

Electromagnetic Fields Directive: why the postponement?

The Directive on the protection of workers exposed to electromagnetic fields adopted in 2004 should have been carried into law in all Member States by 30 April 2008. The EU's Council of Social Affairs Ministers decided it should not be. This article sheds light on why, and the vexed issue of the health effects of electromagnetic waves.

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Welders are exposed to high-level electromagnetic fields. Welding exposes them to very low frequency radiation (50 Hz) which can lead to effects on the nervous system.

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Although it applies only to workplaces, the Electromagnetic Fields Directive illustrates one of many questions raised in European circles by the development of technologies that produce electromagnetic fields: What are the economic implications? And what are the possible health impacts? This latter aspect is central to the policy debate which prompted the European authorities to put off bringing the Directive into effect until 2012 □ a first in health and safety at work matters.

But not only did the Council postpone the transposition deadline, it also undertook to review the Directive's substantive provisions in light of the findings of new studies on the human health impacts of non-ionizing radiation, taking work in progress in the WHO and the International Commission on Non-Ionizing Radiation Protection (ICNIRP) as its yardsticks.

The Council argued that transposition needed to be postponed in order to examine the potential impact of implementing the Directive on the use of electromagnetic fields in medical imaging and certain industrial activities.

To do this in accordance with the European treaty, the Commission has to launch a social partner consultation on the Directive's guidelines. The first stage of consultations got under way in summer 2009. If it is to meet the 2012 deadline, the Commission will need to have a proposal on the Council table by the start of 2010 to give to the institutions the minimum time needed for scrutiny and national transposition.

Occupational exposures

We are all exposed to natural electromagnetic fields, like the earth's magnetic field and the electrical fields produced by storms. Since World War Two, however, increased electricity-based technological innovation has led to the development of work equipment and domestic appliances that are sources of non-ionizing radiations. Most commonly, these include mobile phones, television sets and the microwave ovens in the home, and lasers, magnetic resonance imaging for medical purposes, and welding stations in workplaces.

A large number of workers are exposed to high field strengths. Some categories of worker are at especial risk, like pregnant workers and workers wearing metal medical implants.

The final report of a European research project and a report by the Dutch authorities identified significant source technologies that workers have access and work in close proximity to¹. Both documents recommend that exposure measurements be taken for certain occupations or sectors. These include installation and maintenance of field producing equipment, rectifiers (AC/DC converters) in electrochemical processes, induction heating used in alloying smelter furnaces, welding equipment, medical applications, especially magnetic resonance imaging (MRI) equipment, broadcasting antennas and mobile phone masts.

It is striking how little - if any - data currently exists on exposure levels in many actual work situations. This means that many issues involved in exposure assessment remain unresolved. In some work situations, fields are inhomogeneous and disturbed, unlike the theoretical situations considered. And when workers are very close to the source, measurement can be difficult.

Adopting common exposure assessment standards is therefore essential for the practical implementation of the Directive's provisions and for carrying out epidemiological studies². The current recommendations of

1. EMF-NET project-Final technical report on occupational EMF exposure – deliverable D49, April 2008, <<http://web.jrc.ec.europa.eu/emf-net>> and *Electromagnetic fields in the working environment 2006*, Dutch Ministry of Social Affairs, June 2006.

2. The Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR), a body set up by the Commission, has identified research needs, in particular for occupational exposure. See: *Research needs and methodology to address the remaining knowledge gaps on the potential health effects of EMF 2009*, SCENIHR, Opinion, July 6 2009.

All throughout the debate, the trade unions have resolutely insisted that all the workers concerned should be covered.

The Electromagnetic Fields Directive

The Directive (2004/40/CE) covers electromagnetic fields with frequencies of up to 300 GHz. It refers only to risks associated with effects recognized by the ICNIRP, *i.e.*, short-term effects in the human body caused by the circulation of induced currents and by energy absorption, as well as by contact currents.

Internal induced currents result from the interactions of low frequency fields with the body. These currents are measured by their intensity and density. Energy absorption is the result of exposure to fields of frequencies higher than 10 KHz and can produce rises in temperature. This is measured in the frequency range up to 10 GHz by the specific energy absorption rate or SAR (expressed in watts per kilogram) and above that by the field incident power density.

The Directive is based on the ICNIRP recommendations, therefore laying down values that cannot be exceeded because they are founded on proven health effects. It also incorporates action values that are based on measurable values. Note that action values are fixed for the static fields which are found around magnets including those used in MRI equipment but not exposure limits.

When carrying out their risk assessment, employers must take into account the exposure limits and the situation of workers at particular risk, like pregnant women and pacemaker-wearers. Employers must also take account of indirect effects, like projections of metal objects and the initiation of electro-explosive devices (detonators), etc.

