



November 2011

**The Alliance for MRI welcomes the Commission's proposal to exempt Magnetic Resonance Imaging (MRI) from the limit values set in Directive 2004/40/EC to protect workers from electromagnetic fields (EMF Directive)**

- **This derogation is necessary to ensure the unimpeded use of MRI so that patients have access to the highest standard of care across Europe.**
- **The safe use of this technology is highly regulated. Criteria have been set to eliminate any danger to workers and patients.**
- **MRI has been used for over 25 years, imaging up to 500 million patients without evidence of harm to workers due to exposure to electromagnetic fields.**
- **The Alliance supports the adoption of guidelines to ensure that working practices are in line with the latest technological developments.**

On 14 June the European Commission adopted a proposal to revise the directive on protecting workers from electromagnetic fields. The European Commission's proposal includes a derogation for the medical and research use of MRI from the exposure limit values, which will ensure that this vital technology will continue to be available for all patients.

This revision is a result of the concerns raised by the Alliance for MRI and a recognition by the European Commission that the current Directive severely curtailed the use of MRI to the detriment of patients in Europe<sup>1</sup>.

The derogation for MRI is required as the revised exposure limit values still curtail the use of MRI in areas such as MRI-guided surgery (for example brain surgery) and in imaging vulnerable patients and children, where closer patient contact is required. Furthermore, new research and developments in MRI would be severely restricted, as would routine cleaning and maintenance of MRI equipment.

It is important that the derogation covers all MRI activities, including **clinical use, research, cleaning and maintenance**. In all those activities workers may be exposed to one or more of the types of electromagnetic field generated by an MRI scanner (static magnetic field, switched magnetic field gradients, radio frequency field) at similar levels as are encountered by healthcare workers when the system is in clinical use, with the result that the same exemption is needed.

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<sup>1</sup> [An Investigation into Occupational Exposure to Electromagnetic Fields for Personnel Working With and Around Medical Magnetic Resonance Imaging Equipment](#) prepared for DG Employment and Social Affairs, April 2008

The Alliance for MRI represents workers who are exposed on a daily basis to electromagnetic fields, as well as patients, researchers and scientists. The safe use of MRI is a key concern to all members of the Alliance for MRI.

The safety of MRI is ensured through the established MR safety standard IEC/EN 60601-2-33 which defines criteria for minimizing physiological effects due to exposure to time-varying electromagnetic fields for patients and workers. MRI is free from health risks associated with ionising radiation such as x-rays, which would form the alternative to MRI in many situations.

MRI is a diagnostic technique that uses radio and magnetic waves to produce images of unrivalled quality, particularly of soft tissues that are not well depicted in X-rays. It is essential in the diagnosis and treatment of life-threatening diseases such as cancer, heart disease and brain disorders. MRI is used in mapping brain functions prior to surgeries for diseases such as epilepsy and to advance our understanding of how the brain works. New cutting edge diagnostic and treatment techniques such as MRI-guided surgery are constantly being developed leading to improved patient outcomes.

Europe is currently at the cutting edge of innovations in MRI technology, contributing significantly to the objectives of the EU's 2020 strategy. The EU and member states have invested significantly<sup>2</sup> in MRI technology, given the potential it offers to the future of medicine and understanding of the human body. These investments must no longer be jeopardised through the legal uncertainty caused by the current legislation.

It will also be important that the Commission proposes a further postponement of the deadline for implementation of Directive 2004/40/EC (originally set for April 2012), given that any revision of the directive will not be in place by that date.

The Alliance for MRI welcomes the commitment by the European Commission and the support of many members of the European Parliament to address to find a sustainable solution for MRI in Europe.

## **Background on the Alliance for MRI**

The 'Alliance for MRI' is a coalition of European Parliamentarians, patient groups, leading European scientists and the medical community, who together are seeking to avert the serious threat posed by EU health and safety legislation to the clinical and research use of Magnetic Resonance Imaging (MRI).

The Alliance for MRI was officially launched in March 2007 in response to the implementation of the EU Physical Agents 2004/40/EC (EMF) in April 2008. The Alliance was founded by the European Society of Radiology, the European Federation of Neurological Associations and Dr. Swoboda MEP, Vice-Chairman of the Socialist Group in the European Parliament.

