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COMMISSION STAFF WORKING PAPER

IMPACT ASSESSMENT

Accompanying document to the

Proposal for a
DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

amending Directive 2004/40/EC on minimum health and safety requirements regarding the exposure of workers to the risks arising from physical agents (electromagnetic fields) (eighteenth individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC)

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Including changes after recommendations of the IA Board

18 February 2011

Lead DG: EMPL

Associated DGs: SG, LS, ENTR, INFSO, RTD, ENER, SANCO, MOVE, TRADE, MARKT, ENV

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1. PROCEDURAL ISSUES AND CONSULTATION OF INTERESTED PARTIES

1.1. Background and policy context

1.1.1. Policy context

This impact assessment addresses the question of protection of workers exposed to high levels of electromagnetic fields (EMF) during their work. This concern is part of the general EU policy cast in the Treaty on the Functioning of the European union of giving workers the appropriate health and safety protection against risks encountered during their professional activities. Consequently this document only deals with the (high) exposure of workers during their work and not with the (much lower) exposure encountered by the general public using cellular phone, living close to high power lines or passing through metal detectors at airports.

Workers can be exposed to electromagnetic fields in many sectors of activity: industrial processes such as electrolysis, welding, sealing, broadcasting, electricity generation, etc. or medical procedures such as medical Magnetic Resonance Imaging (MRI). The health consequences of overexposure can be of different kind depending upon the intensity and proximity of the sources on the one hand but also upon the characteristics of the electromagnetic radiation itself, e.g. its frequency or wavelength. The symptoms of acute effects are well defined. In the high frequency range (i.e. broadcasting, radars), severe burns may occur whilst in the low frequency range (i.e. welding, electricity production and distribution), induced currents can cause effects on the function of the central or peripheral nervous system and exposed persons can also experience vertigos, nausea, metallic taste feelings, magnetophosphenes (flashes in the eyes). In very rare cases, dramatic indirect safety effects have also to be deplored when strong magnets attract a ferromagnetic object and crash it on a person inadvertently staying between the magnet and the metallic object.

The issue of protecting workers exposed to EMF was already dealt with at EU level in 2004 with the adoption of directive 2004/40/EC[1] of the EP and the Council.

Very rapidly it appeared that the directive, and in particular the adopted binding exposure limit values, would create major implementation problems and would even impede some essential medical procedures and related research in cutting edge medical applications such as MRI.

The question became critical as the deadline for transposition of the directive by the Member States was getting closer. The Commission postponed the deadline for transposition[2] and decided to undertake a full review of the situation.

1.1.2. Scientific and technical context

In order to clarify the matter, some physics are required here: interactions with matter – from the nuclei of atoms to whole galaxies - are governed by different types of so-called fundamental forces where under gravity (attraction of masses) and electromagnetism (for electrically charged particles).

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[1] Directive 2004/40/EC of the European Parliament and of the Council of 29 April 2004 on the minimum health and safety requirements regarding the exposure of workers to the risks arising from physical agents (electromagnetic fields) (18th individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC). *OJ L 184, 24.5.2004, p. 1.*

[2] Deadline for transposition was 30/4/2008. This deadline was postponed by 4 years by Directive 2008/43/EC of 23 April 2008 (OJ L 94, 24.5.2008, P. 8-12)

The interaction forces of electrically charged particles with other charged particles in their vicinity is materialised by an attracting or repulsive force due to their presence (electric field) and an additional attractive or repulsive field when they are in movement (magnetic field). Each electromagnetic force is characterized by its intensity and its wavelength and related frequency. Both properties have a direct influence on the human body.

In the scientific literature, the non-ionising and ionizing radiation spectrum is divided as follows:

(1) from 0 Hertz to 300 billion Hertz (GHz), the scientists talk about electromagnetic fields and radiation (EMF). This is currently covered by Directive 2004/40/EC;

(2) from 300 GHz (1mm wavelength) to 300 Penta Hertz (1 nanometre wavelength), the scientists refer to the optical radiation domain: this includes the infrared radiation (heat), the visible radiation (light) and the Ultraviolet radiation. The optical domain is covered by Directive 2006/25/EC[3].

(3) From there onwards, we are entering the domain of the ionizing radiation: the frequencies are becoming even higher and the characterisation of each radiation is made by its wavelength only for ease of reference[4]. The radiation becomes sufficiently powerful that it can destructively disturb atomic bounds. Protection of workers and general public exposed to ionizing radiation fall under the scope of the so-called Euratom Treaty. Several directives have been adopted in this field in line with the latest scientific evidence. The directives in force for the ionising radiation domain are Directive 96/29/Euratom[5] (protection of general public and workers) and 97/43/Euratom[6] (specific to medical exposures).

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3 Directive 2006/25/EC of the European Parliament and of the Council of 5 April 2006 on the minimum health and safety requirements regarding the exposure of workers to risks arising from physical agents (artificial optical radiation) (19th individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC). *OJ L 114, 27.4.2006, p. 38.*

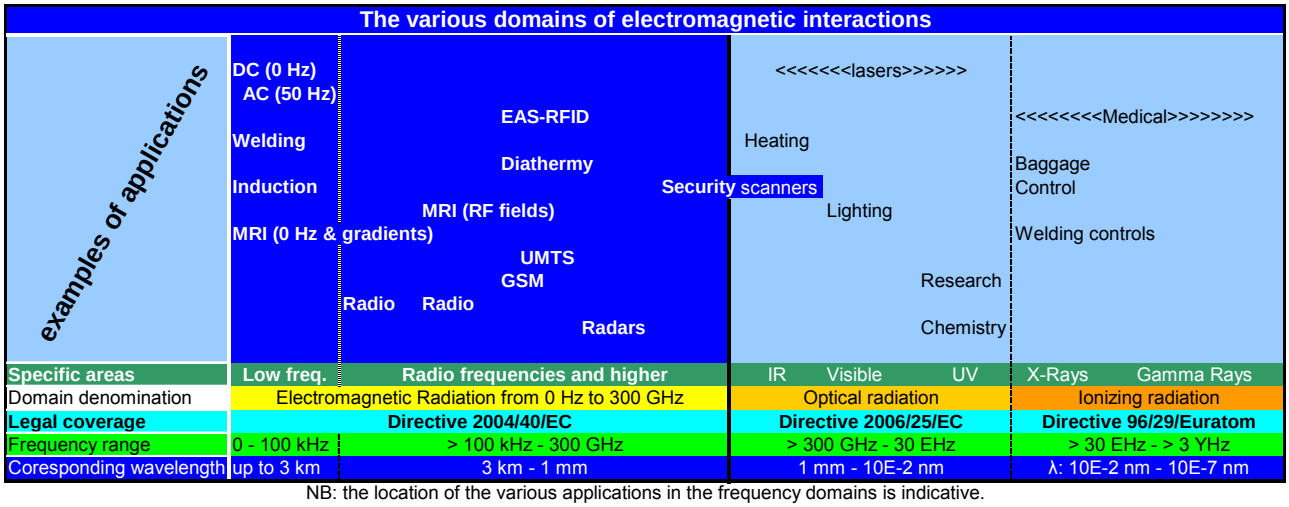
4 Frequency (f) and wavelength (λ) are linked by equation $\lambda.f = c$ where "c" is the speed of light in free space.

5 Council Directive 96/29/Euratom of 13 May 1996 laying down basic safety standards for the protection of the health of workers and the general public against the dangers arising from ionizing radiation. *OJ L 159, 29.6.1996, p. 1–114.*

6 Council Directive 97/43/Euratom of 30 June 1997 on health protection of individuals against the dangers of ionizing radiation in relation to medical exposure, and repealing Directive 84/466/Euratom. *OJ L 180, 9.7.1997, p. 22–27.*

These different types of radiation are represented in the figure 1 below. For EMF, i.e. for the frequency ranges from 0 to 300 GHz, this corresponds on the picture to the areas in dark blue called "*Low freq*." (Low frequencies) and "*Radio frequencies and higher*". The picture also shows some of the activities/equipments that are causing exposure to electromagnetic fields. A wide number of human activities such as transport, communications, broadcasting, industrial processes, medical applications, etc. are using or are affected by EMF.

Figure 1



NB: the location of the various applications in the frequency domains is indicative.

With 3 existing directives EU legislation covers the whole range of sources of radiation. Protection of EU workers will be ensured from 0 Hz to the infinite once directive 2004/40/EC is implemented in all Member States.

The directives have been established on the basis of internationally accepted principles and values. For ionizing radiation, the internationally accepted recommendations are established by ICRP, the International Commission for Radiation Protection[7] created in 1928. ICRP develops, maintains and elaborates the International System of Radiological Protection used worldwide and which has served as basis for directives 96/29/Euratom and 97/43/Euratom referred to in point 3 above. For non ionizing radiation (see points 1.and2. above), and in particular in the area of concern of this report, the internationally accepted recommendations are established by ICNIRP, the International Commission for Non Ionizing Radiation Protection, a daughter organization of ICRP. The members of the ICNIRP main commission and of the specialized working groups are selected for their notoriety in their domain. They are elected for a limited number of years. ICNIRP intends to work independently according to strict internal rules and the validity of their recommendations is checked during a consultation process before publication. [8]

The situation in the EU is - not very different from the situation in other countries. This is confirmed for ionizing radiation where sufficient evidence has demonstrated the need to adhere to binding limit values commonly accepted worldwide. This is also the case for optical radiation although third states often only refer to the international standards which are underlying the principles and limits of our directive.

[7] More details on www.icrp.org
[8] More details on www.icnirp.org

For EMF, the situation is less monolithic: outside the EU[9], some well developed states (including Japan, New Zealand, South Africa, etc.) are making reference to the ICNIRP recommended limit values, the so-called "*basic restrictions*" which have also been taken as reference when drafting Directive 2004/40/EC. Sometimes they do so only for a limited range of the EMF frequency domains, neglecting for instance frequencies below 3000 Hz. In Australia, whilst using the ICNIRP recommendations, some local peculiarities are being developed. In those countries, the values of ICNIRP are not binding or only partially binding probably because of implementation problems with the basic restriction levels suggested by ICNIRP. In the USA, values recommended by IEEE[10] apply. They are higher than the ICNIRP values in the low range of the spectrum – which actually avoids some compliance problems - but equivalent in the higher end (radiofrequencies). For long term effects most countries do not have any restrictions for workers' exposure because of the lack of clear evidence for the current levels of exposure[11].

1.1.3. Organisation and timing

In order to allow the Commission to explore new possibilities in the light of new scientific evidence and forthcoming technologies, the EP and the Council adopted a directive[12] amending directive 2004/40/EC and which postponed the transposition deadline by 4 years from April 2008 to April 2012.

Since then, the Commission has multiplied contacts and consultations with stakeholders. The two phases of the formal consultation of the Social Partners foreseen by Article 154 of the Treaty were also carried out (see results in 1.2.1 below).

An Impact Assessment Steering Group (ISSG) was put in place. This ISSG hold three meetings:

- the first meeting was held on 23 May 2009 with the purpose to inform the colleagues of other DGs on the problems with current directive 2004/40/EC and the consequences in administrative and legislative terms;

- the second meeting took place on 1st September 2009 with the purpose of keeping the colleagues up to date on the ongoing and future initiatives and to invite them to cooperate actively during the coming Inter Service Consultations linked to the launching of the first and second stages of the consultations of the social partners according to Articles 154 (2) and (3) of the TFEU;

- the third meeting took place on 14 July 2010 to discuss a first draft IA Report.

Upon completion of a consolidated draft the document was submitted to the Impact Assessment Board which made a number of comments and recommendations. Taking these into account the following main changes were introduced in the document:

a) a more comprehensive and concrete description of the new exposure limits system which is an integral part of Option B and C1 (section 4 and annex 3),

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9 Source: World Health Organisation (WHO).

10 IEEE: Institute of Electrical and Electronics Engineers; http://www.ieee.org/

11 SCENIHR opinions (2009) http://ec.europa.eu/health/archive/ph_risk/committees/04_scenihr/docs/scenihr_o_024.pdf and http://ec.europa.eu/health/archive/ph_risk/committees/04_scenihr/docs/scenihr_o_007.pdf

12 Directive 2008/46/EC of the European Parliament and of the Council of 23 April 2008 amending Directive 2004/40/EC on minimum health and safety requirements regarding the exposure of workers to the risks arising from physical agents (electromagnetic fields) (18th individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC). *OJ L 114, 26.4.2008, p. 88–89.*

b) a revision of the section relating to the analysis of impacts for each option (section 5),

c) a refocusing of the problem description and, consequently, an adjustment of the objectives,

d) a more transparent presentation of costs, with examples of variability for typical activities.

1.2. Consultation and expertise

1.2.1. Social partners' consultation

For legislative initiatives in the social policy field the Treaty foresees a two stage consultation of the Social Partners. The first one (Article 154 (2) of the TFEU) took place between 1 July and 10 September 2009.

The Commission received 16 replies to this consultation (12 from employers' organisations and 4 from workers' organisations). Most of the contributions were from European Organisations (10 employers; 3 workers); three replies were received from national organisations (2 from UK employers' organisations and one from a German trade union).

The different options where proposed in the form of 5 questions:

1 "Do you consider the current Directive 2004/40/EC sufficient for the health and safety of workers exposed to electromagnetic fields during their work?"

2 "Do you consider that a Community initiative is the best way to ensure a high standard of protection of workers exposed to electromagnetic fields?"

3 *"Do you think that certain categories of workers should be excluded from the scope of any future Community initiative because of reported implementation problems (e.g. medical procedures involving MRI) with some provisions (exposure limit values) of Directive 2004/40/EC?"*

4 *"Would you find non-binding measures such as the production of good practices guides, launching of regular information campaigns, setting-up of appropriate training programs, and drawing-up of voluntary agreement between the social partners of EU on sector level – useful, and for what purpose?"*

5 *"Should a possible future EU initiative cover the long term effects of workers' occupational exposure to electromagnetic fields?"*

The outcomes of the first consultation can be summarized as follows:

- In general, both trade unions and employers agreed that the current directive is not the ideal instrument and that there is a basic need for a new Community initiative to protect workers from electromagnetic fields. On the employer's side there were also some representatives (SMEs and national organisations) which indicated their preference for non-binding instruments instead of a directive.

- The real problem with directive 2004/40/EC was the series of exposure limit values which was seen as too restrictive. To define new exposure limit values seemed to be an acceptable approach

(except for the healthcare sector), provided that they are "practicable", "inspectable"[13], based on solid recent science and expressed in directly measurable units. If the orientation was to go for a revised directive, some attention should be paid to limit the administrative burden.

- It seemed commonly accepted that the limit values in the current directive might be set too low and based on too conservative assumptions; but while the employers were in favour of relaxing the limits, the workers representatives required to include the long term health effects in the future binding instrument.

- Exempting some categories of workers from the scope of the directive was not welcomed by the employers of the industry (except MRI equipment manufacturers). Also, allowing derogations to exposure limits to specific sectors (healthcare) posed some problems for the industry.

- Developing non binding instruments was welcomed by all contributors independent of a new directive.

A second stage of consultation of the Social Partners according to Article 154 (3) of the TFEU took place between 20 May and 5 July 2010. Following the rules for second stage consultations, 9 concrete areas for potential changes were proposed. These suggestions corresponded very much with the options analysed in this impact assessment with the exceptions that a "no change" option was not discussed as the social partners had already expressed their views on this in the first consultation. On the other hand, considering a "complete repeal of the directive" option was irrelevant in this specific context. 27 responses were received: 18 from employers' organizations (10 EU+2 international+1FR+5 UK), 2 from workers' organizations (1 EU+1 DE), 3 from national scientific institutes, 1 from a patients association, 3 experts' personal contributions). All responses were very constructive.

The results can be found in annex 1 and are summarized as follows for each of the 9 areas proposed for change:

Table 1

1	**Coverage of all sectors of activity**
	All stakeholders confirmed that no category of workers should be excluded from the benefits of a legal instrument provided that the instrument gives the appropriate flexibility to continue with activities.
2	**Due flexibility in a controlled working environment**
	To facilitate the continuation and development of activities the Commission proposes to introduce more proportionality. Employers are very much in favour of such approach. Workers' organizations feel that too much flexibility may significantly reduce the protection of the exposed workers if not strictly controlled.

[13] Practicable" and "inspectable": these words have been used by some stakeholders during the various contacts with them. "Practicable" needs to be understood in the sense that the requirements imposed by the directive must be simple to implement, with measurements methods adapted to the level of risk and techniques that can be easily explained to the workers. "Inspectable" means that the company safety managers or governmental labour inspectors must be able to verify most situations on the spot by making measurements or by using verification methods that give immediate and comparable results.

3	**Precise definitions**
	All social partners agreed that directive 2004/40/EC needed clarification of definitions. One of them is the definition and the understanding of the meaning of "adverse" or "acute" effects.
4	**Exposure limit values**
	a) In line with updated scientific recommendations, some relaxation of the "old" limits may be envisaged without reducing the protection of the workers in real terms. While the industry is strongly in favour of such relaxation, workers express some concerns, because they are afraid that new limits may be chosen to enable continuation of business without guarantee for the health of the workers. b) Social partners can agree with the "zoning" approach[14] proposed by the Commission to facilitate the carrying out of the compulsory risk assessment (imposed by framework directive 89/391/EEC).
5	**Measurements and calculations**
	The Commission's proposal is to introduce more guidance to facilitate the risk assessment process, in particular for SMEs. All social partners agree that this would facilitate measurements and calculations. From employers' side there is a request to limit measurements and calculation to those cases where it is really necessary.
6	**Guidance for risk assessments**
	With the same objective, the Commission's proposal is to introduce more guidance for the compulsory risk assessment. The idea is to give orientations to the employers so that the means to comply with the requirements are better adapted to the situation. The "zoning" system referred to for area 4 is related to this objective. At the end of the day, better guidance should limit the costs and burden and also ensure clarification in case of a court case. All social partners welcome more and better guidance to perform risk assessments in general and for exposure to EMF in particular.
7	**Medical surveillance**
	This issue was raised by the medical profession during the Umea conference. In the low frequency range, from 0 to 100 kHz it is very difficult to detect acute effects after the exposure itself. This is different for higher frequencies where the acute effects can be severe burns. Currently, the requirements of directive 2004/40/EC say that for any overexposure a medical examination must be offered to the worker concerned. Considering that there is sometimes a lack of symptoms or of detectable adverse effects after overexposure, the medical examination may not be justified in all cases. Workers and employers representatives are not on the same line on this issue but the idea of

[14] The "zoning" concept is already used by some Member States (e.g. The Netherlands) and has also been developed in the recent CENELEC standard EN50499. The idea is to create certain zones (layers) of risk (low, medium and high) corresponding to intensities of exposure to EMF and to associate to each zone some specific provisions for the carrying out of the risk assessment and for the implementation of preventive protective measures. More details about this in section 4 "Policy options", in particular, option B.

	revisiting the conditions for a medical examination is not controversial.
8	**The specific case of medical applications using nuclear magnetic resonance technology**
	5-8 % of the medical MRI procedures would not be possible, even with exposure limits aligned with the most recent proposals from leading agencies. The Commission proposal is to give an exemption from binding exposure limits to the MRI sector in order to enable the use and development of this technique for the benefit of the patients while compensating this by more stringent qualitative rules to ensure adequate protection of medical personnel. This causes some problems for the employers of the industry who consider this as discrimination. The workers organisations can agree to this approach but under the condition that this is limited in time. Innovative design of equipment should in future limit the risks of overexposure.
9	**Non binding measures**
	The social partners agreed that accompanying non binding measures such as raising awareness campaigns, multiplying training courses and producing good practice guides at national or sectoral levels would be helpful and necessary.
-	– **Final question: willingness of the Social Partners to enter into negotiations on the basis of the proposals above under the terms of Article 154(4) and Article 155 of the Treaty on the Functioning of the EU (TFEU).**
	None of the Social Partners requested to go for this sectoral approach.

1.2.2. External expertise

Next to the formal consultation of Social Partners the Commission gathered complementary information and expertise by:

- numerous contacts with representatives from the industry and their European (BUSINESSEUROPE, ORGALIME, CEEMET) and national federations EEF (UK), AGORIA (BE), with representatives of the SMEs (UEAPME, NORMAPME), with representatives of standardisation bodies (CENELEC). This enumeration is not exhaustive;

- contacts with the scientific community, in particular ICNIRP whose recommendations are used worldwide and served as a basis for the exposure limit values in directive 2004/40/EC; IEEE whose recommendations are used in the USA and by NATO[15]; DG SANCO's committee SCENIHR[16];

- for the specific case of MRI, regular contacts in dedicated working groups, one with representatives of ESR[17] (MRI practitioners) representing also ESMRMB[18] (MRI medical

[15] NATO: North Atlantic Treaty Organization; http://www.nato.int/

[16] SCENIHR: Scientific Committee on Emerging and Newly Identified health Risks; http://ec.europa.eu/health/scientific_committees/emerging/index_en.htm

[17] ESR: European Society of Radiology; http://www.myesr.org

[18] ESMRMB: European Society for Magnetic Resonance and Medical Biology; http://www.esmrmb.org/

research) and Alliance for MRI (MRI patients association) and a second one with representatives of COCIR[19] (MRI equipment manufacturers);

- regular contacts with the social partners and government representatives, formalised through a working party mandated by the Advisory Committee for Safety and Health at Work. This working party, initially created to supervise the preparation of a non binding good practice guide to directive 2004/40/EC saw its mandate expanded to assist the Commission in finding a solution for the medical activities and later for the whole range of affected sectors of activity. During the meetings of this working party scientists and experts were invited to express their views and to explain the latest technical and scientific developments and new recommendations, in particular from ICNIRP and IEEE. WHO and NATO experts were also invited and consulted.

In 2007, DG EMPL selected a contractor to carry out a comprehensive investigation into occupational exposure of workers performing medical MRI. This study[20] which was done in cooperation of ESR (selection of and facilitation of access to representative MRI facilities and selection of worst case scenario procedures) took place from July 2007 to April 2008 and enabled to identify and quantify the problem areas.

