

The Physical Agents (Electromagnetic Fields) Directive and MRI - November 2007

A Report from the BIR MR Committee

Introduction

The European Commission has recently announced a four-year delay to the implementation date of the Physical Agents (EMF) Directive [1]. This is explicitly to allow time for the impact of the Directive on MRI to be assessed in more detail, with a view to substantive amendment.

The BIR, via its MR Committee, has played an important role from the outset in raising awareness both within the UK and Europe, about the possible implications of the proposed directive. It has continued to adopt an active position in collaborating with a variety of organisations with respect to lobbying both the UK parliament and at a European level. Additionally it has acted to highlight the scientific weaknesses of aspects of the directive and the significant implications for clinical working practices and MR research if the directive in its original form were to be implemented.

In summary, the campaign about the Directive has reached an important stage and secured a proposed delay that would have been unimaginable a few years ago. However, what has been achieved is a *delay* to the legislation, not yet a satisfactory substantive change. There are a number of challenges ahead of us yet, and unfortunately it is too soon to say that the problem of the Directive is behind us.

Background

The Directive was adopted by the European Union in 2004 [2]. It contains limits for occupational exposure to time-varying magnetic fields and to RF, adopted from guidelines previously issued by ICNIRP in 1998 [3]. These guidelines are based on cautious interpretation of sparse scientific evidence in order to exclude any possibility of adverse effects, rather than on established thresholds for actual effects.

The MR community in the UK realised at an early stage that there were serious implications for MRI, and from July 2003 attempted to influence negotiation of the Directive, conducted on behalf of the UK by the Health and Safety Executive (HSE). The BIR was particularly active at this stage, and IPeM (Institute of physical Sciences in Medicine) later raised concerns as well. Unfortunately these representations were unsuccessful, and the Directive was adopted with a deadline of 30th April 2008 for adoption into national law (known as transposition) by each member state.

In September 2005, working through the BIR and with the charity Sense About Science, the MR community held a press conference to highlight the issue (Professor Sir Peter Mansfield, Professor Ian Young, Dr Andrew Taylor, Dr Stephen Keevil). This received positive coverage in the print and broadcast media. There was a follow-up campaign of letter writing by the professional bodies, charities and individual eminent scientists.

The issue was then taken up by Lord Hunt of King's Heath, then the Minister at the Department of Work and Pensions with responsibility for the HSE. A series of very constructive meetings was held between Lord Hunt and representatives of the HSE and RCR (Professor Peter Dawson, Dr Andrew Taylor, Dr Stephen Keevil). As a result a stakeholder meeting was held with over 50 representatives of all the professional groups (including the BIR), industry, government agencies and funders. The HSE was left in no doubt as to the perceived scale of the problem and the strength of feeling in the community.

As a result, an HSE working party was set up with representatives of industry, funding bodies and the MR community (Professor Peter Dawson, Dr Andrew Taylor, Dr Stephen Keevil, Dr Liz Moore). This group commissioned Professor Stuart Crozier (University of Queensland) to model EMF exposures in MRI and so establish the extent of any breaches of the limits in the Directive.

In parallel with this, the House of Commons Science and Technology Select Committee launched an inquiry into the issue as part of a wider examination of government use of scientific evidence. A joint submission to the inquiry was made by the RCR, BIR, IPeM, IOP and BC-ISMRM, compiled by Dr Stephen Keevil. Dr Keevil later gave oral evidence to the Committee on behalf of the MR community, with Professor Ray Dolan and Professor Colin Blakemore (Chief Executive of the MRC). The Committee's report in June 2006 was critical of the HSE, the Health Protection Agency (HPA), ICNIRP and the European Commission, and concluded that there was no case for the Directive in the context of MRI [4].

MRI professionals in other EU member states had by this time become aware of the situation. In March 2006 a delegation of European radiologists and scientists under an ESR banner (including Dr Stephen Keevil as an EFOMP representative) met with Commissioner Vladimír Špidla in Brussels. As a result, a contact group was set up with Commission staff and ESR representatives (Professor Gabriel Krestin, Professor David Norris and Dr Stephen Keevil). This group has met regularly ever since. It was decided to commission a further study of EMF exposures in MRI, and after a tendering process this work was awarded to a consortium of scientists from Zurich, Umeå and London (the latter being Professor Jeff Hand and Dr Donald McRobbie). Dr Stephen Keevil represents the ESR on the monitoring committee for this project.

The community has also been active in lobbying ICNIRP, the original source of the exposure limits embodied in the Directive. In February 2007, Professor Penny Gowland (Trustee of ISMRM), Professor Jeff Hand, Dr Stephen Keevil and others attended an ICNIRP workshop in Milan to discuss the issue, receiving a favourable hearing.