In October 2007 the European Commission proposed the postponement of the implementation deadline from April 2008 to April 2012 to allow more time for the evaluation of new data on EMF and its short-term effects on the human body. The

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<sup>2</sup> The EU has allocated €6 million through the 7<sup>th</sup> Research Framework Programme to the further development of MRI, France and Germany have invested over €200 million in the state of the art [Neurospin](#) facility.

Commission stated that it was never the intention of this Directive to impede the practice of MRI and the European Parliament and the Council approved the postponement.

**The Alliance is supported by:**

**27 leading Members of the European Parliament**

János Áder (EPP) HU, Frieda Brepoels (EFA) BE, Derek Clark (EFD) UK, Alejandro Cercas (S&D) ES, Jorgo Chatzimarkakis (ALDE) DE, Frank Engel (EPP) LU, Robert Goebbels (S&D) LU, Françoise Grossetête (EPP) FR, Richard Howitt (S&D) UK, Stephen Hughes (S&D) UK, Ville Itälä (EPP) FI, Anneli Jäätteenmäki (ALDE) FI, Philippe Juvin (EPP) FR, Eija-Riitta Korhola (EPP) FI, Peter Liese (EPP) DE, Elizabeth Lynne (ALDE) UK, Linda McAvan (S&D) UK, Miroslav Mikolášik (EPP) SL, Elisabeth Morin-Chartier (EPP) FR, Dr. Angelika Niebler (EPP) DE, Siiri Oviir (ALDE) EST, Antonio Panzeri Pier (S&D) IT, Frédérique Ries (ALDE) BE, Zuzana Roithová (EPP) CZ, Horst Schnellhardt (EPP) DE, Hannes Swoboda (S&D) AT (Founding member), Thomas Ulmer (EPP) DE, Derek Vaughan (S&D) UK, Dr. Anja Weisgerber (EPP) DE

**15 European and National patient groups**

European Federation of Neurological Associations (Founding member); including the European Parkinson's Disease Association, The European MS Platform and the European Headache Alliance, The European Heart Network, Europa Donna, The European Patients Forum, The International Diabetes Federation – Europe, Alzheimer Europe, The WHO Collaborative Centre for Research, training and treatment in Epilepsy, The Austrian Lung Association, The Austrian Epilepsy Association, Werkgroep Hersentumoren vzw (Belgian Brain Tumour Group), Epilepsy Centres of the Netherlands Foundation: SEIN

**Representative Groups of Scientists**

- European Society of Radiology (Founding Member) and institutional members (below)
- The Wellcome Trust
- Cancer Research UK
- European Society for Magnetic Resonance in Medicine and Biology (ESMRMB)
- European Union of Medical Specialists (UEMS)
- European Brain Council
- Luxembourg Medical Council
- European Institute for Biomedical Imaging Research (EIBIR)
- The Society and College of Radiographers
- European Society for Therapeutic Radiology and Oncology (ESTRO)
- European CanCer Organisation (ECCO)
- European Federation of Organisations for Medical Physics (EFOMP)
- European Federation of Radiographer Societies (EFRS)

**Institutional members of European Society of Radiology:**

- Société Française de Radiologie (SFR)
- Spanish Radiological Society (SERAM)
- Polish Medical Society of Radiology
- Norwegian Society of Radiology
- Royal Belgian Radiological Society
- Luxembourg Society of Radiology

- Deutsche Roentgengesellschaft - German Radiological Society (DRG)
- Radiological Society of the Netherlands
- European Society of Urogenital Radiology (ESUR)
- European Society of Thoracic Imaging (ESTI)
- European Society of Neuroradiology (ESNR)
- Croatian Medical Association & Croatian Society of Radiology
- European Society of Cardiac Radiology (ESCR)
- Italian Society of Radiology (SIRM)
- European Society of Breast Imaging (EUSOBI)
- Romanian Society of Radiology
- Danish Society of Radiology
- Austrian Radiologic Society (ÖRG)
- British Institute of Radiology
- Swedish Society of Medical Radiology
- Bulgarian Association of Radiology
- Sociedade Portuguesa de Radiologia e Medicina Nuclear
- Czech Radiological Society
- Slovak Radiological Society
- Faculty of Radiologists, Royal College of Surgeons in Ireland
- European Society of Head and Neck Radiology
- Cardiovascular and Interventional Radiological Society of Europe
- The Royal College of Radiologists

In addition, a number of individual scientists and patient group representatives have signed up to the Alliance. Further information is available at [www.alliance-for-mri.org](http://www.alliance-for-mri.org)