Between January and September 2009 a study[21] (in the following called "preparatory study" or "FICETTI study") was carried out by a consortium[22] to provide the European Commission with detailed analysis of the potential health, social and economic impacts of a number of policy options. The study also took into account the input from various stakeholders such as representatives of different sectors, universities, research centres, trade unions and military as well as from the discussions of the employers', workers' and governmental representatives in the EMF Working Part of the Advisory Committee on Health and Safety at Work.

In October 2009, the Swedish Presidency organised a 3 day conference[23] on occupational exposure to EMF. During this conference a new approach for limiting exposure of workers was presented by the German Ministry for Employment and Labour (BMAS).

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19 COCIR: European Coordination Committee of the Radiological, Electromedical and Healthcare IT Industry; http://www.cocir.org/

20 Project VT/2007/017: "An Investigation into Occupational Exposure to Electromagnetic Fields for Personnel Working With and Around Medical Magnetic Resonance Imaging Equipment"; final report 4 April 2008.

21 Contract VC/2008/0692 for the "Analysis of health, socio-economic and environmental impacts in connection with possible amendments to Directive 2004/40/EC of the European Parliament and of the Council of 29 April 2004 on the minimum health and safety requirements regarding the exposure of workers to risks arising from physical agents (electromagnetic fields)". Final report: September 2009.

22 "FICETTI Consortium": Main Contractor: Finnish institute of Occupational Health; Subcontractors: The Slovenian Institute of Non-Ionizing radiation (INIS), Central Institute for Labour Protection – National Research Institute (CIOP-PIB, Poland), EMFields Ltd (UK), TRaC-KTL (UK), The National Institute of Occupational Safety and Prevention (ISPESL, Italy), The University of Modena and Reggio Emilia (Italy), The University of Umea (Sweden).

23 Occupational Exposure to Electromagnetic Fields: Paving the way for a future EU initiative; 6-8 October 2009, Umeå University, Sweden.

2. PROBLEM DEFINITION

2.1. What is the problem?

As laid out in the introduction, the issue under discussion is the protection of workers exposed to strong electromagnetic fields. Amongst devices which are producing non-ionizing radiation and are most commonly used in the professional side, one can mention, *inter alia*, induction heating installations, electroplaters, welding devices, crack detection equipment, plasma etchers, radio frequency sputterers and also the equipment used for medical MRI, diathermia and hyperthermia. Amongst particularly affected sectors are the electrolysis, the induction heating, the welding, the broadcasting, the electricity production and distribution and the telecoms sectors. Such radiation appears whenever there are heavy electric currents and/or very strong magnets at or close to the workplace.

Uncertainty still exists in the international community for some parts of the spectrum regarding occupational EMF exposure. Additional research may in the medium term give most precise answers. No biological mechanisms could be validated until now. However, adverse effects on health have been demonstrated when exposure exceeds certain levels. Depending where one puts the reference levels, adverse effects may be disturbing, irritating, painful or really harmful for the worker.

2.2. Who is affected and how?

Many categories of workers may be subject to exposure to electromagnetic fields, for instance:

- Those maintaining antennae, for example in broadcasting, navigation and telecommunications;
- Those working with electricity generation and distribution;
- Those working with dielectric and induction heating systems;
- Those working with resistance welders;
- Drivers of electric locomotives;
- Those involved in electro-chemical processing;
- Those using diathermy, hypothermia and magnetic resonance equipment, for example in health services;
- Those using tape erasing equipment to erase data stored on tapes and other magnetic media;
- Those using crack detection equipment for the non-destructive testing of metallic components;
- Those using plasma etchers in semi-conductor business;
- Those using RF sputterers[24] to apply coatings to components used in a variety of industries;

[24] Sputter deposition is a physical vapor deposition (PVD) method of depositing thin films by sputtering, that is ejecting, material from a "target" which then deposits on a substrate (Wikipedia).

- Those working with Electronic Article Surveillance (EAS) equipment used to prevent theft from shops, libraries etc.

The list above is **not** exhaustive but gives an idea of the variety of sectors of activities concerned by the issue[25]. It is difficult to estimate the number of workers in each of the listed categories. Overall, according to data from the stakeholders, more than 1,500,000 workers (self-employed excluded) in more than 200,000 workplaces are concerned in the EU (table 2).

Table 2

Sector	**Workers**	**Workplaces/assessments**
Electric energy	200,000	3,000
Health care	211,000	13,000
Metal industry	1,019,000	162,140
Telecoms & broadcast	39,500	11,000
Rail	120,000	500
Other	50,000	25,000
Total	1,639,500	214,640

Source: stakeholders' information

Workers of both the medical sector and the industry can be exposed at much higher levels than those defined for the general public. The general public has normally no access to areas where high exposure levels occur. Even the levels produced by antennas (for GSMs and others) and for which the media and some citizens' associations express concerns are far below the levels this report is referring to.

Workers can be affected in different ways and the consequences for health can take different forms depending namely on the characteristics of the exposure:

- Static fields, low frequency fields or high frequency fields, pulsed or sinusoidal (frequency and type of wave factors)

- High or low intensities (power factor)

- Long or short exposure times (time factor). This factor will however not be considered here as science currently confirms the situation prevalent in 2004, i.e. that there is no evidence yet of adverse effects from long term exposure of EMF under the levels considered for short term effects

When dealing with static fields, the main health effects derive from the movements of the body in the field. The movements of the body in the (strong) static field induce an effect materialised by

[25] A more detailed list has been established by the National Radiological Protection Board (UK): NRPB R265 and NRPB-W24.

electrical currents in the body. At certain levels these effects may become harmful. At very high levels there will be an impact on the blood circulation. This effect does not seem to be significant with the currently used static fields. Other effects have been reported when in presence of heavy static fields: vertigos, metallic taste, headaches.

Another (safety) effect linked to the presence of strong static magnetic fields is the attraction power of any ferromagnetic object inadvertently introduced in the vicinity of the source. We are referring here to static magnetic fields such as those used for MRI which are around 100,000 times stronger than the natural earth magnetic field[26]. As a matter of example, if a person enters the room where MRI equipment is operational with a scissor in the hand, the latter will be attracted away and immediately fly like a bullet into the core of the magnet. If a patient is present in the machine or a worker close to the machine at that moment, the consequences will be a severe injury or even fatal.

In the low frequency range above 0 Hz up to 100 kHz the main effect is peripheral and/or central nerve stimulation (PNS, CNS). Muscles are subject to unexpected stimulation which can give annoying feelings at low levels and unintended movements of the limbs at higher levels. The produced effect can be painful. The effect disappears when the cause of the effect (the low frequency field) disappears. Some undesirable effects on the eyes are also reported in the very low frequency range around 20 Hz. They are called magnetophosphenes and can obviously reduce worker's attention.

In the frequencies higher than 100 kHz, the main effect of radiation is burns, internal or external. This effect is much more tangible than the previous ones and even short periods of exposure can lead to injuries which will require a long recovery period.

All these effects are reported by scientists and cannot be rejected as they are proven by the numerous *in vitro, in vivo* and epidemiological studies. A number of the most recent ones been taken into account by ICNIRP, IEEE and BMAs to establish their mot recent recommendations. As a matter of example, in its latest publication "Guidelines for limiting exposures to time-varying electric and magnetic fields (1 Hz to 100kHz)" put on line in November 2010, ICNIRP indicates 53 references wherefrom some 20 are new studies on effects of EMF on living cells or animals carried out over the last 10 years. The other references relate to former guidance but also to publications relating to modelling and literature review on the subject. In the BMAs approach referred to in section 1.2.2., and explained in the "Forschungsbericht 400: Elektromagnetische Felder am Arbeitsplatz" – Abschlussbericht (March 2010), 110 references are used and the number of new studies is similar. Unfortunately, reports on real cases are very scarce.

Table 3 below shows the possible health effects and the associated frequency range(s) that can be encountered in a variety of professional activities.

Table 3

Frequency range	Related activities	Potential Health problems
0 Hz	Magnetic resonance technology Lifting cranes Electrochemical processes	Safety problems: uncontrolled attraction of ferromagnetic metals Health problems: vertigos,

[26] Order of magnitude of the terrestrial magnetic field strength: 50 microTesla (0.5 Gauss).

		metallic taste feeling, headaches
50 Hz	High power lines; Production and distribution of electricity; Welding	Headaches, magnetophosphenes, Unwanted effects on the peripheral nervous system
100 Hz -10,000 kHz	Magnetic resonance technology (gradient fields)	
9 kHz -	Electric welding	Effects on the nervous system
30 kHz -	Industrial induction heating	
300 kHz -	AM-radio Industrial induction heating	
3 MHz -	AM-radio Plastic welding Dielectric pressing Induction hardening FM-radio Wood processing	Burns Thermal stress
300 MHz -	TV Diathermia GSM Dielectric vulcanizing	
3 GHz -	Anti-Theft protection systems Radars Satellites (communication with)	Burns and thermal stress
30 GHz -	Transmission of digital and analogue video signals	

Source: AGORIA (BE) good practice guide

2.3. The underlying drivers of the problem

As indicated in section 2.2., recent research[27] indicates that Directive 2004/40/EC is stricter than necessary in the sense that there is no room for flexibility or proportionality. Since the publication of the recommendations of the International Commission for Non-Ionizing Radiation (ICNIRP) published in 1998, on which the European directive is based, new scientific data have become available on the effects of low-frequency fields. These data suggest that some of the current exposure limits could be too low, too conservative and too difficult to use in practice. Raising the exposure limit values or – at least – expressing them in more practical terms and enabling higher working boundaries (the former "*action value*" of Directive 2004/40/CE) thanks to recent scientific evidence would allow many applications to be used without exaggerated compliance costs whilst still guaranteeing appropriate protection of workers exposed to EMF. This may still leave a limited number of significant applications with major compliance problems but – at least – smarter case handling would be achieved when confronted to EMF emitting source.

As pointed out in section 1.1.1 "Policy Context", 5-8% of the medical MRI procedures will not be possible without rising the exposure limits above the levels suggested by the new BMAS or ICNIRP values. These procedures would become illegal. This is undesirable, because the use of MRI has many advantages for patients: the technique enables diagnostic of diseases as never before, it enables interventional surgery without the use of x-rays and almost every week new applications are developed in the benefit of the patients.

On the other hand, safety and health of medical personal also need to be ensured.

2.4. State of implementation of the legal framework

According to the latest reported information, none of the EU Member States has already completed the transposition of directive 2004/40/EC, currently due for 30 April 2012. Several countries (FI, AT, UK, CZ …) informally indicated their intention to introduce some flexibility to ensure proper use of MRI techniques although this flexibility is not permitted by directive 2004/40/EC. Other countries are currently relying on existing non binding rules (including the ICNIRP recommendations) as practical reference. All Member States are waiting for clarification and for a new initiative from the Commission.

Information of the existing legal framework in the Member States can be found in Annex 2. The overall situation can be captured as follows:

Table 4

Countries with specific legislation covering exposure of workers to EMF in place before Directive 2004/40/EC	AT, BG, CZ, DE, EE, FI, LV, LT, LU, NL, PL, PT, SE, SK, SP
Countries without specific legislation in place	BE, CY, DK, FR, GR, HU, IR, IT, MT, RO, SI, UK

[27] Forschungsbericht 400: Elektromagnetische Felder am Arbeitsplatz – Abschlussbericht, ISSN 0174-4992, März 2010 (BMAS report). ICNIRP Guidelines: Guidelines for limiting exposure to time-varying electric and magnetic fields (1 Hz to 100 kHz): to be published in December 2010.

Countries having issued (additional) non binding recommendations	AT, IT, PL, UK
Countries for which the Commission already received a notification of new national legislation transposing Directive 2004/40/EC	AT, EE, LV, LT, IT, CZ, SK (all have delayed the entry into force until 30/04/2012)

The outcome of the review carried out by the FICETTI contractor shows:

- that all Member States rely on ICNIRP guidelines.
- that Member States do not make differences between sectors but between frequency ranges. The radiofrequency range is often considered in detail and the low frequency range is rather neglected. No exemptions are foreseen by sector or size of enterprises with the notable exception of MRI.
- that Member States have paid more attention on the protection of the general public by issuing recommendations or binding legislation based on Council Recommendation 1999/519/EEC which also relies on the ICNIRP 1998 guidelines.

These statements are also confirmed by the data sent by Member States and third states to the database of WHO[28]. Whilst most states are considering exposure to EMF as a hazard, there is a large variety of legal solutions, the large majority of them relying on the ICNIRP guidance.

2.5. How would the problem evolve, all things being equal?

If everything remains as it is, all 27 Member States will have to transpose the provisions of Directive 2004/40/EC by 30 April 2012. This would annihilate the efforts made by the Commission to find solutions for the announced implementation problems and would not be the outcome expected by the governments, the social partners and most stakeholders.

2.6. Right to act and subsidiarity

Social policy belongs to the shared competences between the EU and the Member States for the aspects specified in the Treaty. In Article 153 1.a of the *TFEU*[29], *improvement of the working environment to protect workers' health and safety* is specifically mentioned.

Subsequent Article 153.2 says:

"To this end, the Council and the European Parliament:
…(b) may adopt, in the fields referred to in paragraph 1(a) to (i), by means of directives, minimum requirements for gradual implementation, having regard to the conditions and technical rules obtaining in each of the Member States. Such directives shall avoid imposing administrative, financial and legal constraints in a way which would hold back the creation and development of small and medium-sized undertakings."

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28 http://www.who.int/docstore/peh-emf/EMFStandards/who-0102/Europe/europe5.htm

29 see the glossary

In this framework, a number of directives (19) have been adopted since 1989. The first one was Council Directive 89/291/EEC of 12 June 1989 on the introduction of measures to encourage improvements in the safety and health of workers at work[30]. This directive is usually referred to as the "Framework directive".

Amongst the subsequent individual directives dealing with specific risks, one may find directives on the protection of workers exposed to: noise, vibration, chemical agents, biological agents, asbestos, manual handling of loads, etc.

On adoption of Directive 2004/40/EC, the Commission, Parliament and Council were of the opinion that Community action was the best way to protect workers from risks arising from occupational exposure to electromagnetic fields. At the time, the co-legislators justified the action at EU level (recital N° 4 of directive 2004/40/EC) by the intention *"to ensure the health and safety of each worker on an individual basis, but also to create a minimum basis of protection for all Community workers, in order to avoid possible distortions of competition"*.

Currently the Commission does not see any new evidence to go into the opposite of the direction chosen by the Parliament and Council in 2004. The need to protect workers remains essential. Considering the situation pointed out under point 2.5 and the need for a review recognized by all parties, it appears that the Commission must act, using it right of initiative.

[30] OJ L 183, 29.6.1989, p. 1.

3. OBJECTIVES

3.1. General, specific and operational objectives

The general objective remains the protection of workers during their professional activities by maintaining and further improving existing levels of protection of both the health and the safety of the workers. As indicated above there is a comprehensive corpus of binding instruments on the EU level put in place to meet this objective.

Exposure of workers to electromagnetic fields is a complex risk. Consequently, as a specific objective, there is a need to define more specific measures to ensure adequate protection of workers exposed and to present the most appropriate solution to protect them without unduly impeding on the use and development of industrial activities and medical techniques (as the current instrument directive 2004/40/EC does) and without imposing disproportionate burden on enterprises, in particular SMEs.

Consequently because of these somewhat conflicting aims the operational objective is to ensure the effectiveness of the protection of workers exposed to EMF. The outcome should be clear, coherent and easy to understand to help increase consistency of implementation.

3.2. Consistency of the objectives with other EU policies and horizontal objectives

These objectives are consistent with the current Europe 2020 Strategy and the Community Strategy for Safety and Health at Work 2007 – 2012 for improving quality and productivity at work (COM(2007)62).

Taking account of the above, and the latest scientific evidence on the subject reassessing the situation is fully justified. DG SANCO is reviewing the situation on a regular basis – lastly in January 2009 - through SCENIHR (see 1.2.2) and the fact that the international leading authorities in the matter are reviewing their recommendations is consistent with this approach.

4. POLICY OPTIONS

4.1. Policy options analysed in detail

The outcomes of the first consultation document for the Social Partners and the supporting work carried out by an external contractor have suggested to operate around an initial set of 7 broad options. This spectrum of options was also supported by stakeholders. Consequently all of them are considered in this impact assessment. Nevertheless, during the stakeholder consultation and the further work undertaken, the options have been refined and some elements have changed.

4.1.1. ***Policy option A:*** *"Do nothing"*

In practical terms this means that Directive 2004/40/EC has to be transposed by 30 April 2012 into legislation in all the Member States. The existing controversial exposure limits become binding limits. To achieve compliance employers will be required to take actions based on workplace risk assessments and in the context of rules considered to be too conservative.

Directive 2004/40/EC foresees that an employer must carry out a (compulsory) risk assessment whenever workers are likely to work with or in the neighbourhood of EMF producing sources. The employer is supposed to compare the real level of exposure at a workplace with a reference level[31], which is directly measurable with an appropriate device: for the electric field the strength is measured in volt per meter and, for the magnetic field, the field strength is measured in ampere per meter (field strength) or in Tesla (magnetic flux density). If the actual exposure is lower than the *action value**, everything is fine: the protective measures in place are appropriate and the assessment process can stop here. If the measured value exceeds the *action value*, a more complex evaluation has to take place to check whether the effect induced in the body of the worker does not exceed a certain level, the *exposure limit value* itself. The main problem with the exposure limit values (ELVs) is that they are not expressed in directly measurable entities and therefore require some modelling and calculations. If after this comparison exercise, the exposure of the worker is likely to exceed the ELV, revised protection measures have to be put in place.

* see the glossary

4.1.2. ***Policy option B:*** *"New Directive with revised exposure limits"*

In this option, the existing exposure limit values of the 2004/40/EC Directive are replaced with new, more practicable, exposure limit values based on latest international recommendations. This revision of limit values has become possible as research has shown that the safety factors between observable physiological reactions and recommended exposure limits can be reduced.

The recommendations on which the new requirements could be based are a) the new guidelines for static magnetic fields and for the extremely low frequency (ELF) range published by ICNIRP during the last quarter of 2010[32], b) the "IEEE Standard for Safety Levels with Respect to Human Exposure to Radio Frequency Electromagnetic Fields, 3 kHz to 300 GHz (C95.1)" and "IEEE Standard for Safety Levels with Respect to Human Exposure to Electromagnetic Fields, 0–3 kHz (C95.6)" and c) the new BMAS proposal referred to in 1.2.2. (last paragraph) and 2.3. For the concrete development of the new system a combination of ICNIRP and BMAs will be used. The

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[31] In Directive 2004/40/EC, this reference level is called the "*action value*".

[32] The new recommendations were officially released on www.icnirp.org on 25 November 2010.

new reference levels would thereby be set at a higher level than the one defined in Directive 2004/40/EC *(action value)* for the frequency range 0 – 100 kHz. This will facilitate compliance for most activities producing or using EMF in that range. The limits will however not be high enough to accommodate all concerns in industry nor those for MRI.

The choice was made not to take the IEEE system which is only used in the USA and partially in Canada. The new system follows mainly the new ICNIRP recommendations recognized worldwide and used as the reference of their protection system by more than 40 well developed states worldwide. However it is supplemented by elements of the system proposed by BMAS in order to introduce the necessary flexibility and proportionality in the low frequency range where most of the implementation problems are.

The most significant characteristics of this new system can be found in annex 3. They concern the low frequency range. For the high frequency range the reference levels and exposure limits remain unchanged.

4.1.3. ***Policy option C1:*** *"New Directive with revised exposure limits and partial exemptions"*

This option is to a large extent identical to option B: New exposure limit values based on the latest international recommendations are introduced. However, conditional exemptions will be foreseen for medical MRI; these activities will be exempted from the requirement to comply with the exposure limit values of the new Directive, but will still remain subject to the other provisions, including EMF risk management requirements. Employers shall put in place protective measures to prevent direct or indirect health risks from EMF for workers. Indirect risks, being e.g. risks from ferromagnetic projectiles or interference with implanted medical devices.

This option implies a differential treatment of the MRI workers. This has advantages in terms of facilitating technological progress (e.g. medical devices), economic development and of enabling high quality health care (MRI); but it has also the disadvantage to restrict the evaluation of the situation to qualitative aspects only.

When drafting this document, the only sector that was deemed to be given an exemption was the medical MRI sector (operation, cleaning, maintenance and R&D activities). All other activities, including medical diathermia, were expected to fall in zone 2 of the new system (see annex 3). In case other (e.g. newly emerging) activities would conflict with the revised limit values it would be possible for the Member States to allow for exemptions from the limit values under strictly controlled conditions. Such exemptions would need to be notified to the Commission.

No limitation in time of the exemption is foreseen. For such limitation, provisions to reduce the strength of the static magnetic field or to overcome the high intensity of the gradient and stray fields need to be introduced. This can only be done by amending the "medical devices" directive. This is not the scope of the Directive.

In order to ensure the effectiveness of the protection of workers in the MRI domain, reinforced qualitative measures will be addressed in an annex of the new directive. The proposed measures which were already included in the second stage consultation document adopted by the Commission in July 2010 are:

– reinforced information measures;

– reinforced training of workers;

– documented and practicable working procedures favouring exposure limitation whenever possible;

– strict administrative procedures for access to MR rooms;

– consultation of personnel on improvements;

– monitoring[33].

It is intended to involve employers, manufacturers, practitioners and health care personnel under the auspices of the Advisory Committee for Safety and Health at Work. The organisation of these consultations would be streamlined in the directive itself (scope, implementation, monitoring and deadlines).

4.1.4. ***Policy option C2:*** *"New Directive with revised exposure limits and complete exemptions for some activities"*

New exposure limit values based on the latest international recommendations are introduced (same as option B). Some sectors/activities (medical MRI) will be exempted entirely from all the requirements of the EMF Directive on the basis that their operation is not, and will probably never be, compatible with its requirements.

