more widely at an ICNIRP/WHO workshop (ICNIRP/WHO, 2003). This evidence was considered in the preparation of the science review and the NRPB's advice.

4.1.2 Selection criteria

The criteria used for assessing the scientific strength of evidence usually include:

- strength of evidence from an individual experiment, which includes the adequacy of the experimental design, the avoidance of potential confounding and the use of appropriate statistical analysis,
- consistency, which includes experimental replication as well as similarity of outcome in different experiments,
- dose-response relationships, the identification of which strengthens the view that the agent in question interacts in a systematic way with a biological process,
- plausibility and coherence, meaning that the suspected causation is biologically plausible and that it does not seriously conflict with current scientific understanding,

In the consultation document, proposals from NRPB were based on evidence consistent with the above criteria. If the overall weight of evidence according to these criteria suggests that there is no effect, then, even if there are some positive studies, the view is taken that such effects have not been convincingly demonstrated. There may, however, be some residual uncertainty suggesting the need for further study.

The criteria listed above can never be applied so rigorously that all studies fall into 'accepted' or 'rejected' categories. The strength of evidence, and the degree to which caution should be exercised when there is apparently conflicting evidence, divides opinion in this field.

Ultimately, the decisions are a matter of scientific judgement, which is why the consultation document reflects the consensus views of expert bodies and the opinions of individual experts.

4.1.3 A cautious approach

Several respondents queried the adoption of a cautious approach to the assessment of biological studies in the consultation document. The exercise of caution was considered necessary because of limitations and uncertainties in the scientific data. The degree to which caution was applied was acknowledged to be a matter of judgement, but it was considered an intrinsic part of the risk assessment process.

In addition, a cautious interpretation was used when there was a strong indication that certain health effects could occur in people exposed to EMFs, although explicit proof of these effects might have been lacking. For example, a conclusion that induced electric fields at power frequencies (50/60 Hz) affect aspects of central nervous system (CNS) function other than the induction of phosphenes has strong scientific support, but no formal proof.

Similarly, caution was applied when a distribution of sensitivity within a population was suspected to exist, even though this could not be well quantified. For example, increased susceptibility to the effects of heat is expected in particular groups of people due to differences in age, health status or medication. However, the degree of susceptibility cannot be precisely determined at present due to a lack of data. These judgements in particular formed the basis for the more restrictive exposure values for members of the public compared with those occupationally exposed.

4.2 Occupational exposure to static magnetic fields

There were several responses from users of magnetic resonance imaging (MRI) equipment suggesting that guidance on occupational exposure to static fields is unnecessarily restrictive. In particular, some respondents objected to the application of time-weighted average exposure restrictions. A review by Schenck (2000) was cited in support of these arguments in addition to two papers concerning volunteer studies at high static field levels up to 8 T. These were incorporated in the science review.

4.2.1 Rationale for restrictions

The principal challenge facing any expert group advising on limits on static magnetic field exposure is the paucity of information relating to possible health effects. At present, most advisory bodies base guidance on the effects reported from a few volunteer studies and from theoretical predictions based on the Lorenz forces exerted on moving ions. These forces induce electric potentials across blood vessels and reduce blood flow, especially in the aorta and around the heart, and modify ion movement through membrane channels. No changes in heart rate and diastolic or systolic blood pressure or other physiological effects were reported in a recent study of healthy volunteers exposed for one hour to a field of 8 T. The electrocardiograph (ECG) was uninterpretable because of the flow potentials generated. It is not clear, however, at what level the effects of

static magnetic fields on the heart become biologically significant, or the degree to which this might be affected by age, health status, medication, etc.

The case for a basic restriction of 2 T derives from a laboratory study carried out in 1992 (Weiss et al, 1992). A significant increase in nausea and vertigo was reported in volunteers exposed to a 4 T field compared to those exposed at 2 T. Phosphenes were noted during eye movement in the higher field, although only in a darkened room. Nevertheless, many advisory bodies, including ICNIRP, suggest that it is reasonable to limit occupational exposure to a level at which these sensations do not occur.