If the action values are exceeded, the employer must assess or calculate whether the exposure values are exceeded. But this obligation does not apply if the work place is open to the public and an evaluation has already been undertaken in accordance with the Council Recommendation for the protection of the public (Council Recommendation 1999/519/EC). It should be borne in mind that action values are measured in the environment while exposure limits must be calculated as being values measured in the human body.

the ICNIRP³ and other international agencies aim only at the avoidance of thermal effects and electrical stimulation in the human body. Some experts argue that this does not go far enough, and that what needs to be considered is the dosimetric quantities, which means factoring in exposure duration⁴. No formula enabling such measures to be taken has yet been adopted at the international level.

Not only do no such common assessment standards exist, but many countries do not yet even have legislation in this field – Belgium, France and Ireland are cases in point – or have legislation that covers only specific situations. Poland, Spain, the Netherlands and Germany – all of which possess legislation – have preventive rules adopted by the national insurance organization.

Many uncertainties

The Directive covers electromagnetic fields with frequencies of between 0 Hz and 300 gigahertz (GHz). It refers only to risks associated with effects recognized by the ICNIRP, *i.e.*, short-term effects in the human body caused by the circulation of induced currents and by energy absorption, as well as by contact currents.

Since the proposal for a Directive covering all physical agents was tabled in 1992, a debate has been going on in the EU Council of Ministers about the relevance of the ICNIRP's proposed exposure limits and the scope of the Directive: What frequency range should be covered? What ranges of equipment are covered or possibly excluded from the Directive? Should certain workers or sectors be put outside the scope of the Directive? The trade unions are clear on all these questions: all throughout the debate, they have resolutely insisted that all the workers concerned should be covered.

It is important to note that when examining the proposal for a Directive, the Council did not set an exposure limit (maximum value) for static fields but only an action value (which requires the employer to take preventive measures or measurements). The Council also rejected the call from the European Coordination Committee of the Radiological and Electromedical Industries and some Member States to exclude MRI equipment from the Directive. Furthermore, the electrical equipment manufacturing industry wrote to Commission President Prodi in 2002 calling for the Commission to base itself on the ICNIRP recommendations rather than the ALARA ("As Low As Reasonably Achievable") principle under which all exposures must be kept at the lowest level reasonably achievable in light of economic and social factors.

Following the adoption of the Directive in 2004, the Commission took two initiatives: it mandated CENELEC - the European standardization body tasked with working out technical standards in electrotechnical matters - to draw up harmonized standards for assessing, measuring and calculating workers' exposure to electromagnetic fields in the 0 Hz to 300 GHz range. This mandate was based not on the Directive that was meant to ensure the protection of workers, but on one governing the harmonization of technical standards for goods (Directive 98/34/CE).

3. " Guidelines for Limiting Exposure to Time-Varying Electric, Magnetic, and Electromagnetic Fields (up to 300 GHz)" , *Health Physics* 1998, 74, 4, p. 494-522.

4. *BioInitiative Report: A Rationale for a Biologically-based Public Exposure Standard for Electromagnetic Fields (ELF and RF)*, <<http://www.bioinitiative.org>>.

So, not only is there no clear legal link between the mandate and the Directive, but also the Directive lays down no technical principles on which for the standards developers to base their work. For example, it does not explain how measurement uncertainties should be factored into the risk assessment procedure.

Additionally, the mandate fails to clarify the respective roles of two possible approaches: one based on the worker exposure assessment to be done by the employer, the other on an assessment of emissions by equipment covered by "internal market" Directives, to be done by the manufacturer or his representative.

The Commission's other initiative is the proposal to have a good practice guide written by a consultant supported by a tripartite working group of the Advisory Committee on Safety and Health at Work, comprised of government, trade union and employer organization representatives. A draft guide has been produced, but cannot be finalized due to trans-

5. *Comments concerning possible MRI restrictions due to the implementation of a EU directive 2007*, Gezondheidsraad, 17.

6. Hill, D, Mcleisch, K, Keevil, S 2005, " Impact of electromagnetic field Exposure Limits in Europe – Is the Future of Interventional MRI Safe?", *Acad Radiol*; 12, p. 1135-1142.

position being postponed and uncertainties about the ultimate content of the Directive.

The crucial role of two States

In hindsight, it is clear that two countries played a key role in the debate which followed the Directive's adoption, resulting in postponement of its transposition and the announcement of its amendment. In both countries, the concerns voiced by medical radiologists as job-specific users of ionizing or non-ionizing radiation sources, were eventually taken up by the public authorities.

In the Netherlands, the Health Council sent the relevant minister an opinion and suggestions for addressing medical community concerns about the possible impacts of transposing the Directive on the use of MRI as a diagnostic tool⁵. The Council's opinion calls among other things for a revision of the Directive's exposure limits, and changes to the method of calculating exposure. It argues that implementing the Directive in practice could restrict the use of MRI.