This option excludes some categories of workers (those working in the medical MRI area) completely from the scope and benefits of a directive and conflicts with an essential requirement of the Framework Directive which is laid down in Article 2.1: *"This Directive shall apply to all sectors of activity,…."*. So far exceptions to that principle are very rare and specific (e. g. firemen during the combating of a fire).

4.1.5. ***Policy option D1:*** *"Replacement of the Directive by a Recommendation"*

The current EMF Directive is replaced by non-binding occupational EMF exposure recommendations, based on the latest international recommendations. The form of these recommendations would be similar to the 1999 Council Recommendation on EMF exposures of the general public.

4.1.6. ***Policy option D2:*** *"Voluntary social partners' agreements"*

The EMF Directive is replaced by a set of voluntary agreements at European or sectoral level between social partners according to the provisions of Article 154.4 of the TFEU. This possibility has not been invoked by any of the social partners participating in the consultations referred to under section 1.2.1.

4.1.7. ***Policy option E:*** *"no EU legislation"*

Directive 2004/40/EC is withdrawn (repealed) while directive 89/391/EEC (Framework Directive) and existing national regulatory provisions on the subject remain in force. Absence of national regulations in some Member States will allow unregulated occupational EMF exposures which may cause increased risk, lowering of equality, etc. For this option, it will be assumed that countries

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[33] A good example for such an approach can be found in a document already developed in The Netherlands. Its preparation required close cooperation between hospitals (employers), practitioners and the medical personnel (workers), under supervision of the competent ministries. The booklet "Using MRI safely: Practical Rules for Employees" can be downloaded from: http://docs.minszw.nl/pdf/92/2008/92_2008_1_22102.pdf

which have already (partially) implemented the EMF Directive would not repeal their EMF legislation.

4.2. Options discarded from further analysis

Alternative options which have not been analysed in detail are: turning to a more sectoral approach, restricting legislation to the provision of safe equipment or an exclusive focus on 'soft' policy instruments such as information campaigns and guidance documents.

A sectoral approach was deemed insufficient as the current legislative corpus at EU level, based on Framework directive 89/391/EEC, addresses risks by covering all categories of workers. There are very few exceptions such as mining and drilling activities and for which the specific risks have been addressed in a specific manner in separate directives. A cross-sectoral approach is justified because the risks for worker's health are linked to the level of exposure per se – irrespective of where it happens.

The provision of safe equipment as required in the low Voltage, the Medical Devices, the Machinery and the Product directives is an important instrument to ensure safety at the working place. Nevertheless, whilst recognizing that these directives are essential tools to protect workers, their provisions are not sufficiently comprehensive to ensure the protection at the workplace. This has been often demonstrated in the past: for instance Directive 94/9/EC of the European Parliament and the Council of 23 March 1994 on the approximation of the laws of the Member States concerning equipment and protective systems intended for use in potentially explosive atmospheres[34] was complemented by Directive 1999/92/EC of the European Parliament and of the Council of 16 December 1999 on minimum requirements for improving the safety and health protection of workers potentially at risk from explosive atmospheres (15th individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC)[35]. In the case of personal protective equipment, Council Directive 89/656/EEC of 30 November 1989 on the minimum health and safety requirements for the use by workers of personal protective equipment at the workplace (third individual directive within the meaning of Article 16 (1) of Directive 89/391/EEC)[36] was immediately followed by Council Directive 89/686/EEC of 21 December 1989 on the approximation of the laws of the Member States relating to personal protective equipment[37].

Information campaigns and guidance tools are seen as important instruments and further efforts of this type will happen whatever option will be chosen. In so far it was not looked at separately.

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34 OJ L 100 of 19.04.1994, p.1
35 OJ L 23, 28.1.2000, p. 57–64
36 OJ L 393, 30.12.1989, p. 18–28
37 OJ L 399, 30.12.1989, p. 18–38

5. ANALYSIS OF IMPACTS

5.1. Starting point for the analysis of impacts

The following sections attempt to identify and analyse the potential social and economic impacts and their importance for each option. As regards social impacts a special attention is given to the impacts on workers' health as they are directly linked to the objectives of the initiative. The economic impacts considered in the analysis are mainly compliance costs and potential impacts on competitiveness.

Wherever possible an attempt has been made to quantify the impacts of the various policy options. Where data could not be obtained or is uncertain, the analysis of the policy options is more qualitative in line with the principle of a proportionate level of analysis.

Discussions with experts and stakeholders indicated that environmental impacts are not likely. Per definition exposure to electromagnetic fields is limited to their immediate surrounding and there is no evidence of any long or medium term impacts on the built environment or on the fauna or flora eventually surrounding such workplaces. In so far there is no starting point to analyse environmental impacts of the options.

A similar limitation applies for exposure of general public to electromagnetic fields. This matter is dealt with by Council Recommendation 99/519/EEC. Members of the public are not supposed to have access to areas where workers are exposed during their work.

5.1.1. Social impacts

Potential negative health effects of exposure to EMF range from direct effects (headache, vertigos, unwanted nerve stimulation, burns) to indirect effects (loss of attention or injury due to the attraction of a metallic object by a strong magnet). Three specific aspects were addressed for each option:

- Overexposures
- Worker concern
- Wider social consequences (availability of MRI, employment, public concern about EMF)

Overexposures

Documented overexposures, exceeding the physiological level are rare, but not unknown. The best-recorded cases have occurred in broadcasting where workers working close to active emitters have been subject to severe burns.

It is estimated (see annex 8) that the immediate cost per case of overexposure is around 8 000 Euros.

Moreover, while in general the exposure limit values proposed will avoid overexposure, specific groups of workers might have a higher sensitivity. Two particularly sensitive groups can be identified: pregnant women and workers wearing a medical implant:

a) Pregnant workers must be considered as “sensitive workers” for two reasons: one is that pregnant women, especially in the final trimester, may have an impaired thermoregulatory

ability, making them potentially more sensitive to the thermal effects of exposure to radiofrequencies. The other issue is the status of the foetus; there is a question as to whether it should be exposed at the occupational or at general-public EMF limits. Obviously this has an implication for the exposure of the mother - and by extension her ability to undertake certain work.

b) There is a definite difference between the options as regards access to the workplace of workers with medical implants (*AIMDs*)[38]. The default situation is that in the absence of specific information to the contrary, workers with medical implants are not excluded from workplaces with high levels of EMF. The current EMF Directive has a clear requirement that specific assessments are done to determine the extent to which the access of such people should be controlled. CENELEC has produced assessment standards specifically to facilitate this.

Worker concern

While keeping in mind that employers should undertake specific EMF risk assessments even in the absence of explicit legislation employees might not feel as comfortable with these assessments carried out for a risk they may even not be aware of if there are no officially approved limit values. Which means that workers could refrain from going in certain areas or could refuse to carry out certain tasks because they believe it is not good for their health.

Avoiding this is one of the main drivers for employers to consider and quantify any EMF risk in the workplace in a transparent way.

Wider social consequences for workers and general public

a) Lack of access of patients to leading-edge healthcare: This is a particular issue for medical MRI.

Some options may render some procedures illegal, thereby inducing the effect of shifting from MRI procedures to x-Ray based procedures and subsequent additional health care costs to be borne by the collectivity.

b) Employment: A very strict legal situation might restrict economic activities and by that have negative impacts on employment.

c) Public concern about EMF: In many countries, compliance with ICNIRP guidelines (possibly with an additional safety factor) is used to ensure that there is no risk to the public from the established effects of EM fields. If there were to be an explicit rejection of the validity of the ICNIRP guidelines then it is feared that public confidence in EMF safety could be adversely affected. This possible effect has not been observed yet and has not been considered essential when comparing the options in section 5.2 and 6.1.

5.1.2. Economic impacts

Following main effects have been considered for comparing the options:

- effect on competitiveness of European businesses

[38] all words and acronyms followed by * can be found in the glossary

- effects on competitiveness of European businesses compared to those outside the EU
- protection of the employers
- costs on enterprises (developed in 5.1.3)

Effects on competitiveness of European businesses

Options promoting a common EU approach will ensure a higher homogeneity of the legal instruments relating to workers exposed to EMF. This should be beneficial for the businesses as compliance costs would be equal in relative terms. An additional advantage of identical rules in different member states is that mobility of skilled workers becomes easier.

However, too restrictive requirements, in particular too conservative exposure limit values could hinder economic activity and in so far reduce competitiveness and growth of Europe.

Effects on competitiveness of European businesses compared to those outside the EU

There is likely to be an impact on some exporting sectors, especially for options with strict requirements MRI equipment producers might lose the competitive edge in MRI equipment production. North America and Japan would probably become the most advanced market which may promote the development of this equipment abroad instead of Europe.

In other areas such as induction heating and electrolysis, a very strict legal framework may encourage companies to build future installations outside Europe but the effect could remain limited as the necessity of revised working procedures and design changes for limiting the exposure would compare very well towards the creation of complete new installations.

It is however impossible to assess quantitatively which impact it could have for the employment numbers as the effects would be subtle and in many cases EMF legislation is only one factor among several which are relevant for location decisions. In terms of quality of employment, no indication of deterioration of employment has been reported yet because of EMF legislation.

Legal protection of employers

Many employers favour clear limits that they can show compliance with, rather than a general safety requirement or a sector-specific voluntary agreement as it would be the case in options D1, D2 and E. Clear limits provided by an external (and perceived as independent) authority are considered as a convincing way to fulfil employers' responsibilities in a transparent manner. Examples of court cases exist where employers had to bear judicial costs which exceeded by far the costs of an effective risk assessment showing compliance with the legislative provisions. As these events are not so frequent this criterion was not considered essential when comparing the options in point 5.2.

5.1.3. Compliance costs

Costs of compliance as calculated below are costs of actions to be undertaken by the employer to meet the requirements. This is valid for all options. They can be summarized as follows and are in line with the general provisions of the Framework Directive

Table 5

Employer's obligations		Action
1.	Awareness raising	Familiarisation with existing legislation, recommendations or sectoral agreement related to occupational exposure to EMF
2.	Determination of exposure and assessment of risks	Familiarisation with EMF measurement issues Purchase of equipment to measure EMF or hiring external experts to measure EMF
3.	Provisions aimed at avoiding or reducing risks	Introduction of protective measures to eliminate or reduce workers' EMF exposure (e.g. shielding, warning signs) or changes in work practice
4.	Worker information and training	Providing training to concerned workers on safe work procedures
5.	Consultation and participation of workers	Consultation and participation of workers within OSH management process

The compliance costs have been grouped into 3 subgroups:

- "generic costs" (common to all sectors or activities)
- "sectoral costs" (specific implementing cost for each sector or, rather, each activity)
- cost related to training requirements.

The cost-estimations are based on visits and case studies conducted in the establishments (mainly SMEs) in sectors concerned, with main types of activities involving exposure to EMF: electricity generation and transmission, electric welding, induction heating, surgical diathermy, RF sealers, broadcasting and MRI.

The advantage of getting cost figures from SME managers is that they are probably based on personal "in field" experience. Therefore it can be assumed that the absolute figures for individual unit costs are close to reality. The other components of the equation, i.e. the number of workers concerned and the number of workplaces to be assessed were directly derived from stakeholders' assumptions. There are probably underestimated. However, as the number of workers and workplaces remain constant across the options, the overall figures can be used to ensure a realistic ranking of the overall costs for the different options.

The compliance costs mainly consist of man-hour costs of the staff or external experts involved in the analysis of risk (EMF measurement) and of introducing protective measures (e.g. shielding, changes in work procedure). Whilst man-hour costs are variable between Member States, costs for material or equipment and "preventive hardware" in general are assumed to be similar in all EU Member States.

Compliance costs thus strongly depend on the labour cost in each Member State. According to EUROSTAT Labour Survey 2008, average gross hourly labour costs vary from 2.43 (Bulgaria) to 37.38 (Belgium) Euros per hour. The average hourly labour cost for across sectors and professions

was calculated by EUROSTAT at 16.13 €. In the FICETTI report the average labour cost used in the calculations was 18.75 € per hour. Stakeholders considered this a reasonable estimate.

Compliance costs are for most parts one-off costs, unless the workplace undergoes substantial technical or working procedures changes. Still some costs may contain a part of recurrence if deemed necessary by the Member State or the employer himself. For instance, Risk Assessments may be made recurrent in some Member States and training may foresee refreshing sessions after a number of years of practice. As such requirements are different for each MS no attempt was made to try to calculate which percentage of cost this would represent. However it was estimated that this recurrence effects would not represent more than a few percents. The cost derived from the interviews during the case studies in particular countries were therefore maintained as a basis for the consolidated overall figures. Other inputs to the analysis include the numbers of workers and assessments that are needed in each sector. More detailed calculations and information on the underlying assumptions can be found in annexes 4 and 5.

Data on costs of compliance with the current directive 2004/40/EC were received from the UK[39] and the Netherlands[40]. Nevertheless, these data are difficult to compare as different methodologies have been applied. They are based on calculations starting from the existing situation in UK and NL. In the UK the accent was put on the risk assessment costs and not on the preventive measures as they were assumed to be in place. In the Netherlands, the approach included estimated figures for preventive/protective "hardware". Both data enabled to reinforce confidence in the model and of this impact assessment.

Impacts on SMEs

The opinions of SMEs and microenterprises on the EMF Directive and its implications were especially solicited in the impact assessment process. Most consulted employers agreed with the principles of the EMF Directive and were willing to perform a simple risk assessment if they knew how to do. SME employers fear that the costs for risk assessments and measurement surveys as requested by Directive 2004/40/EC might be too high. In so far they are opposed to the current directive and they welcome a relaxation of limit values accompanied by specific guidance to facilitate the risk assessment procedure and to organize information and training.

Overall there is a severe information deficit for SMEs, and there is a wish for simplified information at the EU level. Sector-specific simple and short guidance documents (checklist type) will thereby be needed for whichever option will be chosen. Equipment labelling and better manufacturer information, which might facilitate to identify those situations in which no detailed assessment will be required, would also be helpful.

The impact of the relatively high compliance costs for SMEs is well known to the Commission. The problem is not specific to the risk of workers to be overexposed to EMF but is of general nature. The compulsory risk assessment imposed by the framework directive 89/391/EEC for all identified hazards (e.g. falling from height, presence of dangerous chemical substances, potentially explosive atmospheres, exposure to physical agents such as EMF, asbestos, etc.) generates compliance costs that are relatively higher for SMEs. Moreover, the fact that results of the risk assessment and the prevention measures put in place have to be documented de facto generates an additional cost. All

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39 Draft UK Cost-benefit analysis: proposal for a physical agents directive on electromagnetic fields, July 2010, HSE UK.

40 Electromagnetic fields in the working environment, June 2006, Ministry of Social Affairs and Employment, the Netherlands.

these costs may be seen as negative for the SMEs at first glance but should, at the end, guarantee better working conditions and less workers' absenteeism.

The high level group "High Level Group of Independent Stakeholders on Administrative Burdens" (Stoiber group)[41] has identified the current obligation for SMEs to document the outcomes of their risk assessment as one of the legal provisions which may create unnecessary burden on the SMEs. Subsequently, the Commission has decided to review the situation which concerns all risks addressed by EU-OSH legislation. A study will be launched in 2011. Moreover, the European Occupational Health and Safety Agency in Bilbao is currently developing, in close cooperation with the Commission and stakeholders an on-line tool[42] which should facilitate the work (and reduce the cost) to the employers, in particular in SMEs.

5.1.4. Administrative burden and related costs

The additional administrative costs related to the issue of exposure of workers to EMF are considered as low. They consist of recording[43] - and possible notification - of the results of the risks assessments for the "EMF risk". The administrative costs have been estimated with the EU "Standard Cost Model" and the "Administrative Burden Calculator".

5.2. Assessment of the impacts for each option

5.2.1. Impacts of Option A: "Do nothing"

Option A will be the legal framework as from 1/5/2012, if no other EU legislative act is adopted by then.

As far as health impacts are concerned, workers exposed to EMF will be very well protected. Special groups (pregnant women and workers with AIMDs) will also benefit from appropriate protection although this option (the Directive) addresses it in very general terms.

As Directive 2004/40/EC foresees that efficient workers' information and consultation takes place, workers' concerns should also be very limited.

Nevertheless in terms of wider social consequences, there are also negative impacts expected. A UK MRI expert recently confirmed[44] that at least 3.5% of current MRI procedures would be impossible under this option. More importantly, there might be a slowdown or even termination of development of interventional MRI in Europe. The study commanded by DG EMPL (see 1.2.2 "External expertise" above) confirmed the above conclusions with 6 to 8 % of the current 8 to 10 million MRI procedures per year in the EU becoming impossible. It also predicted an adverse impact on the ability of maintenance teams to adequately maintain MRI equipment.

Moreover, the medical sector (MRI practitioners) and the manufacturers of MRI equipment argue that more stringent EMF exposure restrictions could lead to an increase of other health risks. Option A might induce a transfer from MRI procedures to computerised tomography (CT) X-ray scans. The UK's Health Protection Agency estimated the costs of such a potential shift from MRI to CT.

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41 http://ec.europa.eu/enterprise/policies/better-regulation/files/hlg_opinion_working_environment_09052009_en.pdf

42 OIRA: Online Interactive Risk Assessment :http://www.oira.osha.europa.eu/front-page-en

43 Framework directive 89/391/EEC requires that the risk assessments be documented.

44 Presentation "MRI and the Physical Agents Directive" at the ESOF Conference in Turin on 5/7/2010 by Dr Stephen Keevil, King's College London.

Their calculations indicate that the additional collective ionising radiation dose for workers in England and Wales might be 3-5 man-Sievert (man-Sv) per year. This could be scaled by a factor of around 10 for the whole EU. A financial cost of 50k Euros per man-Sv is often used by the experts in ionising radiation optimisation, giving a total annual cost of the increased collective ionising radiation for workers in the EU of approx. 2.5M Euros per year.

The "Alliance for MRI" has provided a similar calculation for increased patient exposure to ionising radiation, and the corresponding figure is approximately additional 175 M Euros to be borne by the EU public community (taxpayers). That means a transfer of MRI procedures to X-Ray procedures will have considerable costs.

Option A impacts also negatively on the economy by requiring many "long" risk assessments and subsequent extensive protective measures which would only be necessary for a limited number of activities (e.g. induction heating, electrochemical processes) with other options. This increases the overall implementation costs. If option A leads to a situation where compliance measures would be much stricter than in competing countries, delocalisation of workplaces might be a consequence. The one-off costs (see 5.1.3.) under option A have been estimated as follows[45]:

Generic costs	111.7
Sectoral/activity specific costs	548.0
Training	0.500
Administrative costs	0.124
Total (M€)	**660.3**

As regards the costs of the possible application of Directive 2004/40/EC (option A), estimates of costs at national level were established by Great Britain and the Netherlands at the time of the adoption of the directive. According to the British estimates which have been updated in 2010, first year costs are in the range of € 57.9 to €196.5 million. For the original significantly lower figures of 2003 (€6.0 to €14.3 million), HSE UK states that due to the unavailability of some data, these costs did not present a complete picture of implementation and policy costs, and could be considered the minimum costs if the Directive were to be implemented to full (100%) compliance[46]. The Dutch estimates of the costs for the companies were ranging between €10 and €12 million per year during the first 2 years and subsequently €6 to €8 million per year[47]. In both UK and NL, the reason for having significant costs after the first year is because national law imposes regular reviews of the working conditions and consequently of the risk assessments.

5.2.2. Impact of policy option B: "New Directive with revised exposure limits"

This option is equivalent to option A in terms of the protection of workers. Exposure limits are for all workers in line with up-to-date scientific recommendations.

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45 All costs have been established by DG EMPL on the basis of FICETTI data and additional information received from stakeholders.

46 Draft UK Cost-benefit analysis: proposal for a physical agents directive on electromagnetic fields, July 2010, HSE UK.

47 Electromagnetic fields in the working environment, June 2006, Ministry of Social Affairs and Employment, the Netherlands

Moreover this option is also beneficial for the particularly sensitive groups. In option B, workers who have declared themselves to be part of one of these groups should remain in the areas of rooms (or workplaces) where exposure levels do not exceed the levels for general public unless a specific evaluation is made on a case by case basis[48].

Option B would improve the effectiveness of the protection of workers in many companies, in particular SMEs, as it introduces changes towards more proportionality and flexibility. Experience shows that by facilitating implementation the protection levels actually raise.

Wider social consequences which are expected for option A in the form of MRI procedures which cannot take place will be reduced, but still not completely avoided. A comparison of the results of the Commission study on MRI (see 1.2.2) with the BMAS values and the recently published ICNIRP recommendations shows that overexposure still can occur. It was however not possible for DG EMPL to get an estimate of the reduction in the percentage of them.

The economic consequences of option B are less negative than of option A. For many applications (see lists in annex 3) transition to the new reference levels (*actions values*) will mean that they are in an area where it would suffice to conduct very simplified risk assessments. In other areas, well guided risk assessments and according preventive measures should do, and the number of areas where more cumbersome risk assessments would be required would be reduced to a minimum (see in annex 3," activities likely to be above upper level of zone 2"). For these activities option B will still have a negative impact on competitiveness and/or their further development and growth.

Thanks to the combined effect of less conservative reference levels (action values) and of more proportionality the compliance costs are lower than for Option A, and amount to:

Generic costs	111.7
Sectoral/activity specific costs	414.6
Training	0.500
Administrative costs	0.124
Total (M€)	**526.9**

5.2.3. Impact of policy option C1: "New Directive with revised exposure limits and partial exemptions"

The impacts of Option C1 are identical to those of Option B except for the MRI sector for which they are more favourable. Medical MRI would not be subject to binding exposure limits.