In the absence of systematic investigation of chronic effects, it is not sufficient to argue that limits for chronic exposure should be based on acute effects only. Despite the widespread clinical use of MRI over the last 20 years, there has been no thorough epidemiological study of the health of people exposed to static fields of this magnitude, either patients, volunteers, clinical staff or manufacturing and/or maintenance staff. There remains, for example, the possibility that certain types of metabolic reaction, reviewed for example by Grissom (1995), are affected by exposure to static magnetic fields greater than 1 T. The 200 mT basic restriction for time-averaged exposure thus reflects those uncertainties regarding the possibility of chronic health effects.

An important step towards the development of a firmer basis for guidance would be the publication of further relevant experimental and epidemiological studies, as suggested in the review by Schenck (2000). The basic restriction of 2 T derives from laboratory studies; it is not clear to what extent the application of this basic restriction poses a problem in everyday practice.

4.3 Guidance on public exposure levels

A clearer distinction was requested between conclusions stemming unambiguously from the data and those stemming from a cautious approach. In particular, the strength of the scientific support for restrictions on public whole-body exposure to static magnetic fields and to frequencies of less than 100 kHz was questioned and it was noted that for RF fields the lower restriction for public whole-body exposure was supported by only one paper.

4.3.1 Static magnetic fields

The 40 mT time-weighted average whole-body restriction for the general public is one-fifth of the occupational level. This is based on consideration of the uncertainties regarding chronic effects, as discussed above for occupational exposure, together with further consideration of the possible presence of more vulnerable subgroups within the general population, and noting the benefits of international harmonisation.

An international INCIRP/WHO workshop was held in April 2004 that addressed the effects of static magnetic fields relevant to human health.

This workshop considered interaction mechanisms, dosimetry, and the biological and health consequences of exposure. The conclusions and recommendations of this workshop when they are published later in 2004, will form an important resource for any future revision of exposure guidelines.

4.3.2 Fields of frequencies below 100 kHz

A question was raised as to the robustness of the scientific data supporting a more restrictive limit for the general public compared with that for workers. It is clear from the literature that epilepsy is a disease characterised by increased electrical excitability in various parts of the brain. Therefore, it seems reasonable to conclude that people suffering, or prone to suffer, from epilepsy will be more susceptible to electric fields induced in the CNS than other people. The degree to which susceptibility might be increased is a matter of scientific judgement, which is why advice was sought from experts in this field. What is less clear is the threshold for these physiologically weak electric field effects in people unaffected by epilepsy.

4.3.3 Fields of frequencies above 100 kHz

The justification for a more restrictive limit for the general public compared with that for workers was questioned. The reduction in the RF whole-body heat load for members of the public is based primarily on the observation that older and vulnerable people are susceptible to heat-related mortality. This particular relationship was quantified in an extensive study spanning Europe (Keatinge et al, 2000). While it was suggested that this approach was supported by reference to a single study, the particular study (Donaldson et al, 2003) is a review article that draws on an extensive body of published work from a wide variety of sources. However, the choice of an acceptable whole-body SAR value for the general public remains a matter for judgement based on the scientific evidence available.

4.4 Options for ELF guidance

There was a suggestion that it might be helpful to offer a range of options concerning electric field interactions in the CNS, based on different sets of experimental data such as electrophysiology *in vitro*, magnetic phosphenes, cognitive effects, etc.

The data relating to these topics on which guidance is based describe different experimental ways of looking at the same phenomena – effects on CNS function – each with their strengths and weaknesses. Electrophysiological investigation *in vitro* benefits from the fact that experimental manipulations can be fairly rigorously controlled, but they are clearly carried out on a restricted number of interacting neurons, and the effect is not readily applicable to a living system. The converse would be true in cognitive studies; even with phosphenes, which are well understood, it is not clear which elements within the retina respond to

the induced fields. The individual pieces of evidence concerning ELF effects on CNS function were considered in their totality.