In the United Kingdom, the first shot across the Directive's bows came with the publication in the September 2005 issue of *Academic Radiology*⁶ of an article on the possible impact of exposure limits on surgical MRI procedures. The authors take issue with the ICNIRP's approach to defining exposure limits for low frequency fields and say that the Directive needs revising as it may prevent anaesthetists and nursing staff from getting close to patients during imaging. The authors argue that the Directive would effectively promote the use of competing CT scan techniques when the health effects of ionizing radiation are known – such equipment exposes patients to sweeping x-ray beams.

Off the back of this, professors of radiology and doctors, including a winner of the Nobel Prize for medicine, wrote an open letter to the Secretary of State for Health calling for changes to the Directive's wording, and cautioning the UK authorities about the Directive's "unwanted side-effects": reducing the value of National Health Service (NHS) investment, and damaging the magnet industry, where the letter-writers say that the UK is the world leader.

In November the same year, the Parliamentary Select Committee on Science and Technology decided to inquire into how government obtains and uses scientific opinions in its policy actions. The report, published in June

The effects of waves on humans

According to the ICNIRP, the main described effects that result from interactions with electromagnetic fields are:

- direct effects resulting from direct interaction of fields with the body;
- indirect effects involving interactions between a field, an intermediate object and a body.

The direct and indirect effects depend on the frequency ranges involved taking into account in particular static field effects (non-time-varying). They cause cutaneous reactions, changes in cardiac function, nausea, vertigo and sensations of flashing lights. For direct effects, two frequency ranges are considered.

Low frequency fields (below 100 kHz)

The standards take into account the effects of induced currents* which can have extreme effects of fibrillation (abnormal activity of muscle fibres). Visual and nervous system effects are observed at lower current densities. The debates are focused on the carcinogenic effects of these fields. In 2002, the International Agency for Research on Cancer classified these fields in Group 2B - "Possibly carcinogenic

to humans" - on the basis of data showing an increased risk of leukaemia for children exposed near to high voltage power lines.

High frequency fields (above 100 kHz)

The main effect taken into account is hyperthermia - high frequency exposure can result in slight or severe burns. The indicator used to quantify this energy absorption in tissues is the SAR (specific energy absorption rate). Auditory effects and electromagnetic hypersensitivity are also described.

Additionally, indirect effects in all frequency ranges are the risk of explosion or fire triggered by electric arcing, and electronic systems being initiated.

The effects in the low frequency range are due to contact currents produced when a body and metal objects come into contact. The effects can be varied: touch perceptions, difficulty in breathing, painful shock, etc.

* Induced currents: when a body is placed in a time-varying electromagnetic field, a surface charge is induced on it, resulting in "induced" currents in the body. Current intensity increases with the body's electrical conductivity and the field intensity.

2006, found no justification for including MRI equipment in the scope of the Directive.

During this period, the UK's Health and Safety Executive (HSE) set up a roundtable with various concerned stakeholders to discuss implementation of the Directive in the United Kingdom. The meeting report shows that the participants called for the Directive to be amended by adopting an exemption for MRI equipment, and for the Commission and European Parliament to be lobbied on it. The HSE then launched a new study to be done by Professor Stuart Crozier of Queensland University (Australia) to assess existing electromagnetic fields around MRI equipment. The results were published in 2007⁷.

Back to the European level

Informed by these national debates, European industry and radiologists' organizations revived the discussion at European level.

In March 2006, the European Society for Magnetic Resonance together with other medical and radiology organizations had a meeting with EU Social Affairs Commissioner Vladimir Spidla, as a result of which the Commissioner agreed to launch a joint campaign with these organizations to measure the exposure of workers around MRI equipment similar to that launched some months earlier in the United Kingdom. They also agreed to look into the possibility of exemptions.

An Alliance for MRI was founded at the European Society of Radiology's (ESR) annual Congress in March 2007. Its supporters included the Vice-President of the European Socialist Party, Hannes Swoboda, and the European Federation of Neurological Associations (EFNA), which brings together European umbrella organisations of neurological patient advocacy groups and is heavily supported by the pharmaceutical industry. The Alliance called on the Commission to put up an amendment to the Directive "to ensure legal certainty for the continued use of MRI"⁸.

The Commission addressed these complaints by financing a study on the exposure of MRI unit workers in Nottingham, Louvain, Cologne and Strasbourg⁹.

On 7 May 2007, the EP's Social Affairs Committee held a give-and-take session on the Directive. Contributions were made by various MEPs who had signed up to the Alliance's call, but the only submission published to date is that of an ESR representative, Stephen Keevil, who also co-authored the article cited above published in *Academic Radiology* journal. He called for MRI equipment to be removed from the scope of the Directive on the grounds that the national recommendations and voluntary standards drawn up by manufacturers were enough to ensure patient and staff safety.