Consequently Option C1 would remove obstacles for the use and development of exempted technologies and access of patients to leading-edge healthcare would be ensured. Having in mind the measures foreseen to compensate the absence of binding exposure limits, the level of protection of MRI workers will be maintained at an appropriate level[49]. The concerns of workers should therefore be very limited.

[48] CENELEC guidance in preparation.

[49] MRI workers indicated during the consultations of the social partners that they are willing to work under the conditions foreseen under C1.

As Option C1 is equal to Option B for the industrial sectors, the competitiveness of industry would equally be improved under this option in comparison to option A.

Costs have been estimated to be:

Generic costs	111.7
Sectoral/activity specific costs	385.1
Training	0.500
Reinforced qualitative measures for MRI	14.25
Administrative costs	0.124
Total (M€)	**511.7**

5.2.4. Impact of policy option C2: "New Directive with revised exposure limits and complete exemptions for some activities"

Having in mind the existing public concern about exposure to EMF, it is considered that this approach would undermine the credibility of the protection system and send a couterproductive message to the international community. This opinion is shared by most stakeholders represented by the Social Partners' organisations. This option would be negatively perceived by the MRI workers and may at the end have a negative impact on the level of their protection.

For all sectors (except MRI) this option would have the same advantages for the employers as the options B and C1, i.e. a certain harmonisation and a more proportionate risk assessment process. Effects on employment and competitiveness would therefore be equivalent to the impacts of Option B.

In option C2 workers involved in the MRI activities would be excluded from the scope of directive. Unless decided differently by the Member States, this option would – de facto – not provide any protection for the workers exposed to EMF in MRI activities. This is reflected in the drop for the compliance costs[50]. Administrative costs are considered the same as for Options A, B and C, but they should realistically be slightly lower. Considering the small amounts involved this has only a marginal importance:

Generic costs	111.7
Sectoral/activity specific costs	385.1
Training	0.500
Administrative costs	0.124
Total (M€)	**497.4**

[50] This is with the assumption that only medical MRI is removed from the scope.

5.2.5. Impact of policy option D1: "Replacement of the Directive by a Recommendation"

This option has the advantage of giving more flexibility to the Member States. As far as social impacts are concerned this option would reduce the effectiveness of the attempt to reach harmonisation and in some cases decrease the level of protection of workers. It may also increase workers' concern.

As regards economic impacts a recommendation would create or maintain competitiveness differentials. For MRI implementation this would not create difficulties but the objective of guaranteeing a high level of protection across all the EU installations may not be attained because of the lack of generalised reinforced qualitative measures. Finally, depending on the situation in each Member State, the protection of the employer in case of a court case would be less favourable.

Costs have been estimated to be in the order of:

Generic costs	39.4
Sectoral/activity specific costs	397.1
Training	0.500
Administrative costs	0.124
Total (M€)	**437.1**

The figure reflects the effect of the patchwork situation which may occur. The reduction of the generic costs reflects the fact that risk awareness may be lower in some Member States.

5.2.6. Impact of policy option D2: "Voluntary social partners' agreements"

During the second stage of the consultation of the social partners neither trade unions nor employers' organisations gave an indication of preferring such a solution. Both groups see this as an issue to be regulated on the European level. However as a matter of consistency and completeness it was decided to examine this option as well.

The same kind of considerations as in option D1 can be used to express the positive and negative impacts of this sectoral approach. Within a Member State the level of protection of workers would not be equivalent in different sectors and the verification of the effectiveness thereof would be more difficult for independent experts and labour inspectorates.

This would also create confusion for workers' and provoke public concern. Moreover it would be more difficult for employers to demonstrate that they fulfilled their responsibilities as regards the protection of workers in case of judicial proceedings.

Costs have been estimated in the order of:

Generic costs	22.5
Sectoral/activity specific costs	397.1
Training	0.500
Administrative costs	0.124

Total (M€)	**420.2**

This estimate is less reliable than those for options A, B and C because of the uncertainties on the generic costs. It should reflect the differential approaches for carrying out a risk assessment in the different sectors.

5.2.7. Impact of policy option E: "no EU legislation"

In the first instance, as regards the social impacts, abstaining from any European level action on EMF would reduce significantly the attention paid to the risks of EMF and would have negative impacts on workers' health and working conditions. Moreover it may raise public concern as the EU would provide guidance for exposure of the public but not anymore for workers exposed to higher risks. Consequently the protection of workers exposed to EMF would not be guaranteed. Also, the EU by repealing an existing directive may send a very negative signal to the international community.

From the strictly legal point of view, even if the EMF risks were not explicitly addressed by any EU Directive, employers should take them into account in their risk assessments in light of the Framework Directive 89/391/EEC.

As far as competitiveness is concerned, no significant effects are expected. However, the lack of guidance and rules for the risk assessment is expected to have counterproductive effects for the carrying out of the various steps of the risk assessment. In absence of any specific EU legislation the employers would need to invest more time and effort to identify risks and decide on the appropriate protective actions. This would have an upward influence on the compliance costs in comparison to Options like C1 and C2 where rules are better defined:

Generic costs	76.3
Sectoral/activity specific costs	397.1
Training	0.500
Administrative costs	0.124
Total (M€)	**474.0**

5.2.8. Variability of costs across Member States and options

The relevance of comparing compliance costs for each option, by size of enterprise, by sector and by Member State was analysed. Defining the activities with exposure to EMF which are specific for an industrial sector are often not straightforward. For instance, you may find similar activities (e. g. welding, RF sealing, article identification, wireless communication) across numerous industrial domains. On the other hand you may also have several and different "EMF producing" workplaces in the same factory.

Apart from the difficulty of defining generic EMF exposure by industrial sector, it is not possible to link the absolute cost to the size of the enterprise, because of the variety of existing situations: for instance one could find 5 welding devices used in a small company (10 workers) manufacturing metallic trailers on demand; one could find 5 similar devices used for machine maintenance purposes in a larger company (e.g. 500 workers) producing shoes. The overall compliance costs will be the same in both cases. Fortunately, in such cases, the costs for preventive and protection

measures will benefit from some costs savings because the risk assessment and design of protection measures will be similar for the 5 workplaces.

For these reasons, establishing a link between sectors and company to assess the variability of costs at company level will end up with a wide bunch of dispersed points on a graph and is not deemed to be a relevant indicator or a trend. It is however recognized that costs will affect SMEs to a larger extent in relative terms.

As can be seen, from the case studies (annex 4) the largest part of the compliance costs is due to labour costs and therefore directly proportional to the level of the salaries in the Member States. The cases where the part of "hardware" for protective measures is significant are rather limited (e.g. Induction heating). The calculation of costs for a specific activity in a Member State can be derived from the assumptions used in the case studies, by taking the same fixed amount for the part related to the "hardware" and using labour costs calculated proportionally for the Member State concerned.

6. COMPARING THE OPTIONS

Whatever the option, benefits cannot be described without difficulty. Benefits on health can only be stated by the fact that below the current or future limits, no adverse effect occurs. This should be in favour of options A to C2.

The comparison of the impacts of each option carried out under point 5.2 can be summarized as follows.

Table 6

	Protection against overexposure	Workers concern taken into account	Wider social impacts	Economic impacts	Compliance + administrative costs
Option A	Achieved	Achieved	6-8% MRI cannot take place, estimated costs of 172 Mio Euro for the general society	Negative impact on growth of medical technology and restriction on economic activities in other areas	660.3
Option B	Achieved	Achieved	A smaller number of MRI cannot take place	Less strong negative impact on growth of medical technology. Other economic activities are not or only very little restricted.	526.9
Option C1	In general achieved, case specific analysis required	In general achieved, but less convincing than with options A and B	No restriction to MRI and its economic development	Signal that flexible solutions can be found	511.7 Costs for MRI reinforced measures included
Option C2	In most areas achieved, but for some areas achievement is not ensured	Safety standards are perceived as not reliable	Signal that economic interests can overrule workers' concerns	Unequal treatment of sectors may create problems.	497.4
Option D1	Protection of Workers dependent on MS	Partially, depending on the effect of the recommendations in the MS	More uncertainty concerning the protection of groups at particular risks	Patchwork of solutions which is not good for mobility and competitiveness	437.1
Option D2	Protection of workers dependent of the content of the	Partially, depending on the effects of the content of the	More uncertainty concerning the protection of groups at	Patchwork of solutions which is not good for mobility and	420.2

	agreement(s)	agreement(s)	particular risks.	competitiveness	
Option E	Not at the level of more stringent options	No	Bad signal to stakeholders. No explicit protection for workers anymore whilst recommendations for general public remain	Lack of guidance may end up in higher assessment costs	474.0

Given new scientific evidence which indicates that exposure limits as provided under option B will ensure protection against overexposure, option A only adds the disadvantages of restricting some activities and overall less willingness to comply.

At the other end of the spectrum of possibilities option D1 (Recommendation), D2 (Voluntary agreement) and E (no EU legislation) can be rejected. Stakeholders and experts expressed strong preference for consistent European legislation which gives employers and employees legal and physical security. Although EMF on its own is not a major issue, consistent European legislation in the field is seen as contributing to the Single European Market. Furthermore, abstaining from any European level action on EMF would reduce significantly the attention paid to the risks of EMF and could have negative health impacts.

The three remaining options are options B (revised exposure limits), C1 (revised exposure limits and conditional exemptions limited to some provisions for medical MRI) and C2 (revised exposure limits and complete exemptions of some activities from the scope of the directive).

Option B has the advantage of consistent rules on EMF with exposure limits which are for a considerable number of the workplaces already high enough, so that there is no longer a threat of overexposure. Compared to option A the number of situations with potential overexposure reduces significantly. Option B is in line with recent scientific evidence. The disadvantage of this option is that there are some activities (like some MRI treatments) where temporary excessive exposure is possible. Completely stopping these activities – which are in some cases closely linked to technological progress and undertaken to directly contribute to the health and well-being of citizens – is problematic.

Option C1 has the advantage of consistent rules on EMF in most areas like for Option B, while accepting derogation from exposure limits for medical MRI and reinforced preventive measures in situations where there is a threat of overexposure. As in the case of option B this must rely on recent scientific evidence. It would be more flexible than option B. The disadvantages of option C1 are that in case of derogation it requires a more stringent and more controlled working environment.

Option C2 also has the advantages of consistent rules on EMF in most areas and allows for flexible solutions in situations where there is a threat of over-exposure. The obligations in terms of risk-assessment are lower for the exempted sector. This also reduces the compliance costs. The disadvantage of this option is that there is no protection against this leading to lower levels of workers protection. Furthermore this option would encourage more heterogeneous protection of employees in contradiction with the letter and spirit of the Framework Directive.

Conclusion on costs: The cost of Option C1 is higher than the costs for less stringent options from C2 to E. However for a rather limited increase of costs Option C1 scores much better than these options for other - more qualitative impacts - and guarantees a high level of protection for the

workers. The cost of Option C1 is significantly lower than the cost for option A and almost equivalent to Option B whilst offering to the MRI sector and the industry the flexibility they need.

Consequently, based on these considerations and in line with the survey results hereafter the Commission therefore prefers **option C1**.

This conclusion is in line with the results of a survey carried out among stakeholders and experts by the FICETTI consortium (annex 9). The findings are as follows:

- Option A is generally considered to have disproportionate economic costs, especially for SMEs
- Option B was difficult to assess in the absence of new exposure guidelines from ICNIRP at the time of the survey. Stakeholders believe Option B has rather high economic consequences but it scores well on social and health impacts
- Option C1 is the only option to score consistently positive in this survey based analysis, despite the fact that the new exposure guidelines were not known at the time just like for Option B. The additional flexibility and proportionality available under this option led to it being ranked ahead of others.
- Option C2 scores badly on economic and neutrally on health and social impact grounds, leading to an overall negative score.
- Options D and E score badly on health and social impact grounds. Option E especially is unpopular with stakeholders.

The detailed assessment also shows that 'soft elements' like information campaigns targeted at specific sectors and practical guides how to implement legislation on the sectoral level should continue to complement the legislative action.

These conclusions indicate an overall preference of the responding stakeholders for option **C1**.[51]

[51] See annex 9 and FICETTI report.

7. MONITORING AND EVALUATION

The framework directive 89/391/EEC and the subsequent 19 individual directives in the sense of its Article 16.1 foresee a regular review of the effectiveness of their implementation. Since 2007, this systematic review has been harmonized and must be performed every 5 years by all Member States for all risks covered by the directives. A report is then prepared by the Commission which can serve as a basis for an evaluation of the situation and for the reporting of implementation difficulties.

Also, committees bringing together national experts from EU Member States are an important part of the process of evaluating and monitoring EU legislation relating to health and safety at work.

First there is the tripartite Advisory Committee for Safety and Health at Work set up by a Council Decision (2003/C218/01). Each Member State has a governmental, an employers' and a workers' representative. This is a good place to report on possible problems or unexpected or unwanted consequences of an EU-OSH initiative. Part of the remit of the Committee is to assist the European Commission in the preparation, the implementation and the evaluation of activities in the fields of safety and health at work.

Secondly, there is the Senior Labour Inspectors Committee (SLIC) set up by Commission decision (95/319/EC). It assists the European Commission in monitoring the enforcement of EU legislation at the local level. SLIC provides opinions, either at the Commission's request or on its own initiative on all problems relating to the enforcement by the Member States of Community law on health and safety at work. This committee which meets several times a year enables exchanges of views, the sharing of inspection experience and good practices and represents an additional forum for firsthand feed-back.

8. ANNEXES

Annex 1

Second stage of consultation of the social partners on the protection of workers from the risks related to exposure to electromagnetic fields at work

ANSWERS TO THE CONSULTATION

Synthesis

The Commission launched the second stage consultation of the European social partners, in accordance with Article 154(3) of the Treaty on the Functioning of the European Union (TFEU), on the content of a new European Union initiative to ensure the protection of workers exposed to electromagnetic fields (EMF) during their work. The relevant document is C (2010)3250 final, published on 20.5.2010.

The Commission received a total of twenty-seven answers from associations, organisations and institutions. In particular: eighteen employers' organisations (10 EU; 2 international; 1FR; 5 UK), two workers' organisations (1EU; 1DE), three national scientific institutions (RO; 2 PL), three private experts and one patients' association (EU) responded to the Commission's questions.

Acronym	Full Name+main activity	Category
Alliance for MRI	Alliance for MRI (radiology)	EU; Patients+Practitioners
ARQIVA	Broadcasting and wireless communication	UK; Employers
BUSINESSEUROPE	Confederation of European Business	EU; Employers
CBI	Business lobbying organisation	UK; Employers
CEA	National Scientific Institute	FR; Employers
CEEMET	Council of European Employers of the Metal, Engineering and Technology-based Industries	EU; Employers
CEEP	European centre of Employers and Enterprises providing Public Services	EU; Employers
CER	Community of European Railways and Infrastructure Companies	EU; Employers
COCIR	Medical MRI Equipment manufacturers	EU; Employers

DGB	Deutscher Gewerkschaftsbund	DE; Workers
EEF	Engineering Employers' Federation	UK; Employers
EMFields Ltd	Consultants for EMF	UK; Private experts
ENTSO-E	Electricity distribution	EU; Employers
ETUC	European Trade Union Confederation	EU; Workers
EURELECTRIC	Electricity production and distribution	EU; Employers
EUROCHLOR	Chemical processes; industrial electrolysis	EU; Employers
Goiceanu (Mr)	National Scientific Institute	RO; Scientists
GSMA	Mobile telecommunication industry	International; Employers
HOSPEEM	European Hospital and Healthcare Employers' Association	EU; Employers
IEMFA	International Electro-Magnetic Fields Alliance	International; Private experts
Israël (Mr)	EMF coordinator for Bulgaria	BG; Scientists
NATO	North Atlantic Treaty Organization (defence)	International; Employers
Polish experts on Bioloelectromagnetic Problems	Polish Society of Radiation Research	PL; Scientists
Polish experts panel	National Interdepartmental Commission	PO; Governmental scientists
SMMT	Society of Motor manufacturers and Traders	UK; Employers
UEAPME	European Association of Craft, Small & Medium-Sized Enterprises	EU; Employers
UK-NHS	National Health Service	UK; Employers

The Commission had requested the Social Partners to:

1. Submit to the Commission an opinion or, where appropriate, a recommendation on the content of the envisaged legislative and non-legislative initiatives pursuant to Article 154 (3) of the TFEU, giving particular attention to the topics identified in section 4 above;

2. To inform the Commission about alternative solutions in particular for the expression of exposure limit values in the range of 0 to 100 kHz and for ways to foster and concretise the aspects linked to the implementation of sound and efficient protection of workers exposed to electromagnetic fields during their work. Alternative solutions for the range from 100 kHz to 300 GHZ are also welcome;

3. Where applicable, to indicate their willingness to enter into negotiations on the basis of the proposals described in this document under the terms of Article 154(4) and Article 155 of the TFEU.

Section 4 of the Commission Document, which is referred to in point 1, raised the following issues:

4.1. Coverage of all sectors of activity

4.2. Precise definitions

4.3. Exposure limit values

4.4. Measurements and calculations

4.5. Guidance for risk assessments

4.6. Due flexibility in a controlled working environment

4.7. Medical surveillance

4.8. The specific case of medical applications and related activities (research, cleaning, maintenance) using nuclear magnetic resonance (MR) technology

4.9. Non-binding measures

Overall, the social partners welcome the initiative to propose a new Directive on EMF, since the present one, Directive 2000/40, is deemed to be to complex and difficult to apply and would hinder some activities and procedures, in particular Magnetic Resonance Imaging (MRI). Some employers pointed out that even if EMF are an issue that has to be tackled, they do not constitute major concerns, since they assume that no evidence of adverse health effect by their normal usage has been found. Only one employers' organisation, EEF, expressed the view that there would be no need for an individual Directive in this field, being the dispositions of the Framework Directive 89/391 sufficient to address priorities and risks.

The responses to the Commission's proposal could be synthesised in this way:

Point 1: *Submit to the Commission an opinion or, where appropriate, a recommendation on the content of the envisaged legislative and non-legislative initiatives pursuant to Article 154 (3) of the TFEU, giving particular attention to the topics identified in section 4 of the document.*

4.1. Coverage of all sectors of activity

Commission's proposal
The Commission considers it important that EU legislation on occupational health and safety covers all workers in all sectors of activity in conformity with Article 2 of Framework Directive 89/391/EEC. This reflects the wishes of a large majority of the social partners' organisations who responded to the first phase of the consultation and does not depart from the provisions of the current directive on the issue.

There is general consensus on the coverage of all sectors of activities by the new proposal. Some organisations pointed out that a degree of flexibility is however needed in order to enable every sector to pursue its activities. NATO underlines that Directive 89/391 does not apply to armed forces.

4.2. Precise definitions

Commission's proposal
As the issue has to do with short-term effects, the Commission is of the opinion that a better understanding of the meaning of adverse health effects could reconcile science and industry. This should allow a flexible system to be developed for defined working conditions in certain activities. In order to be credible the system should reflect the most recent scientific progress and subsequent recommendations. The definitions contained in Article 2 of the directive should therefore be adapted accordingly. There are differing opinions on whether phosphenes, vertigo and nausea should be considered as adverse health effects. They could affect certain aspects of work performance if precision, concentration, short-term reaction time or work at height is required and would de facto affect the safety of workers but not their health. The Commission is of the opinion that the solution may be to distinguish between effects which are harmful to health and effects which can be detrimental to the safety of the worker and may even impair the quality of work. In practice this may lead to a situation where acceptable levels of exposure to EMF depend not only on frequency and intensity of the source but also on the type of work.

Many organisations welcome the effort towards clarity and simplification; definitions should be understandable by all. A distinction between adverse health effects and temporarily physical effects which are only detrimental to safety and not to health is endorsed by most of the employers; a ranging of the effects has also been suggested. CER affirms that a strong subjective element underlies physical effects; therefore it shouldn't be required to take them into consideration. On the contrary, national institutes believe that also physical effects should be taken into account, and that the fact that there is no scientific evidence yet on their link to EMF, this should not mean that the level of safeguard should be reduced. Workers' associations recommend giving precise definitions of what is considered to be "harmful" and don't accept a mutually-exclusive distinction between what is harmful to safety and what is harmful to health.

4.3. Exposure limit values

Commission's proposal

ICNIRP has recently reviewed its recommendations for static fields and is currently reviewing

its recommendations for the low frequency range which goes from just above 0 Hz to 100 kHz. A further review of the recommendations for higher frequencies is expected in the near future. The latter do not seem to be controversial because in most situations and under normal circumstances they are not exceeded. ICNIRP recommendations, both the ones published in 1998 and their new ones as discussed during a consultation process, are nowadays challenged by different agencies: IEEE (USA), ARPANSA (Australia) and very recently by a proposal of

the German Ministry for Employment and Social Affairs (BMAS). The Commission intends to take into account the diversity of recommendations from the scientific world and replace the current system, which comprises one action value and one exposure limit value for each frequency, by a 'multilayer' system facilitating the verification of compliance and the decision by the employer. This is very much in line with suggestions already made by CENELEC (zoning) and Member States or employers' federations that have already undertaken to develop guidance for their workers or members.

The Commission would however suggest maintaining the provision of the directive for frequencies above 100 kHz. The 'zoning' system for frequencies from 0 to 100 kHz would be as follows:

• Zone 0 (blue zone) where the situation is similar to what is acceptable for the public (no action deemed necessary);

• Zone 1 (green zone) where exposure remains under the levels proposed by ICNIRP in 2009 for frequencies up to 100 kHz: as there are no health and safety problems, and giving specific information to staff should be sufficient except for frequencies equal to or lower than 1 Hz where nausea and vertigo may occur. In that particular case, protection measures as for Zone 2 should apply;

• Zone 2 (yellow zone) where exposure is between the ICNIRP 2009 proposed values and the value fixed for Zone 3 (see below): no harmful health problems expected but maybe adverse quality problems or potential workers' safety problems due to appearance of phosphenes. This is the area where required actions and preventive measures are in fact situation/activity-dependent as already indicated under 4.2. A non-exhaustive list of identified activities could be provided in an annex. Measures that should be considered here include: information, specific training and awareness raising, appropriate labelling, and limited access;

• Zone 3 (red zone), where exposure exceeds the current commonly accepted limits proposed by ICNIRP and IEEE for frequencies above 100 kHz and where the exposure is above the limit line of the BMAS proposal. In this zone, no access should be allowed or even possible. If access is required it must take place under strictly controlled conditions, never in routine work.

