With the support of:

FEAM Statement on the EU Physical Agents Directive

FEAM, the Federation of the European Academies of Medicine, welcomes the revised EU Physical Agents Directive 2004/40/EC that provides an exemption for magnetic resonance imaging (MRI) from the electromagnetic field (EMF) exposure limits. We thank the European Commission for taking account of our earlier expression of concerns. We now call on Members of the European Parliament and Council to work together to approve the revised Directive and thereby ensure its rapid implementation, for the benefit of patients and the advancement of research.

Background on previous FEAM activity

FEAM was founded in 1993 with the objective of promoting cooperation between the national Academies of Medicine and extending their policy advisory role on matters concerning medicine and public health from the national to the EU level.

When published in 2004, the Physical Agents Directive 2004/40/EC was intended to set minimum requirements to protect workers from exposure to EMF. In 2006, FEAM published its concerns[1] that the form of the Directive as initially proposed would, if the suggested exposure limits were implemented, inadvertently have a negative impact on the use of MRI, with potentially highly damaging consequences for patient diagnosis and care, and for the conduct of fundamental and applied research. At that time, FEAM noted that:

(i) The proposed exposure limits were not based on sound scientific evidence and were far below those levels known to produce physiological effects.

(ii) There was need for further, specific, risk-benefit assessment regarding exposure limits of the medical staff and technicians supporting patients undergoing MRI examinations.

(iii) If the Directive led to a reduction in the use of diagnostic and interventional MRI procedures, there was likely to be a resultant increase in the use of X-rays with their well-established hazards and consequences for worker and patient safety.

[1] FEAM, April 2006, Report to the European Commission on www.feam.eu.com

We were grateful then that the European Commission listened to the concerns expressed by FEAM and others, and accepted our recommendation to delay revision of the Directive in order to allow sufficient time to collect the evidence and allow expert review of the issues. We are now pleased that the European Commission has accepted the case for a significant change to the proposed revision and has exempted MRI from the binding exposure limits in the Directive. We reiterate that this derogation is essential to ensure that the use of MRI can continue to support a high standard of patient care and advance European research and innovation.

Protecting patients, promoting research

MRI has been used in routine medical practice for three decades, imaging up to 500 million patients. Although MRI will now be exempt from the exposure limits, workers using MRI will be protected by existing safety regulations. For example, the MRI safety standard IEC/EN/60601-2-33 defines the criteria to minimise physiological effects, to optimise conditions for patients and to protect researchers and MRI operators.

In addition to its routine use in medical care, MRI has many roles as an imaging technology in clinical and pre-clinical research, and Europe has been at the forefront of such research[2]. There are continuing exciting methodological advances, for example in Ultra high field MRI scanners, cognitive neuroimaging and in scanners for animal research that contribute to the objectives for reduction, refinement and replacement of animal use. In emphasising one other area, a recent FEAM Statement[3] describes work that exemplifies the value of MRI diagnostic imaging as part of longitudinal evaluation of pathophysiology during brain development and in response to therapeutic interventions in a range of mental disorders. As observed in that Statement and repeated in very recent discussion[4], there are major European opportunities for building critical mass and excellence in the neurosciences that require integration of information from MRI and other sources across basic, clinical and population research.

Next steps for achieving a supportive Directive

In producing this Statement, FEAM has drawn on material collected by other interested groups in the biomedical community[5]. FEAM is committed to continuing to work with these other groups to communicate our messages on how vital it is that the proposal for a revised Directive is now rapidly adopted with the exemption for MRI from the EMF exposure limits. We look forward to engaging with parliamentarians at the EU and Member State levels, and others involved in advising and deciding policy, to ensure that the high standards of clinical care and biomedical research are not compromised.

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[2] For example, in the last 30 years, two Nobel prizes relating to MRI have been awarded to European scientists: in 1991 to Ernst, for basic scientific and methodological developments and in 2003 to Mansfield for use of MRI as a clinical diagnostic tool.

[3] FEAM Statement on Mental Health Policy Issues, November 2010, available on www.feam.eu.com.

[4] FEAM Statement, Objectives and Opportunities for EU Mental Health Policy, August 2011, available on www.feam.eu.com.

[5] In particular, we are grateful to the efforts of the Alliance for MRI (www.myesr.org), the European Science Foundation (www.esf.org) and the UK Research Funders Coalition.

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Additional Academy endorsing this statement:

The Lithuanian Academy of Sciences (Lithuania)

Other networks endorsing this statement:

Alliance for MRI

European Science Foundation

The Federation of the European Academies of Medicine (FEAM) was founded in 1993 in Brussels with the objective of promoting cooperation between the national Academies of Medicine and of extending to the political and administrative authorities of the European Union the advisory role that the Academies exercise in their own countries on matters concerning medical sciences and public health. Since 31 March 1995, FEAM has enjoyed the civil status of an international association with a scientific objective. As an umbrella organisation, it brings together national Academies of thirteen European member states (Austria, Belgium, Czech Republic, France, Germany, Greece, Hungary, Italy, Portugal, the Netherlands, Romania, Spain and the United Kingdom) and aims to reflect the European diversity by seeking the involvement of additional Academies and experts in its scientific activities and by collaborating with other pan-European networks on scientific matters of common interest.

Brussels, November 2011