Around the same time, the ICNIRP put out to its member organizations a draft revision of its guidelines on exposure to static fields. This document substantially modifies

The ICNIRP, an influential voice

The International Commission on Non-Ionizing Radiation Protection (ICNIRP) is a private non-profit organization established in Germany with the aim of promoting the improved protection of humans and the environment from non-ionizing radiation. It claims to develop independent scientific criteria for protection.

The ICNIRP comprises a Main Commission composed of 13 members from 10 countries including 7 EU Member States. The Commission's members are elected by the Commission itself on proposals from the national member organizations of the International Radiation Protection Association (IRPA) and the members of the outgoing Commission. According to its website, the members receive no payment for their ICNIRP duties and cannot be employed by industry. No less significantly, the ICNIRP refuses to enter into contracts with industry.

In 1998, the ICNIRP published recommendations covering for the first time the entire frequency range up to 300 GHz, referred to by the Council Recommendation on the limitation of exposure of the general public (1999/519) and on which the Directive on the exposure of workers (2004/40) is also based. These recommendations propose different values for the public and workers.

In establishing exposure limits, the ICNIRP applies safety factors to take account of scientific uncertainties but not the ALARA principle. The implication is that it sees no scientific basis for considering that electromagnetic fields have long-term effects.

7. *Assessment of electromagnetic fields around magnetic resonance imaging (MRI) equipment* 2007, Health and Safety Executive (HSE).

8. European Society of Radiology press release, <<http://www.myesr.org>>.

9. Capstick, M, et al. *An investigation into occupational exposure to electromagnetic fields for personnel working with and around medical magnetic resonance imaging equipment* 2008, Project VT/2007/017, Foundation for Research on Information Technology in Society - IT²IS (Principle), Imperial College London, 4 April 2008.

the existing guidelines by proposing to raise certain exposure limits and, more especially, dropping the time-averaged value over a working day.

It is worth noting that in the document as finally adopted and published in 2009¹⁰, the threshold value of 2 teslas - which expresses the physical force exerted by magnetic fields on internal electrical charges - is maintained, but changes are made to exposures of the limbs and the time-averaged value over a working day is dropped. In 2004, the Council included neither threshold values nor limit values in the language of the Directive.

The ICNIRP's 2007 non-public proposals, the publication of the 'Crozier study' findings and the preliminary results of the study financed by the Commission were the final impetus that prompted the Commission's October 2007 proposal to shelve and amend the contents of the Directive. The proposal was rushed through as a matter of urgency, with no consultation of the social partners or the Advisory Committee for Safety and Health at Work, and unamended by the European Parliament.

The European Trade Union Confederation (ETUC) voiced its concerns, but no Member State took issue with the Commission's decision. The only institution to sound a critical note was the Economic and Social Committee which, while taking an overall positive view of the proposal, stressed that the Commission was sending out conflicting signals as to its legislative intentions. The Committee also considered that the Commission's reasons were somewhat one-sided, focusing on only a very small group of exposed workers (MRI equipment operators) and did not take account of the effect of postponing action on a much larger group of workers exposed to electromagnetic fields used in various economic sectors, like welding, electrolytic equipment, transmitter aerials, power installations *etc.*

The Council did not make clear why the need for urgency, but did sign up to the proposal's two objectives of postponing the transposition deadline and setting in motion a process of revision of the Directive. The Council's recitals state that "the time required to obtain and analyze (that) new information and to draw up and adopt a new proposal for

a Directive justifies the four-year postponement of the deadline".

The Council Decision is largely based on the Commission-funded study, whose findings are less-than wholly robust, not least due to the absence of detailed data from manufacturers on the design of the magnets and coils used in the equipment covered by the study.

Clearly, then, a consensus on all the health impacts of electromagnetic fields is not around the corner. But there is recognition from international and national authorities that electromagnetic fields have short-term effects that can damage workers' health and put them at serious risk. Is it acceptable for thousands of workers to be left exposed to electromagnetic fields unprotected by law for years to come?

The short answer is 'no'; especially as many Member States lack any regulations in this area. The adoption of preventive measures, knowledge and identification of sources, training for prevention policy officers and modifying work processes may be laborious things to go through, but they are vital if workers are to be properly protected. So precautionary action is needed without delay, and legislation must be brought in. It is also essential to promote research and technical innovations that incorporate protection for workers. ●

A consensus on all the health impacts of electromagnetic fields is not around the corner.

10. ICNIRP 2009, *Guidelines on Limits of Exposure to Static Magnetic Fields* are now published in *Health Physics*, 96, 4, p. 504-514.