This system would replace the current action values and exposure limit values concept in the range under 100 kHz and all the limits would be expressed in the same units, for directly measurable quantities.

There is a general agreement on the need of revising the restrictive values of the present Directive and on the need for them to be directly and easily measurable. The only exception is CER, which endorses to keep those of Directive 2000/40. Some organisations contest the use of ICNIRP recommendations, given that they are undergoing revision and that the draft version of the new

guidance has been criticised. More than one employers' organisation supports a system where ICNIRP values are not compulsory, and different ones can also be used. NATO suggests that the Directive should not include indication of values, since they are subject to modifications, but only some guidance. It is noticed that EMF devices can emit at different levels, therefore emissions are difficult to control (CIOP). BUSINESSEUROPE recommends that the limits should not be related to the type of work carried out, and point out that a high degree of clarity is needed in this issue because in some cases employers can be subject to penal sanctions if they don't respect the requirements. GOICEANU supports limits that are also based on physical effects; COCIR adds the taking into account of non-thermal and long exposure factors. CIOP deems that there should also be a duration limit to exposure. UEAPME questions whether the eventuality of the co-existence of multiple EMF sources is considered.

The zoning system is commonly accepted in principle, but many organisations reserve their evaluation until the final levels are set up. The general estimation is that the zoning system is quite complex, many organisations suggest to merge zone 0 and zone 1, some of them don't agree with the limit of 100 kHz. Several respondents remark that the definition of zone 3 is not very consistent because on the one end it says that "no access should be allowed or even possible", and on the other it implies that access can, even though under strictly controlled conditions, occur. NATO proposes a system based of five restrictive zones; NHS-UK suggests different limits for the public and for the workers; The Polish Society of radiation research advocates internationally harmonised values.

4.4. Measurements and calculations

Commission's proposal
Management of uncertainties has been reported as being a serious difficulty in implementing the exposure limit system set up by the directive even with resort to standards, such as EN50499 developed by CENELEC in 2008 on the basis of the mandate M/351 of 17 May 2004 given by the Commission to CENELEC in order to meet the requirements of Article 3(3) of the directive currently in force: *'3. for the assessment, measurement and/or calculation of workers' exposure to electromagnetic fields, until harmonised European standards from the European Committee for Electrotechnical Standardisation (CENELEC) cover all relevant assessment, measurement and calculation situations, Member States may employ other scientifically based standards or guidelines'.* As in any activity where measurements are made, each value is affected by a degree of uncertainty. In most cases this uncertainty tends to be limited (a few percent) and can accepted without problem. Unfortunately when measuring electric or magnetic fields the 'errors' can become very high (up to 100 % of the measured value). From a technical point of view this may be dealt with when the measurements concern process controls and triggering signals. This may however become an issue from a legal point of view – at least in some Member States – when it comes to comparing a measurement and an exposure limit value, especially when the latter is expressed in non directly measurable quantities. Consequently, uncertainty plays an important role in assessing human exposure to EMF since it affects the results of measurements and numerical calculations. The directive does not address this problem in depth and the new proposal will need to give clear guidance in this respect. Moreover, the way to deal with pulsed, non-sinusoidal signals and harmonics should also be covered, bearing in mind that in the new system such complex and costly

measurements and evaluations should be limited to cases where exposure is likely to exceed the upper limit of Zone 2.

There seems to be an urge for directly measurable calculations, also feasible by non specialists. EURELECTRIC and others support considering the use of CENELEC as advisory and not compulsory, and that other parameters can be used too. In general, there is an urge for directly measurable values, simple and understandable by all. EURELECTRIC endorses the use of measurable rather than internal quantities. Several employers' organisations advocate the use of a practical approach, and many of them suggest that measurements should only be done when there is likelihood of exceeding zone-1 limit, due to the costs that constant measurement would imply, especially on small businesses. Also, a science-based approach is supported, that only takes into account proven risks to health. CIOP requests different parameters for the research sector.

4.5. Guidance for risk assessments

Commission's proposal

According to expert reports, employers do not always realise that there will be situations where their staff may be exposed to a high electric and/or magnetic field. This is for instance the case in establishments using just one welding device, an induction furnace, an in-house electric transformer, a microwave drying system, etc. Consequently, exposure to EMF is not normally considered as a risk and it must be recognised that it is probably not seen as one of the major sources of illness or accidents in such enterprises. Therefore appropriate guidance should be given to raise awareness and simplify the risk assessment procedure. The Commission is aware that some Member States and sectoral associations have already put in place simple but effective tools to help employers take account of risks linked to exposure to EMF. Moreover, the EN50499 standard referred to in point 4.4 above entails a similar approach. These tools and means have the great advantage of simplifying the compulsory risk assessment and of limiting the burden when the situation does not require extensive efforts.

This approach leads to a simple but effective risk assessment, thereby boosting overall implementation.

The new proposal for a directive will not exempt any employer from carrying out a risk assessment and documenting it as already provided for in Directive 89/391/EEC but will introduce to a large extent the desired simplification and proportionality. Assessment time and costs will thus be reduced whenever possible without jeopardising workers' health and safety.

Guidance on risk assessment is broadly welcome; assessment should be a simple and not overly burdensome practice. Some organisations propose a proportionality approach; some others add that only when zone 1 is likely to be exceeded such assessment should be made. CEEP supports the provision to employers of indicative exposure measures. UEAPME advocates the creation of safe-equipment lists. EURELETRIC adds that it would also support the introduction of lists of equipment which is not considered safe. ETUC expresses its concerns on the creation of the lists; asks for repeated exposure to be taken into account; and affirms that they would welcome guidance to assessment of sector-specific risks. CIOP underlines that the "CE" labelling of equipment does not duly take into account health risks and that this should be tackled. BUSINESSEUROP and others advocate the use of standards other than those of CENELEC. UEAPME suggests carrying out awareness-raising activities the use of simplified and proportionate risk-assessment tool for the SMEs.

4.6. Due flexibility in a controlled working environment

Commission's proposal
As can be noted from points 4.2 to 4.4 relating to short-term effects, the Commission recognises the need for an appropriate and proportional approach for all sectors of activity. Exposure to electric and/or magnetic fields above some levels can have effects on the human body; however, these effects are not necessarily adverse to health. The Commission has taken due note of the latest conclusions of the SCENIHR[11] relating to possible long-term effects. One may conclude from SCENIHR's opinion that there is currently no consistent evidence of long-term adverse effects on adult human bodies (with very few exceptions for young children) and therefore no possibility to take them into consideration for a quantifiable approach in a binding legal instrument. The Commission is however of the opinion that a precautionary approach should be part of the preventive measures developed in the new instrument. In practice this would entail the inclusion of a generic principle to avoid presence in an exposed zone whenever a worker's presence is not necessary to carry out an activity. This is already stated in the directive under Article 5(2) f): '….. *(f) limitation of the duration and intensity of the exposure;*'. Whilst cognitive and/or adverse health effects do appear above certain levels, they can be overcome and their nature (nerve stimulation) may be acceptable under certain circumstances for instance in a controlled environment. This flexibility to accept occasional overriding of the upper limit of Zone 2 would obviously have to be counterbalanced by appropriate training and preparation, a thorough risk assessment, adapted exposure level measurements and transparent, documented monitoring. A specific annex would address this issue in some detail for the different areas of the frequency spectrum up to 100 kHz. Above that frequency, where the exposure limit values should remain unchanged, the adverse effects consist in internal or external burns from which the human body may not recover immediately. This cannot be accepted. However, heating of tissues does not necessarily occur if the exposure time is very short. The importance of this parameter is underestimated in the present directive. It is intended that the proposal should make clearer the interpretation to be given to exposure time and averaging over it so as to tie in with current publications of ICNIRP and IEEE.

Most of the respondents are in favour of a certain degree of flexibility, and believe this should apply to all sectors; workers in particular deem that it should be strictly controlled that the protection of the worker is not hampered. Most of them (the employers) use a scientific-based approach, saying that since no scientific evidence exists on adverse health effects on EMF in the long term, as SCENIHR demonstrates, the Directive should not cover this issue. NATO, in the same line, suggests a "*de minimis*" approach. Some organisations reject the use of a precautionary approach. CIOP accepts a certain degree of flexibility provided that minimum health requirements are complied with. The workers' representations and EMF Alliance don't agree. Some question the appropriateness on the use of precautionary principle. CEA points out that a balance should be found between the need of protection for the workers and the burdens on the undertakings, especially SMEs. BUSINESSEUROPE underlines that training should not be considered as a basic action to counterbalance the use of flexibility. Many organisations of different nature advocate the taking into account of the exposure time, and also of the case of repeated exposure (ETUC).Workers' representatives, as well as scientific institutions, believe that long term effects

should be taken into account, in particular, EMF Alliance point out that gradual accumulation, intrinsic amplification and interaction with other agents are factors that can imply adverse health effects of EMF exposure, based on sound empirical scientific research.

4.7. Medical surveillance

Commission's proposal
Doctors present at the Umea Conference of October 2009 admitted that they found it difficult to identify effects from exposure to EMF, especially with routine medical surveillance. They also felt there was a need for guidelines on how to handle overexposure as moderate overexposure could not be expected to produce any effects once the exposure is over. The actual question was: what should be looked for after heavy exposure, except for burns? The experts were of the opinion that the exposure limit value as suggested in the directive was not a useful indicator for health examinations. An open question remains concerning the need for special protection of persons at increased risk, e.g. pregnant women, persons with implants and persons with certain neurological or cardiac diseases. In view of these medical opinions, which seem to be quite widely held, it is suggested that Article 8 of the directive be revised. In addition, and this was also suggested by the medical experts present at the Umea Conference, there is a need to establish guidance in this field. The Commission proposes the setting-up of an appropriate working party under the Advisory Committee on Safety and Health at Work to develop such guidance.

Many respondents observe that there is not enough knowledge at the time of type of surveillance needed and/or possible and on way it should be carried on. Especially at frequencies lower than 100 kHz effects are difficult to diagnose. Most of the employers' representations believe that surveillance should only be compulsory in case of overexposure, also due to the costs they would have to incur otherwise. CEEP esteems that there is no need for compulsory surveillance at all. Workers deem instead that there should be a constant monitoring of the workers, that after-accident investigation should always be performed, and that the related files should be archived in order to assess long term effects.

4.8. The specific case of medical applications and related activities (research, cleaning, maintenance) using nuclear magnetic resonance (MR) technology

Commission's proposal
MR technology is used in medical applications such as magnetic resonance imaging (MRI) and magnetic resonance spectroscopy (MRS). These methods are very powerful and have improved patient care immensely in terms of diagnosis and follow-up of diseases and opened new perspectives for interventional medical procedures. Currently, the existing provisions would preclude the use of such equipment and methods as they would not comply with the limit values of the directive. Therefore the Commission has to find a way of providing a high level of protection for workers dealing with MR techniques while at the same time permitting the development and full use of MR medical procedures.

A study ordered by the Commission on the subject of medical MRI[12] showed that compulsory compliance with the exposure limit values of the directive would indeed hamper the further use of MRI. However, the study indicated that the problem affects a relatively limited number of procedures - less than 10% - and are restricted to the frequency range from 0 Hz to 10 kHz used in MR medical techniques. For the large majority of the procedures - more than 90% - compliance with the provisions of the directive would de facto be assured without any change in the current way of working or, in a limited number of cases, by slightly adjusting working practices during the medical procedures.

By way of example, and bearing in mind the technical specifications of the current machines - a large majority of which use a 1.5T or 3.0T (rarely 7.0 T) static magnetic field – 'slightly adjusting working practices' to bring the level of exposure under the current exposure limit values would imply the following recommendations:

– do not come closer than 0.5m from the entry of the bore when not absolutely necessary to

assist the patient;

– just walk normally in the MRI room (~ 4km/h);

– do not stay close to the bore when (image) acquisition is in progress;

– do not remain in the room when it can be avoided.

procedures still represents – per year in the EU - between 400 000 and 500 000 medical procedures that would contravene the directive because a presence close to the patient cannot be avoided or in cases of emergency, e.g. for the patient.

Analyses were conducted to compare exposure levels for these critical cases with a different set of limit values (for instance, IEEE values in the USA) and no ideal solution could be found. Therefore, the Commission envisages the possibility of exempting the medical MR sector and activities related to the use and development of medical MR techniques from binding exposure limit values. However, workers' health and safety would continue to be protected through reinforced qualitative preventative and protective measures to be included in the proposal for revision of the directive:

– reinforced information measures;

– reinforced training of workers;

– documented and practicable working procedures favouring exposure limitation whenever

possible;

– strict administrative procedures for access to MR rooms;

– consultation of personnel on improvements;

– monitoring.

Qualitative elements that reassure the Commission when proposing exemption from binding exposure limits are that the presence of workers in exposure situations is very limited in their normal working time and most of the workers are skilled people who can easily be made

aware of good practices. Moreover, most instances of exposure would not be far above the new proposed limits announced under 4.3 above.

Appropriate and commonly agreed qualitative prevention and protection measures should be implemented in a harmonised way ideally in all the medical MR facilities existing in the EU (more than 8 000). European organisations of MR practitioners and manufacturers have already indicated their willingness to give their full support to this approach. Contacts between Commission services and stakeholders have been pursued since July 2006. They have already led to the successful completion of the study referred to in paragraph 3 of this section. In a second phase, which is still in progress, discussions have focused on the implementation of a common, effective and reliable system, to be adopted for all EU MR facilities with the support of the workers and employers of the sectors concerned.

Employers' and business associations directly implicated in the MR resonance sector, as well as Alliance for MRI fully support the exemption of MRI from the exposure-values requirements. In particular, it is noticed that vulnerable patients need assistance and that there is already a strong health and safety culture in health-care sector. It has also been underlined (NHS-UK) that this may lead physicians to recur to more dangerous techniques such as ionising radiations. Some organisations simply affirm they don't think to be concerned by this issue. Workers and science-experts think that exemptions *per se* are not a good idea, but accept that some specific rules for individual sectors can be set, provided there is enough protection and health monitoring for workers and that this is periodically reviewed (ETUC). NATO disagrees with the introduction of whatever type of exemption. CIOP suggest that limitation of exposure levels should not be defined; CEA requests exemptions also for research activities, especially the experimental phases.

4.9. Non-binding measures

Commission's proposal

The Commission agrees with the social partners that the complexity of the matter and the scarce expertise, in particular in SMEs, justify supplementing the revised directive with nonbinding initiatives.

For example, the Commission, assisted by the Advisory Committee on Safety and Health at Work, has already begun drawing up a guide on prevention and good practice which will cover the main risk activities and situations. A first draft was prepared in line with the provisions of the current directive but it will have to be adapted in order to suit the revised directive.

For difficult situations where workers face very high exposure levels, precise evaluations will be necessary and appropriate standards developed by CENELEC will be the best solution. However, for lower exposure levels more simple guidance will have to be developed in the language of the ‘end users’. The Commission is of the opinion that an active role by the social partners is of crucial importance for effective prevention and that the employers’ and workers’ organisations have an essential role to play in developing and encouraging dissemination to their members of non-binding but well-adapted tools. The Commission intends to invite the Advisory Committee on Safety and Health at Work to play a more proactive role in this field in the future.

Furthermore, the Commission intends to ask the European Agency for Safety and Health at Work to step up information, guidance and awareness-raising activities on the ground with a

view to enhancing protection against exposure to EMF in selected sectors. Such activities, including a possible European information and awareness campaign, would be undertaken with the close involvement of the Member States and social partners.

All the organisations generally welcome the need for non binding measures and guidelines. Some have expressly agreed on the creation of a working party. CER indicate that they wouldn't want this kind of measures to be included in the text of the Directive. The role of social partners in the creation of guiding documents has been underlined. NATO warns about the risk of increasing fear by performing awareness raising campaigns.

> **Point 2:** *To inform the Commission about alternative solutions in particular for the expression of exposure limit values in the range of 0 to 100 kHz and for ways to foster and concretise the aspects linked to the implementation of sound and efficient protection of workers exposed to electromagnetic fields during their work. Alternative solutions for the range from 100 kHz to 300 GHZ are also welcome.*

Point 2 received few answers: ETUC suggest the creation of an experts committee, the elimination of risk exposure and the finding of measures to tackle EMF risks, like good practices. CEEP believes that existing measures are enough: CEA insist on taking long term effects into account; and UEAPME only wishes that the limits between the zones are always directly measurable.

> **Point 3:** *Where applicable, to indicate their willingness to enter into negotiations on the basis of the proposals described in this document under the terms of Article 154(4) and Article 155 of the TFEU.*

Regarding point 3 there does not seem to be a real will to enter into negotiations. ETUC only wish to participate in the drafting of eventual guidance; CEEP does not exclude negotiations, EMF Alliance say they are open to negotiate; NHS-UK believes social partners would lack technical knowledge to complete such an exercise. Finally, BUSINESSEUROPE don't see the need for negotiations since they think the proposal of the Commission is good enough.

Annex 2

Current legislative situation in the EU Member States as regards exposure of workers to EMF

Sources of information

Official European Commission information

NATIONAL PROVISIONS COMMUNICATED BY THE MEMBER STATES CONCERNING:

Directive 2004/40/EC of the European Parliament and of the Council of 29 April 2004 on the minimum health and safety requirements regarding the exposure of workers to the risks arising from physical agents (electromagnetic fields) (18th individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC)

The official webpage of the EC reports the following situation:

For Belgium ,Bulgaria ,Denmark, Germany, Ireland, Greece, Spain, France, Cyprus, Luxembourg, Hungary, Malta, Netherlands, Poland, Portugal, Romania, Slovenia, Finland, Sweden and United Kingdom

there is no national law specific to the EMF Directive that has been finalised or published.

For seven countries:

Austria, Estonia, Latvia, Lithuania, Italy, Czech Republic and Slovakia

the European Commission is aware of national legislation. It should be noted that all these countries report that they intend to fully implement the EMF Directive by 2012 and therefore have not yet fully done so.

Austria

The Austrian legislation called VORNORM ÖVE/ÖNORM E 8850:2006-02-01 is available in German at:

http://www.beuth.de/langanzeige/OEVE%2FOENORM+E+8850/88537115.html

for a cost of 103.68 Euros. Discussion with Austrian colleagues indicates that this is little more than a translation of the ICNIRP guidelines and has no practical information on implementation.

Estonia

The relevant legislation is RT I 2002, 15, 83. We have obtained this standard in the Estonian language and it appears to be a translation of the IEEE EMF guidelines (although it has not been possible to obtain a translation) and therefore contains rather different limits than the EMF Directive itself.

Latvia

The Latvian legislation is available in English. The relevant legislation for the EMF directive is:

Cabinet Regulation No 745, Adopted 5 September 2006: Labour Protection Requirements for the Protection of Workers from the Risk Arising from the Electromagnetic Field in the Work Environment, issued pursuant to Section 25, Paragraph 18 of the Labour Protection Law

It is very close to the EMF Directive itself and does not contain any practical implementation information. Another document, Guide 1.6: "Labour Protection Requirements for the Protection of Workers from the Risk Arising from the Electromagnetic Field in the Work Environment" does have practical information.

Lithuania

The relevant legislation is:

Regulations on Protection of Workers from the Risks Arising From Electromagnetic Fields, approved by Order No. A1-119 of the Minister of Social Security and Labour of 25 April 2006 (Official Gazette, 2006, No. 47-1691)

Italy

The Italian legislation is:

Decreto legislativo 9 aprile 2008, n. 81, "Attuazione dell'articolo 1 della legge 3 agosto 2007, n. 123, in materia di tutela della salute e della sicurezza nei luoghi di lavoro" pubblicato nella Gazzetta Ufficiale n. 101 del 30 aprile 2008 Supplemento Ordinario n. 108

This Legislative Decree has 13 sections and 306 articles and 51 technical annexes. It covers many workplace risks and makes the general protection principles of the Framework Directive (391/89/EEC) binding from January 2009. The EMF part is based on Directive 2004/40/CE and is binding from April 2012. There is also a practical Guide to implementation:

Decreto Legislativo 81/2008, Titolo VIII, Capo I, II, III e IV sulla prevenzione e protezione dai rischi dovuti all' esposizione ad agenti fisici nei luoghi di lavoro. Prime indicazioni applicative

Czech Republic

The relevant Czech legislation is:

Nařízení vlády č. 1/2008 Sb., o ochraně zdraví před neionizujícím zářením

Legal act: Nařízení vlády , number: 1/2008 ; Official Journal: Sbirka Zakonu CR , Publication date: 09/01/2008

There is no English translation available. It appears to be very close to a direct implementation of the ICNIRP guidelines.

Slovakia

The relevant Slovakian legislation is:

Nariadenie vlády Slovenskej republiky č. 329/2006 Z. z. o minimálnych zdravotných a bezpečnostných požiadavkách na ochranu zamestnancov pred rizikami súvisiacimi s expozíciou elektromagnetickému poľu

Legal act: nariadenie , number: 329/2006 ; Official Journal: Zbierka zákonov SR , number: 113 , Publication date: 31/05/2006 , Entry into force: 01/06/2006.

There is no English translation available. It appears to be based on the EMF directive, but with considerably more background information.

The official European Commission information on the implementation status of Directive 2004/40/EC does not provide all available information. To supplement this, information was gathered using questionnaires sent to EU member states' regulators in 2007-2008 Directive, and then updated. This information is provided in the tables below.

Current status in each country regarding EMF Directive 2004/40/EC?