4.5 Other issues

A few respondents made comments on specific biological issues raised by the review. For example, one respondent suggested there should be some detailed discussion of the physiological effects of melatonin, both as an antioxidant and of its more general relevance to health. Such detailed discussion was not within the scope of the consultation document although the issue is considered to be important. A subgroup of the AGNIR is considering these and other issues as part of an extensive review of the effects of EMFs on pineal physiology.

Some respondents suggested particular corrections to the text, or the inclusion of newer or additional references. Based on these comments, the text has been amended accordingly.

5 DOSIMETRY

There were relatively few comments on the numerical dosimetry discussed in the consultation document. The areas of concern related to induced electric fields and current density from power frequency fields and clarification of thermal dosimetry in the head relating SAR to temperature rise.

5.1 Induced fields at power frequencies

There was concern that the current densities induced by fields from power lines could be higher than the normal endogenous current densities induced by the beating heart, the brain, the pineal gland and the thalamus. It was also pointed out that there could be even higher values in the legs. Although this comparison of endogeneous and externally induced fields is of interest, the basic restrictions are not derived by comparison with endogeneous values of current density but from a consideration of possible adverse health effects on the CNS and retina. Dosimetry can then be used to obtain the external applied field values that correspond to these basic restrictions in current density. Also the basic restrictions apply to the CNS and retina and not to the rest of the body such as the legs.

One respondent indicated that the average value of induced electric field from a 50 Hz electric field in the body, estimated from the measured potential difference between the head and the foot, was much higher than the values given in the consultation document. However, the values presented are the averages over 1 cm^2 in the brain and retina only. The induced field varies throughout the body

and for a grounded person the maximum induced field will occur in the ankle. The basic restrictions apply to the brain and retina only.

5.2 Thermal dosimetry

One respondent pointed out, correctly, that the earlier of the two cited papers by Hirata et al (1999) on heating of the eye does not address heat loss from the eye to blood. Consequently, the large temperature rises found in this paper are probably unrealistic. However, the subsequent paper by the same authors (Hirata et al, 2000) uses a model proposed by Lagendijk (1982) and subsequently used by many other authors, whereby heat loss to the surrounding tissues – thence to blood – is described by a convective heat transfer coefficient (65 W m^{-2} °C^{-1}). This includes, in a lumped form, the effect of blood flow in the choroid/sclera/retina. In deriving a basic restriction on localised SAR, it is necessary to consider all frequencies up to 10 GHz, and not only those used by mobile phones. The temperature rise in the eye per unit SAR seems likely to increase towards the upper limit of this frequency range. The respondent concluded that the occupational limit on localised SAR of 10 W kg^{-1} is adequate for human eye protection. The overall body of studies to date tends to support this conclusion; however, there is still a paucity of theoretical and experimental work relevant to humans, and the physiological parameters used in computational models are subject to considerable uncertainty. These factors indicate the need for further research.

One respondent noticed an apparent contradiction in the paper by Wainwright (2000) which was cited in the consultation document. At the ICNIRP occupational exposure limit for RF, a maximum temperature of 38.1°C was found in the brain, and this did not seem to agree with the 1.6°C temperature rise cited in another part of the paper. Subsequently, these results were recomputed using a refined anatomical model. It was found that the highest ratios of temperature rise to SAR had in fact occurred in muscle rather than in the brain. Removing the spurious entries results in a temperature rise of 1.2°C in the brain corresponding to a SAR of 10 W kg^{-1}. This is very close to the results of several other authors cited. A temperature rise of up to 2°C is regarded as acceptable for tissues of the head other than the brain and retina. The revised temperature values imply a basic restriction on SAR of 8 W kg^{-1} averaged over a 10 g cube for occupational exposure. This is sufficiently close to the ICNIRP value averaged over any 10 g of contiguous tissue that it is not considered necessary to reduce the basic restriction to 5 W kg^{-1}, as was proposed in the consultation document.