The Alliance for MRI was established in March 2007 as an umbrella group for the campaign at European level [5]. It consists of MEPs, professional bodies (including SCoR), funding bodies (including the Wellcome Trust), patient groups and individual scientists, and has received invaluable support from FIPRA, a public affairs consultancy based in Brussels [6], and the trade body COCIR. In May 2007, Dr Stephen Keevil and Professor Guy Frija briefed the European Parliament Committee on Employment and Social Affairs on the issue, and in June 2007 the Alliance hosted a lunch for MEPs and Commission staff (including Commissioner Špidla) at which Professor Krestin spoke and Dr Keevil presented the results of the Crozier study. Following this, the Commission began to indicate that a delay in the transposition deadline for the Directive might be proposed, with a delay of one or two years being mooted initially.

Current Position

On 26th October 2007, the Commission proposed a four-year delay in the transposition deadline [7] , until 30th April 2012. A few excerpts from the Commission statement are given here, indicating that the delay is motivated by the evidence that has been submitted in relation to impact on MRI, and that a substantive amendment is anticipated.
[The Directive] could have affected the use of technologies such as Magnetic Resonance Imaging (MRI)...

... "Postponement of the transposition will allow time to review the current Directive and amend those provisions which have been shown to be problematic by recent scientific studies...

... this postponement is being carried out in order to prepare a substantive amendment to the Directive. The future amendment will aim to ensure that limits will not have an adverse effect on the practice of MRI, whilst ensuring appropriate protection of personnel...

[ICNIRP] is currently revising its recommendations for occupational limit values for static and low frequency electromagnetic fields... Those revisions are expected to yield results in the form of new, less stringent, recommended limit values for occupational exposure at the end of 2008.

The Commission announcement has been warmly welcomed by the MR community and in the media. In some quarters the view has been expressed that the problem has now been solved, and we can relax and get on with more important things. Unfortunately, while the delay is certainly very welcome and a vindication of our long campaign, this assumption is something of an oversimplification.

The Future

The Commission proposal takes the form of a new Directive (being referred to as Directive 2): because the transposition deadline was written into the original Directive (Directive 1), a new Directive is the only way to amend it. Directive 2 has to be agreed by the European Parliament and the Council of Ministers. The Commission has found an accelerated route for this to occur without the need for the usual tripartite consultation with governments, industry and trade unions, and it seems likely that Directive 2 will be adopted before the end of 2007. It is expected that Directive 3 (which hopefully will contain substantial amendments to the exposure limits) will be drafted by the end of 2009, allowing consultation, adoption and transposition by 2012.

The opportunities to influence the exposure limits within the new directive and to maintain pressure to obtain a balanced perspective on hypothetical risks and the clear health benefits from MR are significantly shorter than the publicised four year delay. Decisions on the new content and updates to the original ICNIRP guidance, on which the original directive was based, are anticipated to be made in the next eighteen months. The majority of the remaining time until 2012 will be taken up with consultation and negotiations between interested parties and member states. This period is not an effective time to significantly influence the exposure levels and the basic rationale of the directive. It is essential that the various scientists, clinicians and professional groups, that have to date been galvanised into action and have collaborated so effectively in achieving this delay to the directive, continue to excerpt their expertise. To this end, the BIR is at early stages of discussion with the major groups involved to host a multidisciplinary and multi-organisation working party. The purpose of this working party will be to create a forum to monitor developments and maintain lobbying pressure. This will hopefully ensure appropriate points of view and science are presented to the EU by our UK representatives on the various European committees. Additionally the working party will also provide a unified point of contact for collaboration with other interested groups and partner organisations within the EU as a whole. The MR Committee will continue to keep members informed of developments in connection with the directive.

Prepared on behalf of the BIR MR Committee by Stephen Keevil and Andrew Jones.

[1] Referred to here as the Directive - although it should be remembered that there are four Physical Agents Directives, and the other three (covering noise, optical radiation and vibration) are not affected by this delay.

[2] <http://www.senseaboutscience.org.uk/pdf/PhysicalAgentsDirective.pdf>

[3] <http://www.icnirp.org/documents/emfgdl.pdf>

[4] <http://www.publications.parliament.uk/pa/cm200506/cmselect/cmsctech/1654/1654.pdf>

[5] <http://allianceformri.org>

[6] <http://www.fipra.com/>

[7]

<http://europa.eu/rapid/pressReleasesAction.do?reference=IP/07/1610&format=HTML&aged=0&language=EN&guiLanguage=en>