AUSTRIA	Transposition process finalized. Entry into force postponed until 30/4/2012
BELGIUM	Drafting regulations for the transposition of the EC Directive to the national legislation. On ice.
BULGARIA	Drafting regulations for the transposition of the EC Directive to the national legislation. On ice.
CYPRUS	Drafting regulations for the transposition of the EC Directive to the national legislation. On ice.
CZECH REP.	Transposition process finalized. Entry into force postponed until 30/4/2012
DENMARK	No additional information. On ice.
ESTONIA	Transposition process finalized. Entry into force postponed until 30/4/2012
FINLAND	The tripartite standing committee has drafted a Decree, but they are waiting for additional information as regards medical MRI technology. On ice.
FRANCE	The process of implementation, in progress, has been stopped due to the claim of Radiologists. On ice.
GERMANY	Implementation will be executed by means of an Ordinance. A Draft Ordinance is prepared by the Federal Ministry at present, so that the Directive can be implemented whenever required.
GREECE	No additional information. On ice.
HUNGARY	No additional information.
IRELAND	The first draft of the transposed Regulations has been prepared. On ice.
ITALY	The frame of a specific regulation on MR diagnostic equipment, mostly addressed to the protection of the patient, limits of exposure to magnetic static field for diagnostic MR workers are defined, similar to what established in ICNIRP guidelines of 1994. It is also established that SAR levels on the workers must not exceed the value given for the patient (that may reach 4 W/kg). NB: this is exceeding the limits of Directive 2004/40/EC
LATVIA	EU directive 2004/40/EC is already transposed in Cabinet Regulation No.745 "Labour Protection Requirements for the Protection of Workers from the Risk Arising from the Electromagnetic Field in the Work Environment" (Adopted 5, September 2006), will come into force whenever required.

LITHUANIA	Regulations on protection of workers from the risks arising from electromagnetic fields approved by the order of minister of social security and labour No. A1-119 of April 25, 2006. The regulations will come into force whenever required.
LUXEMBOURG	No additional information. On ice.
MALTA	No additional information. On ice.
NETHERLANDS	Drafting regulations for the transposition of the EC Directive to the national legislation. On ice.
POLAND	Regulation of the Minister of Labour and Social Policy, concerning permissible occupational EMF (and other environmental ambient factors) exposure, Journal of Laws 217/2002, item 1833 (in Polish). In addition, more than 10 regulations and several standards related to OSH practice (e.g. related to the Framework Directive provisions)
PORTUGAL	No additional information. On ice.
ROMANIA	No additional information. On ice.
SLOVAKIA	Order on the minimum health and safety requirements regarding the exposure of workers to the EMF of Slovak Rep. NO. 328/2006 Coll. in force from 1.6.2006. Delayed.
SLOVENIA	Drafting regulations for the transposition of the EC Directive to the national legislation. On ice.
SPAIN	The technical stage of the project has been completed. Legal tasks are being managed on the basis of the technical reports issued by the National Institute of Safety and Hygiene at Work. On ice.
SWEDEN	On ice.
UK	Working with key stakeholders with the aim of completing a detailed understanding of the impact of the directive, which will enable us to develop practical solutions and regulations to implement the directive. On ice

Existing National legislation/recommendation/standard dealing with the minimum health and safety requirements regarding the exposure of workers to the risks arising from electromagnetic fields (independently of Directive 2004/40/EC.

AUSTRIA	Standards.
BELGIUM	No.
BULGARIA	Ordinance No. 7/Governmental News No.88/1999 for the minimal requirements for healthy and safety work conditions; Bulgarian national standard (BNS) 14525-90.
CYPRUS	No.
CZECH REP.	The national Government Order No. 480/2000 Coll., available in Czech language on the website.
DENMARK	No
ESTONIA	Government decree no 54 (25.01.2002) "Occupational exposure limits and measurement of physical risk factors" in Estonian https://www.riigiteataja.ee/ert/act.jsp?id=12823094
FINLAND	A decree on high frequency equipment available in Finnish and Swedish.
FRANCE	No.
GERMANY	The accident prevention regulation BGV B11 "Electromagnetic Fields" with the additional BG Regulations BGR B11 have been released in 2001; BGV B11 at http://www.bgfe.de/bilder/pdf/bgv_b11_a03-2002.pdf and the BGR B11 at http://www.bgfe.de/bilder/pdf/bgr_b11_a06-2006.pdf .
GREECE	No
HUNGARY	No.
IRELAND	No.
ITALY	The national railway company Trenitalia published two standards (low and high frequencies) on EMF measurements on trains, both for workers and general public.
LATVIA	Cabinet Regulation No.745 "Labour Protection Requirements for the Protection of Workers from the Risk Arising from the Electromagnetic Field in the Work Environment" in English http://www.osha.lv/legislation/index.stm.

LITHUANIA	Lithuanian hygiene norm HN 110:2001 “Industrial frequency (50Hz) electromagnetic field in the working place. Permissible values of the parameters and measuring requirements” and labour No. 660/174 of December 21, 2001 in Lithuanian. Lithuanian hygiene norm HN 80:2000 “Electromagnetic field in the working places and living environment. Permissible values of the parameters and measuring requirements in 10 kHz-300 GHz zone” approved by the order of minister of health and No. 361 of June 27, 2000 in Lithuanian.
LUXEMBOURG	ITM-CL 179.4 - public document, only available in French language and the "RECOMMANDATION DU CONSEIL du 12 juillet 1999 relative à la limitation de l’exposition du public aux champs électromagnétiques (de 0 Hz à 300 GHz)".
MALTA	No
NETHERLANDS	Regulation on electromagnetic fields in Article 6.12 of the “Arbobesluit”.
POLAND	Polish Standard PN-T-06580:2002. Labour protection in electromagnetic fields and radiation of the frequency range from 0 Hz to 300 GHz. Part 1: Terminology. Part 3. Methods of measurement and evaluation of the field on the work stands (in Polish). Regulation of the Minister of Labour and Social Policy, concerning permissible occupational EMF (and other environmental ambient factors) exposure, Journal of Laws 217/2002, item 1833 (in Polish). Additional regulations related to pregnant workers and to young workers' exposure
PORTUGAL	No
ROMANIA	No
SLOVAKIA	Order of Slovak Rep. NO. 328/2006 Coll. Of Laws on the minimum health and safety requirements regarding the exposure of workers to the EMF (in force from 1.6.2006) in Slovak http://www.bozpo.sk/public/legis/bozp/06_329.pdf.
SLOVENIA	No.
SPAIN	Royal Decree 1066/2001, of September 28 (Official Journal of September 29) as amended by Royal Decree 424/2005, of April 15 (Official Journal of April 29) in Spanish http://www.mtas.es/insht/legislation/RD/radiofre.htm
SWEDEN	Current ordinance covers exposure for electromagnetic fields in the frequency range 3 MHz – 300 GHz and offers protection against thermal effects, the values given corresponds to the action values in the directive. In the low frequency range SWEA has no ordinance, only a prudent avoidance recommendation aimed towards magnetic fields at power frequencies.

UK	No specific UK legislation relating to control of personal exposure to EMFs. Control is exercised through the general duties of the Health and Safety at Work etc Act 1974, the Management of Health and Safety at Work Regulations 1999 and by reference to ICNIRP guidelines. http://www.hpa.org.uk/radiation/publications/documents_of_nrpb/abstracts/absd15-2htm http://www.hpa.org.uk/radiation/understand/information_sheets/icnirp_exp_guidelines.htm This is relevant to 50Hz exposures but is also used at higher frequencies, for example for MF and HF broadcast sites. Reports for these are published by BBC World Services in the European Broadcasting Union Technical Reviews http://www.ebu.ch/en/technical/trev/trev_305-emf.pdf and http://www.ebu.ch/en/technical/trev/trev_306-emf_hf.pdf .

Annex 3
Details on the new exposure limitation system proposed for option B and option C1 (except for MRI)

Option B and C1 introduce new and more practical exposure limits but also a more practical concept:

- The system distinguishes between the lower frequency range (0 to 100.000 Hz or 100 kHz) and for the higher frequency range (100 kHz to 300 GHz) because the effects on the human body are different.

- For the lower frequencies, options B and C1 introduce a new system ("zoning" or "layer" system) based on the revised recommendations. A first, simple, risk evaluation must enable the employer to position worker's exposure in zone 1 (relatively low exposure) or in zone 2 (higher exposure). If the result indicates that the exposure is in zone 2 an additional detailed risk assessment is needed. The kind and extend of the protective/preventive measures to be put in place will be a consequence of the outcome. The low range is actually the range where most of the compliance problems exist. Important sectors/activities such as electricity production and distribution, welding, industrial electrolysis, some induction heating systems, and also MRI are concerned.

- In line with the unchanged scientific recommendations, the limit values for higher frequencies remain as defined in Dir. 2004/40/EC.

When a worker is likely to be exposed to EMF under the current directive 2004/40/EC regime, an employer has to measure the existing electric and/or magnetic fields at the workplace. If the result(s) is (are) under the (frequency dependent) level of the so-called *action value*, no further action is required. If the measurement exceeds the *action value*, then the employer has to investigate and has to ensure by appropriate but rather complicated means that the actual *exposure limit value* has not been exceeded. This is a cumbersome activity and requires specific calculation techniques based on experimental models. There is no alternative and, as an additional complication, the current exposure limit values are expressed in non directly measurable variables.

It is important to note that in the "old" system adopted under Directive 2004/40/EC on the basis of the 1998 ICNIRP recommendations as well as in the new system based on ICNIRP 2010 and BMAs values the establishment of the exposure limit values are derived from the same "risk or hazard threshold" value above which all scientists recognize that there are direct effects. However, in order to take into account experimental errors, consequences of extrapolation from research on animals, differences between human groups (kids, elderly people), a safety factor has been introduced between the "risk or hazard threshold" and the actual exposure limit. This factor is 10 for workers in ICNIRP system. BMAs however considers that there is sufficient scientific evidence to be less conservative and the safety factor is only $\sqrt{10}$. According to BMAs authors this reduced factor reflects the improved knowledge in electrophysiology, biological diversity, modelling and measurement in the low frequency range. This approach can be considered as safe for workers.

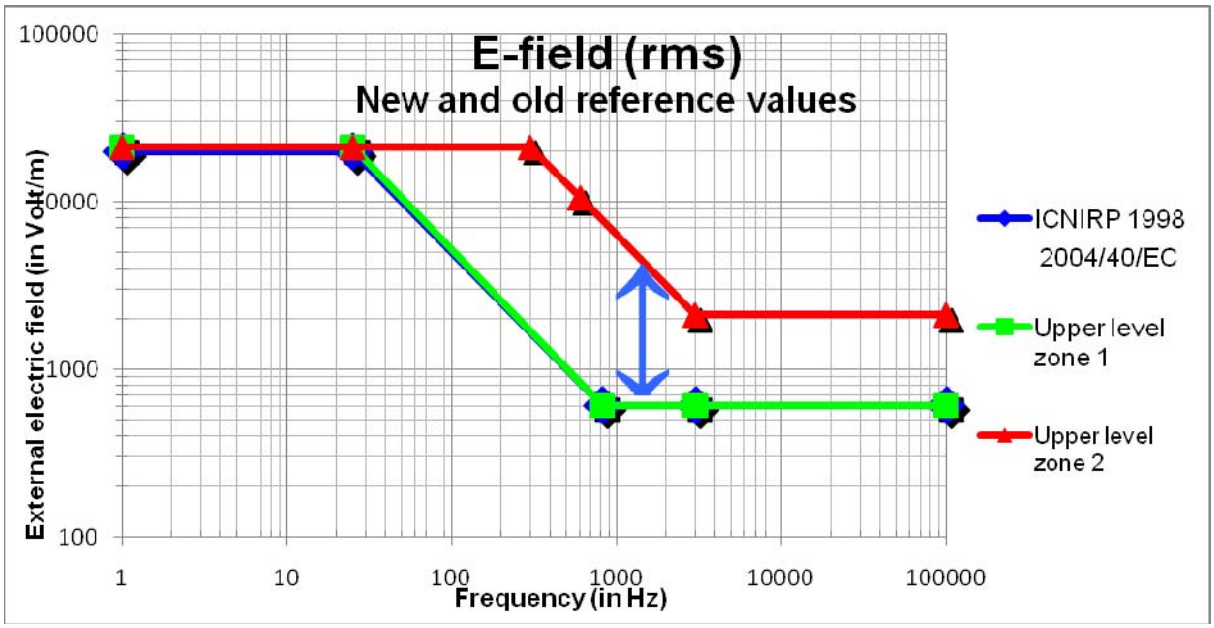
In the new proposed system, the unique and directly measurable value (*action value*) will be replaced in the low frequency range by a set of two values, a lower one (end of zone 1) and a higher one (end of zone 2). No sophisticated evaluation means will be necessary if an activity located in Zone 1 or Zone 2. Only the preventive measures will be different (more intensive in Zone 2).

The revised scientific recommendations allow to set the upper level of zone 2 significantly higher than the previous *action value* for most frequencies so that *de facto*, many actors who found themselves to be exceeding the former *action value* and were obliged to go for the extensive compliance check will now be in zone 2, i.e. under the upper level referred to above.

With this new system, it is expected that only a limited number of activities may need to go for the detailed compliance check. From recent information received from Dutch experts, only some MRI procedures and some induction heating installations would still be concerned. Some work areas in the electrolysis sector may also be affected.

In order to illustrate the principles laid down above, the figures hereunder show:

Figure 1: the old and new reference values for exposure to an <u>electric field</u>:



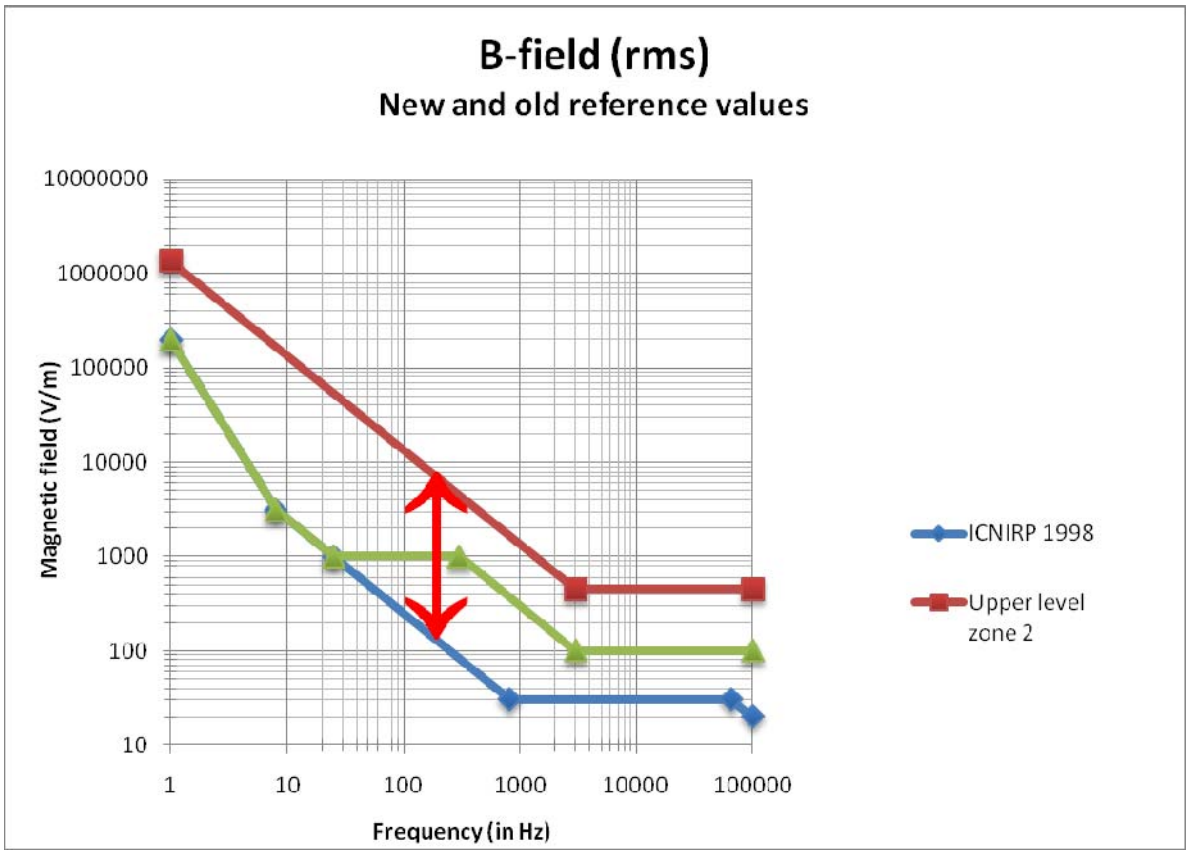
<u>In blue:</u> the figure shows the current *action values* for each frequency for electric fields. For any situation where the actual exposure level is higher than this *action value*, a comprehensive and rather complex compliance check has to be carried out.

<u>In green:</u> the proposed upper level of "zone 1": this separation is intended to classify some activities in the so-called "zone 1". The positive consequences will be that for those activities exposing workers under that level (guidance will be in an annex to the directive), no further action will be needed beyond clear signalisation (necessary to avoid access to special groups with implants or pregnant women for instance) and simple information to workers.

<u>In red:</u> upper level of "zone 2": if an activity cannot be classified in zone 1, verification (simple measurements) will be required to compare with this upper level. Preventive measures and more extensive training of the workers will be necessary. Guidance will be given in the directive.

In the few cases still exceeding this upper level, the situation will be similar to the situation under Directive 2004/40/EC. Exposure limits will however be expressed in more accessible variables (see figure 3). The differences between the old *action values* and the new values are of a factor of 5 or more, while for other frequencies, i.e. very low frequencies, the limit values remain untouched.

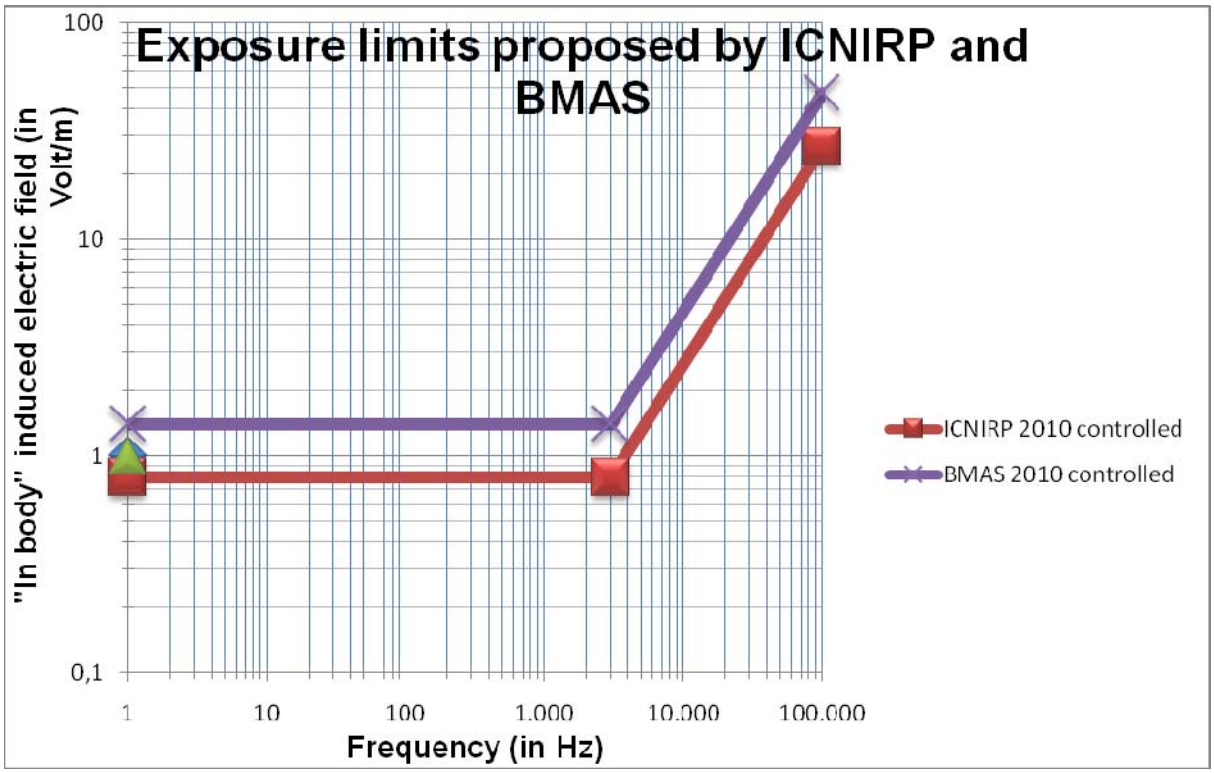
Figure 2: the old and new reference values for the B (magnetic)-field (in µT):



The same principles as for the electric fields will apply.

The current *action values* are in blue: in the past, every situation above that line required a comprehensive verification towards the actual limit values (see Figure 3). With the new system, all measured fields under the red line guarantee compliance with the exposure limits. Again, one can notice significant improvements (relaxation) for some frequencies. Moreover, for situations for which the exposure level is in zone 1, the compliance will be limited to very simple measures. Guidance will be given in the directive.

Figure 3: new exposure limit values (ELVs):



For the remaining situations, whenever the upper level of zone 2 is exceeded, a more comprehensive evaluation will have to be carried out (via modelling etc.). The results, expressed in "in situ" or "in body" induced electric fields, will have to be compared to the new exposure limit values of figure 3. Those ELVs are expressed in different units as the current ones and must not be exceeded. To enable the comparison between the actually measured level and the limit value specific calculations and modelling are required based on published models.

The exposure limit values proposed by BMAS and ICNIRP only differ by the choice of a different safety factor. The system would favour the use of slightly higher BMAS values (ICNIRP values times the square root of 3) to be consistent with the choice of the upper level 2 (see fig. 1 & 2) derived from the BMAS approach.