6 SCIENTIFIC UNCERTAINTY

A number of comments were received on interpretation of the scientific data and related uncertainty, particularly concerning the application of the Precautionary

Principle and aspects of precaution in addition to the application of restrictions on exposure.

Respondents variously queried:

- why NRPB was addressing these issues and expressing concern at what they interpreted as a departure from its remit of providing advice based on the science,
- whether it was appropriate to apply 'precaution' to EMFs,
- whether the application of precautionary measures might not lead to blighting of properties, such as those near power lines.

Other questions concerned the details of precautionary measures that might be implemented, their cost and other consequences.

Some respondents expressed views indicating exposure restrictions should be based entirely on a precautionary approach, leading to much more restrictive values.

Other respondents welcomed the NRPB approach and expressed the view that the way in which precaution enters into the derivation of exposure guidelines was presented in a coherent, fair and understandable manner.

6.1 Comments and responses

6.1.1 Caution and precaution

From specific comments received it was clear that there was scope for clarification of a number of issues, in particular, clarification of the meaning of the words 'caution' and 'cautious' and the words 'precaution' and 'precautionary'.

In response to this, the following definitions have been provided for the terms as used by NRPB in the scientific review and advice documents (NRPB, 2004a,b):

- 'caution' and 'cautious' are used strictly to describe the approach taken in evaluating scientific data and in particular the uncertainties associated with these data and in making judgements as to their relevance to exposure restrictions.
- 'precaution' and 'precautionary' are used strictly in relation to possible additional measures that might be considered in the light of the uncertainties associated with the evidence of long-term adverse effects of exposure.

6.1.2 Scientific uncertainty and aspects of further precaution

Some respondents questioned why NRPB was addressing these issues. NRPB did so in response to a request from government to specifically include aspects of scientific uncertainty and precaution in providing its advice. It is the

view of NRPB that consideration of scientific uncertainty is important to a cautious interpretation of the science and in considering the possible need for further precaution.

6.1.3 Exposure guidelines and the Precautionary Principle

The view was expressed that the exposure guidelines being recommended by NRPB were based on factors additional to the interpretation of the science. NRPB understands why such a view might arise but this is not the case. Discussion and background information on the Precautionary Principle were included in the consultation document because it had been previously widely raised and quoted as a driver for reducing exposure restrictions where there is suspicion but no conclusive scientific evidence of harm. However, it is the cautious approach to the interpretation of the scientific data that is one of the key elements in the recommendation to adopt the ICNIRP basic restrictions on exposure.

6.1.4 Harmonisation of guidelines

A number of respondents noted that adopting the ICNIRP values brings the UK into line with recommendations from the World Health Organization (WHO), the European Union Council and other national committees. The NRPB recommendations on limiting exposure are based on a comprehensive review and cautious interpretation of the scientific data relevant to EMFs and human health. NRPB is a national collaborative partner of the WHO, whose International EMF Project incorporates an initiative to harmonise approaches to establishing guidelines to limit exposure to EMFs (http://www.who.int/peh-emf/standards /en/). NRPB has played an active role in supporting this work. The approach of NRPB to reviewing the scientific literature and assessing the basis for limiting exposure is entirely consistent with that recommended by WHO. It is the view of NRPB that, where values of basic restrictions are indicated which are close to the internationally accepted ICNIRP values, there is neither scientific reason nor practical advantage in recommending values that differ from those of ICNIRP.

