



Alliance for MRI welcomes derogation for MRI in revised Directive on electromagnetic fields

- **MEP says will “clarify the law” on MRI**
- **Clears way for continued MRI use against life-threatening disease**

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The Alliance for MRI welcomes the European Commission’s proposal to exempt magnetic resonance imaging (MRI) technology from the exposure limits in the revision of Directive 2004/40/EC¹ on electromagnetic fields.

The derogation is part of a wide-ranging update of the directive, which the European Parliament and Council are expected to act on later this year. The derogation for MRI is required as the revised exposure limits still curtail the use of MRI in areas such as MRI-guided surgery, imaging vulnerable patients and children. New research and developments in MRI would also be severely restricted, as would routine cleaning and maintenance of MRI equipment.

“This proposal is good news for patients around Europe, and we look forward to its quick adoption, which will clarify the law on MRI,” said Hannes Swoboda, a leading Member of the European Parliament and founding Member of the Alliance for MRI.

“This proposal ensures that patients across Europe will be able to receive the highest standard of care and will not be forced into the undesirable alternative of x-rays. We very much hope that the Polish Presidency will seek early agreement in Council particularly given their commitment to brain disease where MRI is a key tool for diagnosis and treatment” said Mary Baker, leading Patient Group Advocate and President of the European Brain Council.

The directive corrects the unforeseen negative impact on magnetic resonance imaging of the previous directive, which will be important for Europe as a whole.

“Europe is currently at the forefront of this technology and with this revision the Commission demonstrated that it supports this vital technology,” said Dr. Gabriel Krestin, Vice-President of the European Society of Radiology.

The new proposal is part of the European Commission health and safety legislation to protect workers. MRI will be exempt from the exposure limit values of the directive but workers using MRI will be protected through existing regulations, which ensure its safe use. The established MR safety standard IEC/EN 60601-2-33 defines criteria for minimizing physiological effects due to exposure to time-varying electromagnetic fields, aiming to eliminate danger to patients and workers. The Alliance for MRI also supports other qualitative measures proposed in the directive and the adoption of guidelines to ensure working practices are in line with technological developments.

ENDS

¹ Directive 2004/40/EC on “the minimum health and safety requirements regarding the exposure of workers to the risks arising from physical agents (electromagnetic fields)”



Background on the Alliance for MRI

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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 deadline 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 recognized the problem of MRI in Directive 2004/40/EC and proposed the first-ever postponement of an implementation deadline from April 2008 to April 2012 to allow time for scientific studies to analyse the impact of the Directive on the use of MRI. These studies proved that the exposure limits in the directive were detrimental to patient care. They would restrict and limit the use of MRI in interventional applications 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 will routine cleaning and maintenance of MRI equipment.

Following further consultations, the Commission decided to revise the Directive in order to find a lasting solution for MR culminating in today's proposal. The Alliance for MRI was instrumental in bringing about this revision.

MRI has been used for over 25 years, imaging up to 500 million patients without evidence of harm to workers due to EMF exposure. It is also well known that MRI is free from most health risks associated with ionising radiation such as x-rays, which would form the alternative to MRI in many situations.

MRI is central to the diagnosis and treatment of major life-threatening diseases such as cancer, cardio-vascular diseases, musculoskeletal and neurologic disorders. Emerging molecular MR imaging techniques are poised to make major contributions in the area of oncology. Currently MRI is the most accurate tool for detecting breast cancer in young patients with genetic predisposition. Cardiac MRI has made huge strides in recent years, for example allowing for the assessment of the functioning of heart muscle in heart-attack patients. Functional MRI, mapping out areas of the brain that are responsible for specific sensory and motor tasks, is making important contributions to neuroscience as well as improving the outcome of brain surgery for patients.

The Alliance is supported by:

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, 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

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
- 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

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