Examples of situations likely to be in Zone 1(from different sources)

For these cases, either nothing (offices) or a simple signalisation on the equipment or in the immediate vicinity should be sufficient.

Working environments for which it can be assumed a priori that the level 1 will not be exceeded are:

- offices (incl. computer equipment, cable networks, radio communication equipment; exc. tape erasers)
- hand-held motor-operated electric tools
- transportable motor operated electric tools (incl. electrically operated garden appliances)
- household and similar electrical appliances (incl. mobile equipment fitted with heating elements; battery chargers; heaters; vacuum cleaners for dirt and water; cookers, ovens and cooking elements for industrial and commercial use; heating elements for waterbeds; microwave ovens for industrial and commercial use)
- electrical installations:
  - low voltage network < 1000 V
  - low voltage components with power less than 200 kVA
  - workplaces at min. 60 cm distance from low voltage components with power not exceeding 1000 kVA
  - power transformers connected to low voltage networks (<1000 V between phases) with power up to 200 kVA
  - workplaces at min. 60 cm from power transformers connected to low voltage networks (< 1000 V between phases) with power not higher than 1000 kVA
- electric motors and electric pumps, subject to
  - the power being lower than 200 kVA
  - the workplace being at least 60 cm distance and the power not exceeding 1000 kVA
- testing instruments (exc. non-destructive magnetic testing)
- installation and maintenance
  - electrical hand-held tools (exc. welding equipment)
- detection of articles and people
  - RFID 1 Hz - 100 kHz
- electricity production and distribution

  - bus bars/conductor rails in substations
  - above ground high voltage cables
  - electricity substations
  - switch gear
- induction heating
  - automated systems
- welding
  - automated systems
  - arc welding - cable
- medical applications
  - shallow hyperthermia
  - pain control, stimulation of bone growth etc.
  - incubators, lamps for phototherapy, wireless communication systems etc.
  - deep hyperthermia
  - electrosurgery
- transport and traction systems
  - rail transport powered by direct current
  - vehicles, ships, aircraft
  - (large) electric motors
- transport and haulage systems
  - rail transport powered by alternating current (50 Hz; HSLs)
- detection of articles and people
  - EAS 0.01 - 20 kHz (magnetic)
  - EAS 20 - 100 kHz (resonant inductive)
  - metal detectors
- dielectric heating
- electricity production and distribution

- electrochemical processes (except specific places)
- induction heating
- research applications
- Other working environments
    - induction hobs in hotel & catering industry (food preparation)
    - tape erasers

Example of situations likely to be in Zone 2

For these cases, a clear signalisation and clear markings (or fences, guardrails, as appropriate) must be foreseen for delimitation. Simple measurements should also be made with a simple but well functioning device (measurement uncertainties do not play a role here). Specific training should be given to workers and foremen.

- plastic sealers
- wood gluing equipment
- power stations
- air cooled coils in capacitor banks
- current supply systems (bus bars)
- electrolysis hall (parts of)
- larger furnaces
- arc welding – cable
- MRI – during scanning
- use of - 'open magnetron'
- non-destructive magnetic testing

Examples of situations likely to exceed the upper level of Zone 2

For these cases, extensive and precise measurements have to be carried out for compliance verification with the exposure limits. Grids, fences or sufficient distance must guarantee avoidance of overexposure. Specific training should be given for workers and foremen.

- trouble shooting during installation and maintenance
- proximity of rectifiers in electrochemical processes
- induction heating (small melting furnaces)
- semi-automated spot and induction welding

- MRI (static and gradient fields)

Annex 4
Case studies to determine compliance costs

Note: these case studies are based on the surveys made by the FICETTI contractors in 2009. Figures have been modified on the basis of better information received since from stakeholders themselves and experts. Corrections have been introduced in the costs calculations made by FICETTI.

The aim of the case studies is to look at a company in a specific sector and try to quantify the impact of each policy option on that company in terms of compliance costs. The assessment of the impacts requires an interpretation of exactly what that company would have to do under each option. For the purpose of these case studies it was assumed by FICETTI that the assessments follow the general procedure set in the European Standard EN50499 on the assessment of workers' exposure to electric, magnetic and electromagnetic fields at the workplace. The compliance costs include also where necessary the cost of introducing the protection controls (procedures and/or hardware).

The case studies were conducted in UK, Finland and Poland.

The case studies have been made for the following types of workplaces and equipment:

(1) Electricity generation and transmission

(2) Electric welding

(3) Induction heating

(4) Surgical diathermy

(5) RF sealers

(6) Broadcasting

(7) MRI

The case studies were conducted in small and medium enterprises. The compliance cost per establishment obtained in these case studies is used as the unit cost for the calculation of costs per sector in Annex 5.

1. Case study: Electricity generation and transmission

- *Present situation*

  The electricity generation and transmission industry already effectively works to ICNIRP occupational EMF limits for both electric and magnetic field at 50 Hz.

- *Policy options impact*

  Policy Option A

  There may be some compliance issues, but these are problems that should already be addressed under the requirements of the Framework Directive.

  Policy Option B

  The impact of this policy option depends on the new limits. If the existing Action Values are changed to be more in line with Exposure Limit Values for electric fields, this could also reduce impact. As can be seen from figure I in annex 3, it is foreseen to have a slight relaxation at 50Hz.

  Policy Option C

  C1 would be acceptable as it is similar to the current situation. C2 would be a problem as arbitrary exemptions are not acceptable to workers of this sector. Costs would be unchanged.

  Policy Option D

  The costs would be the same as other options, but there is concern about the validity of sector-specific negotiated outcomes.

  Policy Option E

  Because the electricity industry already complies with ICNIRP guidelines, the costs for this option would be as A. However, there is concern that de facto national limits might be imposed if no pan-European legislative framework is developed.

  It is estimated that for the UK, the effort involved in occupational EMF compliance for the electricity generation and transmission industries requires approximately 2 persons with an average cost of 1250 €.

  Extending this to all EU countries with an estimated number of 3000 concerned workplaces, the approximate costs would be 3.75M Euros. This does not change with baseline or with policy option, as this sector will continue to comply with ICNIRP values:

Option	Cost per workplace (Euros)
A	1250
B	1250

C1	1250
C2	1250
D1	1250
D2	1250
E	1250

- *Summary*

  Electricity generation and transmission is effectively at Option A. There is likely to be very little cost difference across the various policy options, but the industry as a whole would prefer Option C1. Options D and E were rejected in the consultations.

2. Case study: Electric Welding

The survey was conducted in a medium-sized company in UK with between 100 and 200 employees. Good health and safety strategy were in place and implemented, with a health and safety officer/small team in place, though not full-time – they have other duties.

- *Present situation*

The UK Government in 2000 accepted the use of ICNIRP EMF guidelines, to replace the earlier single-tier NRPB guidelines. NRPB aligned its own advice on EMF exposure with ICNIRP in 2004. On those bases, the best available scientific advices, and stated government policy, are both to use ICNIRP guidelines.

HSE *itself*, as part of its response to the FICETTI questionnaire, stated that the UK position was:

"The HSE believes that this current system of regulations based on the Framework Directive, referencing the ICNIRP recommendations coupled with EMF guidance provide a satisfactory, proportionate system for controlling occupational exposure to EMF risks".

The authors of this case study visited HSE on 25th March 2009 to elucidate this matter further, and were informed that:

"HSE's approach is to use the ICNIRP basic restrictions not as an actual restriction, but as a starting point for exploring risk in more detail. The ALARP principle should be followed, and erosion of ICNIRP safety factors can be appropriate, if indicated by discretion and judgement."

From the interviews carried out by FICETTI, it appears that very few employers in the UK are aware of the HSE position; the authors of this case study have been very involved in occupational EMF assessment in the UK for many years, and have never seen it stated explicitly. Indeed, it is the experience of the authors that most companies (and probably almost all companies in the SME sector) have little-to-no awareness at all of EMF issues or any conception that any of their activities might be associated with any sort of EMF risk.

In practice, the regulatory situation in the UK for SMEs may be close to Policy Option E, with any investigation of EMF risk only likely to be triggered after worker concern has been expressed. Several larger enterprises have chosen to be more proactive and have voluntarily chosen to ensure that their employees' EMF exposures are below the ICNIRP basic restrictions (equivalent to the Exposure Limit Values of the EMF Directive).

Application of EMF Directive implementation framework

Welding companies have equipment which is beyond the a priori compliant workplaces and equipment listed in Table 1 of the European Standard EN50499. This means that an EMF assessment will be needed. Despite the requirements for equipment labelling contained in the Machinery Directive, little or no welding equipment currently on the market and designed for professional use is supplied with emission/exposure information.

The CENELEC welding standards require that a manufacturer shows compliance with general public exposure limits, but in general this is not equipment used in welding companies.

In the absence of manufacturers' information welding companies will need to make EMF exposure assessments. It is a feature of welding equipment that the high magnetic fields that they generate are localised to the regions close to the cables and welding arc so that there is no real need to consider the contributions of other equipment to exposure. This makes the assessment comparatively easy.

Expertise and costs

Very few welding companies have existing in-house expertise in the assessment of workers' exposure to electromagnetic fields. The main factors that would allow them to develop this expertise are:

- Resources (willingness of management to invest in the issue)
- Technical knowledge about processes and equipment
- Existing health and safety infrastructure
- Familiarity with measurement of other agents, such as noise
- Willingness to consider a new "problem"
- Acceptance that an assessment may identify situations where remedial action is needed.

It is possible that companies could invest the time and effort to develop this expertise, and if they chose to do so then the cost would likely be about ten person-days. The average wage for the sort of person who might be charged with this task (from the employer's side) is estimated at around 25k Euros per year (technician or recent graduate). Allowing 50% overhead, and 230 days at work per year, this is equivalent to approximately 1630 Euros. In addition to this is the cost of buying (or hiring) measurement equipment. The purchase of a suitable meter would cost approximately 4000 Euros; to hire one for four days might cost 500 Euros.

A measurement programme would probably trigger questions from employees about possible effects on health, and even questions about related issues such as mobile phones and overhead power lines. An exposure assessment programme would probably have to include the provision of authoritative health information to employees. It would be necessary to maintain up-to-date knowledge about the current scientific consensus in order to do this. There are very useful websites, such as those of the World Health Organisation, which are updated regularly and which provide rapid responses to particular media stories. However, it would require some effort to keep up-to-date, and this may prove to be a significant burden for a small-to-medium enterprise, or for a small health and safety team within a bigger organisation.

The alternative would be to rely on external expertise; the cost of a competent consultant is likely to be approximately 1500 Euros per day on site, and the work could be done in one day. The in-house actions to perform the measurement would include the cost of buying and maintaining a magnetic field meter (calibration costs are likely to be higher than purchase cost over time) and the cost of preparation of staff to conduct measurements.

- *Policy options impact*

Option A. Most welding machines produce exposures complying with the requirements of the EMF Directive, but may need application of e.g. Dimbylow approach[52], or possibly computational modelling. There is no real need for frequent monitoring unless the job changes – certainly not more frequently than yearly. The cost would be 1500 Euros for an external expert, plus perhaps 2 days' in-house activity to setup/manage the assessment and disseminate the information. The average wage for the sort of person who might be charged with this task (from the employer's side) is perhaps 25k Euros per year (technician or recent graduate). Allowing 50% overhead, and 230 days at work per year, this is equivalent to approximately 325 Euros. The total compliance cost per establishment is therefore at around **1825 Euros**.

It is assumed that a competent assessment will show that the welders are compliant with the requirements of the EMF Directive, or that simple low-cost measures (such as telling workers to not sit on cables) will be sufficient to demonstrate compliance.

There is not likely to be any impact on gender equality for welding; the existing hazards are such that any concerns about pregnancy outcome/effects on pregnant women will already be addressed by a reasonable employer.

The Directive requires an assessment of possible impact on AIMD[53] users, and there may be a cost associated with this assessment if there are any AIMD users in the workforce. It is very difficult to compare this cost with the situation with no EMF Directive; it is possible that the analysis would be cheaper under Option A than E because of the implementation framework (including CENELEC standards) that accompanies the Directive, and which should allow more focused and straightforward determination of any measures needed to restrict exposures of AIMD wearers. However, for the purposes of this case study this aspect is not considered further.

Option B has the same requirements as option A, but with different limits. The introduced guidance might allow in-house assessment if Actions Values were closer to ELVs, but in practice it may be cheaper to use an external expert and the costs will be as option A. Considering that 70% of the employers would continue to hire external expertise (1825€) and 30% would take advantage of in house expertise (325€), the average sectoral costs would be: **1375€**.

Options C1 and C2 are effectively the same as option B.

Option D1 is the same as B; the Framework Directive already requires a risk assessment that includes EMF; and if the exposure guidelines are based on the same limits as B then the costs would be the same: **1375€**

Option D2 Without knowing what these sectoral agreements would say, it's not possible to easily cost this option. Assuming that it will require some assessment, it is likely to require measurements anyway. So it would be equivalent to Option B: **1375€**

Option E This requires EMF to be considered as part of a general risk assessment under the Framework Directive. Without exposure limits, companies will use national exposure guidelines – in the UK this is the advice of HPA, which is equivalent to ICNIRP occupational guidelines but used as a starting point for risk management. In practice there

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52 Explain in footnote

53 AIMD - Active Implantable Medical Devices

is no advice on how to do risk assessment beyond the use of these guidelines and a welding company would need to seek outside help. In this respect it's probably more costly than option B if done properly. For the purposes of this case study it is costed as the same as option B.

Option	Cost per establishment (Euros)
A	1825
B	1375
C1	1375
C2	1375
D1	1375
D2	1375
E	1375

- *Summary*

  - Electric welding is a technology that falls within Table 2 of EN50499 and normally in zone 2 (annex 3). An EMF assessment will be needed.

  - There is little to no manufacturer's information available.

  - The welders can be treated as isolated sources in most situations – there is no need to consider summed exposures.

  - Options A-C provide a specific system (including CENELEC standards) for the assessment of exposure of workers with AIMDs that would not be provided by Options D and E.

3. Case study: Induction heating

The survey was conducted in a small company in UK with between 10 and 20 employees. Basic health and safety strategy was in place and implemented on an *ad hoc* basis. No OHS officer/team in place.

- *Present situation*

The UK Government in 2000 accepted the use of ICNIRP EMF guidelines, to replace the earlier single-tier NRPB guidelines. NRPB aligned its own advice on EMF exposure with ICNIRP in 2004. On those bases, the best available scientific advices, and stated government policy, are both to use ICNIRP guidelines.

In practice, the regulatory situation in the UK for SMEs seems close to Policy Option E, with any investigation of EMF risk only likely to be triggered after worker concern has been expressed. Several larger enterprises have chosen to be more proactive and have voluntarily chosen to ensure that their employees' EMF exposures are below the ICNIRP basic restrictions (equivalent to the Exposure Limit Values of the EMF Directive).

Application of EMF Directive implementation framework

Induction heating companies have equipment which may overpose workers working too closely to the furnace. This means that an EMF assessment will be needed. Induction heating equipment is usually specialised, and often unique in its configuration. There will be little or no emission/exposure information supplied by the manufacturer, and induction heating companies will need to make EMF exposure assessments.

Expertise and costs

Very few induction heating companies have existing in-house expertise in the assessment of workers' exposure to electromagnetic fields. The main contributors that would allow them to develop this expertise are:

- Resource (willingness of management to invest in the issue)
- Technical knowledge about processes and equipment
- Existing health and safety infrastructure
- Familiarity with measurement of other agents, such as noise
- Willingness to consider a new "problem"
- Acceptance that an assessment may identify situations where remedial action is needed.

It is possible that companies could invest the time and effort to develop this expertise, and if they chose to do so then the cost would likely be about ten person-days. The average wage for the sort of person who might be charged with this task (from the employer's side) is perhaps 25k Euros per year (technician or recent graduate). Allowing 50% overhead, and 230 days at work per year, this is equivalent to approximately 1575 Euros. In addition to this is the cost of buying (or hiring) measurement equipment. To buy a suitable meter would be approximately 4000 Euros; to hire one for four days might cost 500 Euros.

A measurement programme would probably trigger questions from employees about possible effects on health, and even questions about related issues such as mobile phones and overhead power lines. An exposure assessment programme would probably have to include the provision of authoritative health information to employees. It would be necessary to maintain up-to-date knowledge about the current scientific consensus in order to do this. There are very useful websites, such as those of the World Health Organisation, which are updated regularly and which provide rapid responses to particular media stories. However, it would require some effort to keep up-to-date, and this may prove to be a significant burden for a small-to-medium enterprise, or for a small health and safety team within a bigger organisation.

The alternative would be to rely on external expertise; the cost of a competent consultant is likely to be approximately 1500 Euros per day on site, and the work could be done in one day. Balanced against this is the cost of buying and maintaining a magnetic field meter (calibration costs are likely to be higher than purchase cost over time) and the cost of staff development.

- *Policy options impact*

Option A Many induction heating machines produce exposures which do not comply with the requirements of the EMF Directive and any assessment is likely to lead to measures having to be taken to reduce exposure by changing working practices. The cost of assessment would be 1500 Euros for an external expert, plus perhaps 2 days' in-house activity to setup/manage the assessment and disseminate the information. The average wage for the sort of person who might be charged with this task (from the employer's side) is perhaps 25k Euros per year (technician or recent graduate). Allowing 50% overhead, and 230 days at work per year, this is equivalent to approximately 325 Euros. Total estimate (step 1): **1825€**

There is very little that can be done to moderate exposures from induction heating equipment except change in working practice, which might include zoning. Practically, shielding is not effective for most induction heaters, though there my some benefit for higher frequency (100 kHz and upwards) machines that are physically small and are not already shielded.

It is assumed that changes in working practice would be successful in reducing exposures to below the ELVs of the EMF Directive 2004/40/EC. It is estimated that determination and implementation of such measures would require an external consultant for one day, at a cost of 1500 Euros (to determine and advise on necessary changes in working practice and to define areas to which access might need to be controlled). There would be an additional cost to the enterprise in implementing changes to working practices and zoning; this is estimated at 115 Euros of employee time (one day) and 75 Euros for signage and minor changes to the workplace; if barriers to control access were needed then the cost of these would be approximately 500 Euros. Total estimate (step 2): **2190€**.

The total compliance cost including the measurement of EMF by external expert and the following in-house and external expertise involved in ensuring the compliance as regards the protection controls for Option A would then be **4015 Euros** (1500 + 325 + 1500 + 115 + 75 + 500 = 4015 Euros). This is of course a "worst-case average" estimate; some induction heating companies will require no or few measures to moderate exposures; some may require significant physical changes to the workplace.

The Directive requires an assessment of possible impact on AIMD users, and there may be a cost associated with this assessment if there are any AIMD users in the workforce. It is very difficult to compare this cost with the situation with no EMF Directive; it is possible that the analysis would be cheaper under Option A than E because of the implementation framework (including CENELEC standards) that accompanies the Directive, and which should allow more focused and straightforward determination of any measures needed to restrict exposures of AIMD wearers. However, for the purposes of this case study this aspect is not considered further.

Option B has the same requirements as option A, but with different limits. It might allow in-house assessment if AVs were closer to ELVs, but in practice it will be cheaper to use an external expert and the assessment costs will be as Option A. It is likely though that the results of assessment would indicate that compliance problems would be much less widespread with this option because the induction heating frequencies that are most problematic are those where revised action values would allow higher exposures. Therefore the cost has been estimated at **2680€**, considering that 50% of the companies would hire external expertise (4015€) and the other 50% would decide for internal solutions (325+325+690 for implementing measures = 1340€).

Options C1 and C2 is effectively the same as B for these companies because most induction heating companies are unable to determine risk themselves: **2680€**

Option D1 is the same as B; the Framework Directive already requires a risk assessment that includes EMF; and if the exposure guidelines are based on the same limits as B then the costs would be the same.

Option D2 Without knowing what these sectoral agreements would say, it is not possible to easily cost this option. Assuming that it will require some assessment it is likely to require measurements anyway. So it would be equivalent to Option B.

Option E This requires EMF to be considered as part of a general risk assessment under the Framework Directive. Without exposure limits, companies will use national exposure guidelines – in the UK this is the advice of HPA, which is equivalent to ICNIRP occupational guidelines but used as a starting point for risk management. In practice there is no advice on how to do risk assessment beyond the use of these guidelines and an induction heating company would need to seek outside help. In this respect it's probably more costly than option B if done properly. For the purposes of this case study it is costed as the same as option B.

Option	Cost per establishment (Euros)
A	4015
B	2680
C1	2680
C2	2680
D1	2680

D2	2680
E	2680

- *Summary*

  - Induction heating is a technology that falls within Table 2 "Equipment likely to require further assessment" of EN50499. Exposure may exceed the zone 2 upper level (annex 3). An EMF assessment will be needed.

  - Exposures are likely to exceed the ELVs, and remedial measures such as guardrails and changes to working practices will probably be needed.

  - Options A-C provide a specific system (including CENELEC standards) for the assessment of exposure of workers with AIMDs that would not be provided by Options D and E.

4. Case study: Surgical diathermy

The presented case study concerns estimation of the impact of the defined policy options on the use of electrosurgical units in the medical care enterprises, based on the current situation in Poland.

There are approx. 2500 electrosurgical devices used in Polish hospitals (operating theatres, surgery rooms) and health centres – in about 1000 establishments in total. The number of devices in one establishment usually ranges between 1 and 15. In the largest hospitals even 30-40 units are used.

The surgeon is the most exposed person from the health care staff. The number of surgeons operating these devices in Poland can be estimated at 7500-10000, assuming that one device can be used by 3-4 doctors.

The total number of workers exposed to electromagnetic fields produced by electrosurgical units can be higher (approx. 15000-20000) when nurses, operating-theatre attendants, anaesthesiologists are included.

Case study was made on the base of 3 visits in health care establishments.