6.1.5 Specific details on precautionary measures

The proposals to consider further precaution were interpreted by some respondents as a specific call for precautionary measures to be implemented. This led to requests for details of specific precautionary measures to be set out. It was not the intention of NRPB to deal with such matters either in the consultation document or in the formal advice and science review documents. As an input to such considerations of further precaution, the consultation document proposed a study highlighting and contrasting two exposure scenarios: power frequency magnetic field exposure of children and exposure to mobile phone RF fields. NRPB also proposed that advisory bodies should listen and respond to public concern over the issue of EMFs and health and that a study such as mentioned above could involve an element of bringing together all stakeholders. These proposals were made in the light of ongoing development of a policy of

precaution being developed by the WHO and it was anticipated that the outcome of such a comparative study would provide valuable information for WHO and others involved in decision making. The view of NRPB is that such a course of action can be considered by government in response to the more general advice from NRPB on aspects of precaution.

6.1.6 Other national approaches

Some respondents expressed the view that the quantitative restrictions on exposure recommended by NRPB were not based on a precautionary approach while some other national ones are. The basis for quantitative restrictions on exposure is in accord with the recommendations of WHO, ICNIRP, the EC and many national expert bodies. Where more restrictive EMF exposure limits appear to have been implemented in some other countries, the scientific basis for this and the process of scientific review, quality assessment, and relevance to protecting human health is not explicit. WHO has set out criteria by which studies should be judged in respect of their relevance and applicability to the development of exposure guidelines. These are discussed in some detail in the science review document.

WHO has a project to arrive at a common approach in interpreting the science and formulating exposure guidelines, and many countries including the UK are involved in this process. WHO lists over 30 countries as having adopted the ICNIRP guidelines or which are in the process of considering whether to do so. It would appear likely that those countries who have recently joined the enlarged European Union will consider adopting also the EC Recommendation on limiting public exposure to EMFs (CEU 1999) and will eventually be subject to the EC Physical Agents Directive for occupational EMF exposure (EPCEU 2004). Both of these EC documents are based on the ICNIRP exposure guidelines.

There are a few countries that have recommended more restrictive exposure values based on a precautionary approach and in some instances there appear to be regions or cities within a country where the regional values may differ from the national ones. It should be noted that WHO recommends that precautionary approaches should not undermine science based exposure guidelines.

An example that is much quoted where such a precautionary approach has been taken is in Italy (see the appendix).

7 OTHER COMMENTS AND RESPONSES

Some respondents were uncertain how the general proposal to use the ICNIRP guidelines should be practically implemented and in particular how reference levels should be interpreted in assessing compliance with basic restrictions on exposure.

There was some concern about what were perceived to be the over-conservative nature of the values of the ICNIRP reference levels; particularly those related to the general public. In turn this may have been interpreted as causing unnecessary restrictions on normal operations, for example, in areas such as broadcasting and power distribution.

NRPB has noted such concerns and has sought to explain further in its advice how protection is safeguarded with respect to compliance with the basic restrictions on exposure using the ICNIRP reference levels and appropriate dosimetry techniques.

It was pointed out that the public reference levels were incorrectly drawn in figures 7.1a and 7.2a of the consultation document, and that the 'Isolated' and 'Grounded' labels in figures 7.3 and 7.4 were reversed. These figures have therefore been amended in the advice and science review documents.

7.1 Practical system of protection

7.1.1 Basic restrictions

The basic restrictions on induced current density and SAR recommended by NRPB are those published by ICNIRP (1998). This recommendation results from a comprehensive review of the science (NRPB, 2004b). It recognises the uncertainties in the scientific data on which basic restrictions can be quantified and considers, particularly in relation to international harmonisation, that the ICNIRP guidelines provide appropriate values.

NRPB considers that its recommendation for two sets of values corresponding to 'occupational' and 'general public' exposure is justified in the light of the evidence from the science review and that the basic restrictions provide appropriate general community protection against adverse effects of exposure to EMFs.

Basic restrictions are expressed in those physical quantities that are closely related to the biological effects. Thus, at low frequencies, the restrictions are in terms of induced current density. At radiofrequencies, the restrictions are expressed as values of whole-body or localised SAR. For frequencies greater than 10 GHz, the restriction quantity is incident power density on the surface of the body.

