BJR doi: 10.1259/bjr.20130492

Received: 5 August 2013 | Revised: 2 October 2013 | Accepted: 3 October 2013



Cite this article as:
Keevil SF, Lomas DJ. The European Union physical agents (electromagnetic fields) directive: an update for the MRI community. Br J Radiol 2013;86:20130492.

## INVITED COMMENTARY

# The European Union physical agents (electromagnetic fields) directive: an update for the MRI community

**[1,2]S F KEEVIL, PhD, FIPEM and [3]D J LOMAS, FRCR, FRCP**

[1]Department of Medical Physics, Guy's and St Thomas' NHS Foundation Trust, St Thomas' Hospital, London, UK
[2]Department of Biomedical Engineering, King's College London, St Thomas' Hospital, London, UK
[3]Department of Radiology, University of Cambridge and Addenbrooke's Hospital, Cambridge, UK

Address correspondence to: Professor Stephen F. Keevil
E-mail: *stephen.keevil@kcl.ac.uk*

Members of the MRI community in Europe will be all too aware of the problems posed by the European Union (EU) Physical Agents (Electromagnetic Fields) Directive (2004/40/EU) [1,2] and of the long-standing campaign to mitigate its impact on our clinical and research activities [3,4]. These efforts appear to have succeeded at last, and the 2004 legislation has been replaced by a new directive in which MRI is treated as a special case, although some important caveats remain. The aim of this commentary is to bring colleagues up to date with these developments and to explain what is likely to happen over the next few years as the issue finally draws to a conclusion.

To summarise the history briefly, in 2003, the MRI community became aware of a proposal for an EU directive intended to protect workers from adverse effects of exposure to electromagnetic fields (EMFs). The potentially detrimental impact on our work of the very conservative EMF exposure limits contained in the proposal was quickly realised. Early attempts to influence events were unsuccessful, and the directive was duly adopted by the EU in 2004. A campaign was launched to lobby national governments and the EU institutions to amend the directive before it was implemented by member states. The Alliance for MRI (http://www.myesr.org/cms/website.php?id=/en/eu_affairs_research/alliance_for_mri.htm) was set up as an umbrella body to coordinate efforts by the MRI community, professional societies, concerned politicians and (very importantly) patient groups. This campaign bore fruit in 2007, when the European Commission announced postponement of the deadline for implementation of the directive (originally 30 April 2008) by 4 years to allow time for a solution to be found. Then, in June 2011, the Commission proposed a replacement directive, in which the EMF exposure limits would not apply to MRI workers, but instead harmonised safe working practices would be developed to ensure workers' health and safety. However, this proposal encountered significant political opposition from influential EU member state governments, and in April 2012 a further implementation delay of 18 months was announced. Following another year of negotiations, accompanied by further intense lobbying by the Alliance, a compromise agreement was finally reached in April 2013. This resulted in adoption of a new EMF directive (2013/35/EU) by the European Parliament in plenary session on 11 June 2013 and by the Council on 20 June 2013 [5]. Article 17 of this new directive contains words that are welcomed by all of us involved in this long campaign: "Directive 2004/40/EC is repealed from 29 June 2013".

Directive 2013/35/EU retains the exemption (or derogation) from EMF exposure limits (or "exposure limit values") that was such an important feature of the 2011 proposal, but in the course of negotiation, some conditions have been added. Article 10 of the directive sets out the scope of the derogation, stating that the exposure limits may be exceeded during "the installation, testing, use, development, maintenance of or research related to magnetic resonance imaging (MRI) equipment for patients in the health sector", provided that certain conditions are met. These conditions are that (i) a risk assessment has been carried out and has shown that the exposure limits are exceeded; (ii) "given the state of the art, all technical and/or organisational measures have been applied"; (iii) "the circumstances duly justify exceeding the exposure limit values; (iv) "the characteristics of the workplace, work equipment or work practices have been taken into account"; and (v) the manufacturer's instructions for use, issued in accordance with the CE marking of the scanner, are followed.

Uncertainties remain regarding the scope and conditions of this derogation. The rather cumbersome and ambiguous wording of the scope was the result of efforts to ensure that the derogation covers more than just imaging of patients for clinical purposes. The conditions (ii) and (iii) are very difficult to interpret, with condition (iii), in particular, being a catch-all that could mean almost anything. These ambiguities result from the need to reconcile the wide range of positions held by member states and will likely

result in different interpretations in different European countries with their own views as to what constitute duly justified circumstances. Condition (i) reiterates the requirement for risk assessment that is already contained in existing legislation. However, it also carries with it a risk of unnecessary literal interpretation: given the difficulties inherent in showing that the exposure limits are exceeded, how rigorously must this be demonstrated to trigger a derogation, which means that these limits no longer apply? Conditions (iv) and (v) are clearly more pragmatic, with condition (v) introducing a reliance on the safety provisions of the Medical Devices Directive that has been a key element of our arguments over the years.

The deadline for implementation of the new directive is 1 July 2016. Before then, the European Commission will issue a non-binding practical guide, which we believe (in a change to previous plans) will now include MRI as well as all other applications of EMFs. This guide may go some way towards resolving the ambiguities inherent in Article 10, and, hopefully, the relevant material will be developed in consultation with the MRI community. The call for tenders for this work has been delayed, and in the meantime, national authorities will be carrying out their own preparations. In the UK, for example, the Health and Safety Executive has very sensibly decided to press on with the development of national guidance. This guidance is being prepared in close co-operation with the MRI community, particularly the British Institute of Radiology (BIR) MR Safety Working Party, which includes representatives from all of the relevant professional bodies and government agencies. This partnership approach could perhaps provide a model for MRI community representatives in other European countries to develop similar dialogues with their own regulators.

Repeal of the 2004 EMF Directive and introduction of a derogation for MRI in the new directive that has been adopted to replace it are both welcome and appropriate. However, there is still work to be done at the European and national levels to make sure that what has been gained through painstaking negotiation is not lost through inappropriate implementation. In the UK, we are confident that, by building on past co-operation, a satisfactory conclusion to this issue can be achieved. More work may be needed in countries where governments were less easily persuaded of the need for a derogation and acquiesced only once that derogation had been surrounded with conditions so ambiguous as to allow almost unlimited latitude for interpretation.

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