7.1.2 Reference levels

Over the past few years, there has been extensive dosimetry work published on the quantitative relationships between external fields and internal basic restrictions. This work has predominantly covered ELF and RF fields. The published work is based on computational modelling of such interactions using a variety of numerical methods and anatomically realistic voxel phantoms. These phantoms have been derived from medical scanning images of people. NRPB has taken a leading position in developing voxel phantoms and in publishing

results useful for the process of linking external fields and internal basic restriction quantities.

Induced current density and SAR are physical quantities inside the body that cannot be readily measured. In order to enable the assessment of compliance, computational methods are used to link external field strengths in the absence of the body to quantities inside the body equivalent to the values of the basic restrictions. These external field values are frequency dependent and are calculated for exposure conditions expected to give maximal coupling of the person with the field. That is, they lean towards caution. These values are termed reference or investigation levels and are values with which measured field values may be compared for the purpose of compliance assessment. It is emphasised that reference levels are not, and should not be used as, limits or restrictions on exposure but represent a tool to be used in assessing compliance with basic restrictions. The reference levels additionally provide a guide to the need to address the likelihood of indirect effects of exposure.

This system, first developed by NRPB, provides a framework for the health and safety professional to assess compliance with the basic restrictions. It has proved effective in practice and has been adopted by a number of national advisory bodies, and by ICNIRP.

NRPB recognises that the reference levels corresponding to the ICNIRP low frequency basic restrictions are generally conservative. This is, for the main part, due to the particular dosimetry models used by ICNIRP that tend to yield conservative results. For RF fields the reference levels for members of the public are generally conservative for assessing compliance with basic restrictions on SAR. However, the exception is for small children exposed at frequencies between about 50 and 100 MHz and above about 1 GHz where worst-case calculations indicate that the basic restriction may be exceeded by a small margin as illustrated in the science review. NRPB recommends that the appropriateness of the field reference levels for exposure of the general public should be reviewed for such conditions.

Overall, the ICNIRP reference levels provide an appropriate tool for use at the initial stage of compliance assessment. NRPB is not a technical standards body and does not wish to be prescriptive in specifying how subsequent more detailed compliance assessments might be carried out. Different professionals undertaking such assessments will have access to different types and models of measurement equipment and a variety of computational and experimental tools.

7.2 Acknowledgement

NRPB thanks all respondents to the consultation document for their valuable comments and suggestions.

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APPENDIX

ITALIAN LAW AND REGULATIONS

This appendix is included as an example of where a precautionary approach has been taken leading to more restrictive exposure values than found in science based exposure guidelines.

A1 Framework law

In Italy, regulations limiting exposure of the general public to EMFs are set under a framework law on 'Protection against exposure to electric, magnetic and electromagnetic fields' [1].

This framework law was intended to set out the basic principles for:

- health protection of workers and members of the general public from the effects of exposure to certain levels of electric, magnetic and electromagnetic fields,
- promotion of scientific research for the assessment of long-term side-effects and adopting precautionary measures in compliance with the principle of precaution provided for by Paragraph 2 of Article 174 of the Treaty on European Union,
- environmental and landscape protection and promotion of technology innovation and actions for decontamination intended to minimise the intensity and effects of electric, magnetic and electromagnetic fields making use of the best available technologies.

Exposure limits, for the general public, are set out in two sets of regulations under the framework law [2,3].

A1.1 Sources other than power lines and fixed systems for telecommunications

Exposure limits for all sources excluding power lines, fixed systems for telecommunication (other than for police and military) and radio and TV broadcasting are based on the restrictions set out in the EU Council Recommendation for limiting EMF exposure of the general public [4]. These restrictions are applied in their entirety and are based on the ICNIRP EMF exposure guidelines [5].

A1.2 Power lines

For power lines, exposure limits apply that are identical to the ICNIRP 50 Hz magnetic and electric field reference levels. These are (translated from Italian):

> 'In case of exposure to electric and magnetic fields generated by power lines, the following exposure limits must not be exceeded: 100 μT for the magnetic flux density and 5 kV m^{-1} for the electric field strength, both expressed as rms values.'

As a precautionary measure a further set of values are recommended. These are termed 'attention values' and, for power frequency magnetic fields, are set out as follows:

> 'As a cautionary measure to protect against any possible long-term effects that might be related to power frequency (50 Hz) magnetic fields, an attention value of 10 μT is adopted in children's playgrounds, residential dwellings, school premises, and in areas where people are staying for 4 hours or more per day. The attention value is the median of values recorded over 24 hours, under normal operational conditions.'

Further for the design of new power lines a set of 'quality goals' is established as follows:

> 'In designing new power lines in the neighbourhood of children's playgrounds, residential dwellings, school premises, and in areas where people are staying for 4 hours or more per day, as well as in planning developments in the proximity of existing electric power lines and installations, including the categories mentioned above, a quality goal of 3 μT is adopted for the purpose of progressively minimising exposures to electric and magnetic fields generated by 50 Hz power lines. The quality goal is the median of values recorded over 24 hours, under normal operational conditions.'

For power lines therefore, 'attention values' and 'quality goals' are constructs, not quantitatively based on science as are the 'power line exposure limits', but are recommended as precautionary measures.

A1.3 Fixed systems for telecommunications

In the case of fixed systems for telecommunication (other than for police and military applications) and radio and TV broadcasting in the frequency range 100 kHz – 300 GHz, exposure limits and attention values are intended to prevent both short-term effects and possible long-term effects. Quality goals aimed at the progressive minimisation of exposure are also recommended. Thus, in this case, limits on exposure, attention values and quality goals all appear to be set on the basis of a precautionary approach.

The exposure limits, attention values and quality goals are expressed in terms of electric and magnetic field strength values (and equivalent power densities).

Depending on frequency, the exposure limits are set at between one-tenth to one-third of the ICNIRP field reference levels.

The attention values are adopted in children's playgrounds, residential dwellings, school premises, and in areas where people are staying for 4 hours or more per day, as well as in outdoor annexes that may be used as residential environments, such as balconies, terraces, courtyards, but excluding roof pavings. Depending on frequency, the values are set at around one-tenth of the field exposure limits, i.e. 6 V m^{-1} and 0.16 A m^{-1}.

Quality goal values numerically equal to the attention values are set to progressively minimise exposure in highly frequented outdoor areas.

A2 Summary

In summary, the Italian framework law is based additionally on matters other than the scientific evidence for adverse health effects and contains specific references to the Precautionary Principle and environment and landscape protection. The regulations under the law are based on a precautionary approach with limits on exposure that do not consistently draw on the scientific evidence for adverse health effects.

A3 References

[1] Law 22 February 2001, No. 36. Framework law on the protection against exposure to electric, magnetic, and electromagnetic fields. *Official Gazette of the Italian Republic,* No. 55. 3 July 2001.

[2] Decree of the President of the Council of Ministers 8 July 2003. Establishment of exposure limits, attention values, and quality goals to protect the population against electric, magnetic, and electromagnetic fields generated at frequencies between 100 kHz and 300 GHz. *Official Gazette of the Italian Republic,* No. 199. 28 August 2003.

[3] Decree of the President of the Council of Ministers 8 July 2003. Establishment of exposure limits, attention values, and quality goals to protect the population against power frequency (50 Hz) electric and magnetic fields generated by power lines. *Official Gazette of the Italian Republic,* no. 200, 29 August 2003.

[4] Council Recommendation of 12 July 1999 on the Limitation of Exposure of the General Public to Electromagnetic Fields (0 Hz to 300 GHz). *Official Journal of the European Community*, **L199**, 59 (1999/519/EC). http://europa.eu.int/comm/health/ph/programmes/pollution/ph_fields_cr_en.pdf.

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