- *Present situation*

In Poland the Framework Directive 89/391/EEC is fully implemented. It means that all risks in the working environment (including those related to electromagnetic fields - EMF) should be identified and eliminated or appropriately limited. All requirements concerning detailed obligations for employers (systematic risk assessment, prevention of occupational risks and provision of information, training and education, medical surveillance) are justified by the provisions of general legislation called the Labour Code and others law regulations.

Poland has national mandatory legislation concerning occupational exposure to EMF (dated 1977 for frequency range 100 kHz – 300 MHz, covering EMF frequency produced by electrosurgical devices). The current regulation concerning the exposure limitations for EMF for the 0 Hz - 300 GHz frequency range was worked out in 1999 (recently issued by PL Journal of Laws 217/2002, item 1833). Separate occupational safety regulations have been also established regarding the obligation to carry out periodical testing of EMF existing in the working environment. Regulations are periodically revised and, if necessary, updated under the umbrella of the Interdepartmental Commission for Maximum Admissible Concentrations and Intensities for Agents Harmful to Health in the Working Environment, which is the scientific advisory body established by the Prime Minister of the Polish government. The last draft amendments concerned implementation of exposure limitation specified in the Directive 2004/40/EC into Polish law to reach full compliance of national regulations with Directive in this scope.

Special attention was paid to pregnant woman and young workers (below 18 years old). The thresholds of permissible occupational exposure for them were established as non-occupational exposure limits only (similarly to general public exposure).

According to national legislation, workers exposed to EMF are under medical surveillance with special focus on the cardiovascular and neurological functions. The medical

examination is repeated periodically for every 4 years. The ultimate decision about scope and frequency of surveillance is made by a physician.

Electrosurgical devices are sources of strong electric field and they are taken into account during worker's exposure and risk assessment (e.g. currently according to EN 50499). As a consequence of the long-standing EMF regulations concerning the electrosurgical devices in force the following requirements as regards the working conditions are met:

- workplaces are subject to occupational safety and health (OSH) periodical inspections (National Labour and Sanitary Inspectorate);
- the equipments that are sources of occupational exposure have been identified and labelled;
- health care staff using these devices is informed and trained (on exposure levels, procedures for avoiding hazards).

The above mentioned national requirements concerning workers exposed to EMF produced by electrosurgical units were effectively in place in the visited establishments.

- *Policy options impact*

Policy Option A

The assessment of surgeons and other health care staff (assisting physicians and nurses) exposure to EMF should be performed based on the results of measurements of electric and magnetic fields strengths. Currently all environmental factors (including EMF) can only be measured by testing laboratories accredited by the national accreditation body according to the requirements EN ISO/IEC 17025. Apart from this and in consideration of needed knowledge and experience, performing the measurements by the employer with the use of hired equipment is not permitted.

Because the level of exposure depends on: selected mode of device operation, type of active electrode used and location of cables connecting electrodes with the generator, the measurements should investigate the conditions of worst case of exposure adequate to typical working situations (e.g. the use the monopolar electrode, highest output power). It allows to evaluate the maximum level of exposure and simplifies the process of investigation (decreasing time of measurement session and costs). Another possibility to reduce the number of investigated devices and the costs of assessment is created by the fact that usually in the electrosurgical units of different types are used in similar conditions. The results of measurements for one device can be adapted for other.

The level of EMF exposure of medical staff can be assessed with the use of directly measured parameters: electric field strength, magnetic field strength. EMF exposure at the workplace are measured following the national legislations and standards or in the case of lack of such a document, following the internationally published standards. Polish standard PN-T-06580:2002 that determines a protocol for EMF measurements and workers' exposure assessment is harmonized with national mandatory legislation concerning occupational exposure to EMF.

The measurement results are the basis for the risk assessment and for appropriate technical and/or organisational measures for exposure mitigation. Of greatest importance is to give

sufficient information concerning possible risks related to work in the direct vicinity of EMF sources. Information on safe work practices is given to workers during initial (before employment) and periodic repeated occupational health and safety trainings. It demands accessible information (e.g. from papers, guides, internet) concerning methods of risk reduction and the effective use of them by employers. The reduction of the surgeon's exposure can be reached without special expenses by the proper positioning of the cables supplying the active electrode (e.g. by avoiding cables being in contact with the bodies of workers). The exposure of other persons from the medical staff is relatively weak if they do not have direct contact with the cables. These methods can be used without consultant's knowledge and help.

The costs of measurements are the main costs of health care staff risk assessment arising from electromagnetic fields produced by electrosurgical devices. The average cost of measurements for one device in Poland is approx. 80-120 Euro. Assessment of workers' exposure to electromagnetic fields, preparing guidelines for safe work, marking the device can be done by the establishments themselves on the basis of the measurement results. The cost of these activities would likely be about two person-days in case of the use up to 10 electrosurgical devices and proportionally higher for a greater number of units. The average wage for the sort of person who might be charged with this task (from the employer's side) is perhaps 25 k Euros (12k Euros in Poland) per year. Allowing 50% overhead, and 230 days at work per year, this is equivalent to approximately 325 (160) Euros for two days work. The total maximum cost with the measurements of 10 devices would be 1360 Euro (10 measurements@120€+160 for work. It is assumed that this would be twice this cost (**2720€**) when carried out in the "average country where the cost is 18.75€ per hour. The costs would be similar if external expert is hired to prepare the assessment and guidelines of methods of safe work.

Preparation of the risks assessment (measumrements), education, training and medical surveillance of workers with the reference to EMF do not impose additional costs on the establishments because these activities are conducted irrespective of the kind of environmental agent as a result of the implementation of Framework Directive 89/391/EEC

Considering the fact that electrosurgical devices usually produce strong electric fields and in accordance with Polish regulations, employment of pregnant women for activities in the vicinity of this equipment is prohibited. One of the important benefits is that mandatory regulations contribute to the well-being of employees who can feel safer if measures limiting their exposure are in place.

Policy Option B

The main approach to risk assessment mentioned above will not change. A new limit value can force the revision of thresholds of permissible occupational exposure in the national regulations. In consequence, theoretically it can affect the results of risk assessment, but practically significant changes in this scope are not possible.

Policy Option C

The main approach to risk assessment mentioned above will not change. There is no difference regarding the policy option C1 and C2.

Policy Option D

The lack of mandatory regulations can affect the level of protection against EMF and decrease knowledge and awareness of employers on occupational risk related to EMF exposure. Though requirements of Framework Directive 89/391/EEC will remain in force, it is possible that employers may try to avoid exposure assessment and the use of measures to decrease the risk level. There is no difference regarding the policy options D1 and D2.

Policy Option E

Poland has national regulations concerning occupational exposure to EMF. If they remain in force, exposure assessment is still realized as for Policy Option A. This situation can create problems in countries in which there are no national regulations. Employers should still comply with requirements of Framework Directive 89/391/EEC.

For the purposes of this case study the costs for different policy options would be similar (based on the situation in Poland, in the case of company with 10 electrosurgical devices):

Option	Cost per establishment – 10 devices on average (Euros)
A	2720 (1360)
B	2720 (1360)
C1	2720 (1360)
C2	2720 (1360)
D1	2720 (1360)
D2	2720 (1360)
E	2720 (1360)

- *Summary*

According to requirements of Framework Directive 89/391/EEC irrespective of any Policy Option the employers are obliged to perform risk assessment related to EMF produced by different sources (including electrosurgical devices). Suitable identification of anexisting problem is the first step. In case of electrosurgical units measurements of EMF at the workplace are needed. It will not be possible to avoid costs for the health care companies. Available information for employers about methods of risk assessment and reduction of the workers' exposure can decrease costs.

Mandatory regulations can increase the costs of companies but they give benefits for the workers (better feeling of safety and well-being and increasing knowledge as a result of training).

5. Case study: RF sealers

We assume we have a small company, hiring 10 people, and they are doing plastic welding, producing tarpaulins and lorry covers. The company has 4 RF sealers with a nominal frequency of 27 MHz. The company is located in Sweden.

- *Present situation*

Sweden has since 1987 had legally enforced limits for RF electromagnetic fields. These are somewhat stricter than those of the present EU directive from 2004. Sweden has also adopted the framework directive 89/391/EEC and has a demand for systematic work environmental risk assessment. So in principle not very much would change when the new directive will come in force.

- *Policy options impact*

Policy Option A

In principle to make an assessment of the exposure to radiofrequency fields from the RF sealers there is need to call in an expert. It is not possible for the company to do this by themselves since the emissions from the machines are very much dependent on how the installation is built, what plastic material is being welded, etc. Therefore there is only limited use of the manual from the manufacturer of the machine.

Both the electric and the magnetic fields have to be measured. The exposure is also very inhomogeneous and it is therefore necessary to do a spatial averaging of the fields over the body of the worker. Thre might also be a need for doing a time average of the measured values. In the frequency range the machine is working there is also a demand to survey the contact and the induced currents. Thus, there is a demand to measure 5 parameters: E, H, contact and induced current, and frequency.

When doing exposure assessments for radiofrequency fields one has to determine the worst case of exposure for a particular working situation. It is not always possible to cover all situations during one measurement session, but it is necessary to make sure that the exposure assessment is done as to take into account the worst case scenario.

It is usually not a question if the actions levels are exceeded or not, but rather how close can one come to the machine before they are exceeded.

To do the survey there is need for experts with the appropriate instrumentation and knowledge on how to use them. The time for each sealing machine to be under survey can be estimated to about 2 hours and about 1 hour for the work after the measurements in form of protocols and information of the outcomes to the employer and the workers.

For a company with 4 machines this would mean an expert time of 12 h. Added to this is the travel time since it is likely that the few experts that exist on this are not located nearby. The cost for the initial survey for this company could thus be estimated to be in the order of 3000 Euro (2 days).

The survey needs to be repeated on a regular time basis, perhaps every second or third year since the machines change over time if the maintenance program is not correct. These follow-up surveys should be less expensive since the previous protocol may be of help.

Policy Option B

This option would not change from the above since measurements are needed regardless of what the limits are since these machines produce intense RF fields, and it is not a question if you exceed the limits but rather how close to the machine you can go before exceeding the limits. Moreover, ELVs higher frequencies are not affected by the new limits (annex 3).

Policy Option C

The mandatory risk assessment would probably have to be done by external experts so there will be no difference towards with options A and B. There is also no difference regarding the policy option C1 and C2.

Policy Option D

With non binding recommendations it is questionable if the company will do an exposure assessment. However, a risk assessment carried out on the basis of recommendations or sectoral agreements would probably arrive at the same costs as for the previous options. There is no difference regarding the policy option D1 and D2.

Policy Option E

The cost of a proper risk assessment under the framework directive regime would also arrive to similar costs in this particular case.

With the Framework Directive were fully-implemented, all options would require EMF assessment and the costs for different policy options would become:

Option	Average cost per establishment (Euros)
A	3000
B	3000
C1	3000
C2	3000
D1	3000
D2	3000
E	3000

- *Summary*

For all options measurements are needed since the information from the manufacturer is seldom enough for a complete risk assessment. There is a need to measure the electric and the magnetic fields as well as induced and contact current. This calls for an expert to do and therefore the costs can be high.

6. Case study: Broadcasting

This case study deals with the occupational exposure to radiofrequency fields from broadcasting and telecommunication base station antennas during mast work. The stakeholder considered in this case study is an owner of the broadcasting towers/mast and has employees who are doing mast work (installations, maintenance). The case study is made in Finland and it considers mainly RF frequencies as lower frequencies are not an issue in the broadcasting towers.

- *Present situation*

Finland has legislation concerning the maximum allowed exposure to radiofrequency fields (f >100 kHz). Radiation authority of Finland has issued a guideline concerning radiation safety of the FM- and TV-station mast work based on this legislation. The exposure limits of the Finnish regulation correspond with the Directive 2004/40/EC in its current form. The employers and trade unions have also made together occupational safety guidance for mast work which considers also EMF. This guidance is in line with the Finnish legislation and gives more practical instructions.

The company has the resources and skills to make the exposure assessments by themselves. Workers wear personal EMF meters that will sound alarm in case the exposure limits are exceeded during the mast work. Mast workers have yearly safety training days in which the EMF issues are always included. Training includes the use of measurement devices and correct working practices close to the EMF sources. Mast workers are under medical surveillance in which a special attention is paid for the cardio respiratory, musculoskeletal, neurological and sense organ functions. The medical examination includes the national guidelines given for the medical examinations for working in jobs with high risk of health (item non ionizing radiation, Finnish Institute of Occupational Health, 2006). The medical examinations are made every three years for workers under the age of 40, every 2 years for workers under 50 and yearly for workers over 50. These medical examinations are mandatory for the license to work on broadcasting masts. Workers with pacemakers are not allowed to work at the broadcasting sites.

The EMF exposure has been measured in all TV and Radio broadcasting masts and based on these measurements the working practices have been made. Working practices may include safety time limits for staying at certain locations or the reduction of transmitting powers during work tasks. All workers carry personal alarm devices that sound alarm if the exposure limits are exceeded. Workers have been informed how to act in these cases.

- *Policy options impact*

Policy Option A

The present situation is already in line with the policy option A. However, broadcasting sites are very challenging places to make exposure assessments and for example measurements of limb induced currents may be difficult. If the procedures for exposure measurements are not clear additional costs may arise or compliance may be difficult to prove. Policy option A would, nevertheless, incur small costs as the company checks the compliance with the provisions. In this case it is estimated to take half days working time to do this task. The average wage for the sort of person who might be charged with this task (from the employer's side) is perhaps 45k Euros per year (engineer). Allowing 50% overhead and 230 working days in a year this is equivalent to approximately **150 €**.

Policy Option B

At this moment in time it is likely that the ICNIRP will not revise the guidelines for the RF frequencies in the near future:

"... it is the opinion of ICNIRP that the scientific literature published since the 1998 guidelines has provided *no evidence of any adverse effects below the basic restrictions and does not necessitate an immediate revision of its guidance on limiting exposure to high frequency electromagnetic fields." (Statement on the "Guidelines for limiting exposure to time-varying electric, magnetic and electromagnetic fields (up to 300 GHz). Health Physics 97(3):257-259; 2009.)*

Because of no new scientific evidence for higher frequencies, the system proposed for options B and C will no modify the ELVs in this range of the frequency spectrum. ICNIRP existing recommendations will be used as for directive 2004/40/EC.

Policy Option C

The broadcasting sector will not be concerned by any partial or complete exemption. Therefore, both options C1 and C2 would not have impact as the present situation would remain. The costs for checking the compliance would still apply being approximately 150 €, according to the estimate given in policy option A.

Policy Option D

In a case of non-binding occupational EMF exposure recommendation (D1) the current situation would not change as the recommendations would likely be based on ICNIRP recommendations that are the basis of the current practices. The costs for checking the compliance would still apply being approximately 150 €, according to the calculations given in policy option A.

In a case of voluntary agreements at European or sectoral level between social partners (D2) the impacts would likely be minor ones. The sectoral agreements would likely continue to uphold the present situation and the limits would have a scientific basis as this is the point telecommunication sector emphasises.

Policy Option E

This policy option would not change the current practices as the companies would likely uphold the current practices that have been proven effective. It may, however, produce problems if Member States have different national limits. Pan-European companies having expatriates may have difficulties if occupational exposure limits change according to the country. This may increase costs as more than one set of personal protective devices are required. Furthermore, it will be difficult to explain to the workers why the limits differ in the same task in different countries. This situation is considered to be very unlikely.

For the purposes of this case study the costs for different policy options would be:

Option	Cost per establishment (Euros)

A	150
B	150
C1	150
C2	150
D1	150
D2	150
E	150

Occupational health care and mast working licence practices are different in different Member States. In Finland the system for the mast workers periodical health checks is extensive but it is likely that the practices differ between member states. The economic impact of policy options for the costs of medical examinations would therefore differ greatly among member states. One of the problems related to the comparison of the costs is due to the fact that no internationally approved method for the health examinations or procedures exists.

- *Summary*

Broadcasting and telecommunication sectors are generally following the ICNIRP guidelines throughout the EU and therefore the impacts of the different policy options would be minor for the individual broadcasting/telecommunication companies. As the EU council recommendation on the limitation of exposure of the general public to electromagnetic fields (1999/519/EC) is based on the ICNIRP general public limits many EU member states have adopted ICNIRP based legislation/recommendation for the general public exposure. It is an advantage to the operators to have a common basis for both general public and occupational exposure limits. If either one is changed it might reduce the credibility of another one.

7. Case study: MRI

This case study is slightly different from the others in that it considers the totality of MRI usage in the EU rather than in an individual workplace. This is because it is very difficult to establish financial costs for each MRI facility – this will depend on the detailed usage modalities.

- *Present situation*

Background

There are millions of MRI patient examinations in the EU annually. It is estimated that there are approximately 8000 MRI suites and perhaps 110,000 (wherefrom 3000 installation/maintenance personnel) potentially-exposed workers[54]. Few workers will be exposed to the RF or switched-gradient fields – this will mostly be a problem for interventional procedures primarily, which are likely to be a few percent (6 to 8% as indicated in the main document) of the total number of MRI procedures. There may also be some RF or gradient field exposure of staff that have to be close to the bore during scanning, for instance when small children or people under medication are being scanned. So even outside interventional MRI there may be some RF and switched gradient exposure. However, the issue of workers moving through static fields will be an issue for all MRI systems.

Application of EMF Directive implementation framework

MRI suites can present a range of potential hazards – including the indirect effects of magnetic fields (such as projectile risk) and noise. There is therefore already a good risk management regime in place in MRI facilities. According to FICETTI any direct risk from EMF hazard has not usually been included explicitly in this regime as the practitioners consider that measures taken to minimise potential adverse consequences in patients will protect workers. The IEC 60601-2-33 standard has been extended to cover occupational EMF exposures from MRI, and used in conjunction with existing site guidelines on safe working, the MRI community considers that workers are fully-protected even though the EMF Directive exposure limit values will not always be met.

- *Expertise and costs*

MRI suites usually have access to high-quality advice on risk, and the MRI staffs are well-educated and aware of the totality of risk in their working environment. Where less EMF-aware staff has access to MRI facilities (for example cleaners) strict risk-management regimes are in place to address the other workplace risks. It is very likely that MRI facilities either have access to sufficient EMF expertise to be able to manage the direct EMF risk adequately or could develop it at low cost.

- *Costed policy options impact*

Option A It has been estimated that perhaps 500,000 MRI procedures would not be possible if Option A were fully-implemented. It might of course be possible to make

[54] These figures are based on ESR and COCIR data and differ from the figures given by FICETTI.

technical changes to MRI equipment (for example changing the gradient-field pulse shape) to reduce this number.

There will also be an effect on the commercial activities of MRI manufacturers, but like the extent and cost of technical changes, this is very difficult to estimate and is likely to be a rather small component of the total costs to society. For similar reasons, and because most of them operate within integrated healthcare systems, it is difficult to establish an exact financial cost to specific MRI facilities. However, there will be a cost to society of curtailment of MRI activities and whilst this may be primarily a health detriment, it may be possible to assign financial costs to it.

The FICETTI consortium asked the UK's Health Protection Agency to consider the potential shift from MRI to X-ray computed tomography (CT) that Option A might engender. Their calculations (details in the FICETTI report) indicate that the increased collective ionising radiation dose for workers in England and Wales might be 3-5 man Sv per year. This could be scaled by a factor of perhaps 10 for the whole EU. A financial cost of 50k Euros per man Sv is often used in ionising radiation optimisation, giving a total annual financial cost of perhaps 2.5M Euros[55].

The Alliance for MRI has provided a similar calculation for increased patient exposure to ionising radiation, and the corresponding figure is approximately 175M Euros. They also suggest a figure five times larger for lost “opportunity cost” from an inability to employ interventional MRI in the future, but this figure is very speculative indeed.

The Directive requires an assessment of possible impact on AIMD users, but again this is an issue that will already be addressed in MRI facility risk management systems.

In its calculations, FICETTI has considered the costs related to the shifting to X-rays as compliance costs although they are of a different nature: they apply to the general society and not to the employers; moreover, the sectoral cost for an effective risk assessment has been neglected because the MRI community considers that this aspects has already been covered because they are compliant with the IEC standards referred to above. This is of course not acceptable as such for Option A. Therefore, it has been estimated that under option A a comprehensive risk assessment should be carried out including measurements etc. As there are a number of similarities with the case of induction heating, the sectoral cost component has been estimated at **€4015**.

Option B The impact of this option will be equivalent to option A as far as compliance costs are concerned. Whatever the number of cases of overexposure, the extent of the risk assessment will be the same as for option A: **€4015**

Option C1 MRI facilities are already subject to an overall risk-management regime, and the practitioners are confident that they would be able to manage EMF risk even where the exposure limit values are exceeded. However, even if there are no exposure limit values to compare exposure with, a "light" risk assessment will remain mandatory. For a 2 days in-house expertise, the cost has been estimated at **€325**.

[55] In contrast with EMF, the effects of exposure to ionising radiation are well known and quantified. There are internationally accepted "health costs" for each dose increment to the society. This is valid for workers and patients as well.

Option C2 is complete exemption for the sector. This might be a low-cost option (effectively the same as Option C1): **€325**.

Options D1 Depending on the provisions laid down in the recommendations the obligations may be different in the Member States. On the other hand the Framework Directive already requires a risk assessment that includes EMF. It is difficult to estimate in how far this will affect the costs. The lack of precise rules for the carrying out of the additional risk assessment may end up in an increase of costs. The has been estimated to be the hiring of one day external expertise on top of the 2 days internal expertise: **1825€**

Option D2 The requirements of the employees may influence the content of the sectoral agreement in the sense of more verifications. This is estimated to be of the same order as for option D1: **1825€**

Option E: This requires EMF to be considered as part of a general risk assessment under the Framework Directive. There is a concern that without a pan-EU agreement in place on how to address MRI, there is the potential for health, social and economic inequalities between different countries. The result would probably end up with a compromise solution, different from Member State to member State: **1825€**.

Option	Cost per installation (Euros)
A	4015
B	4015
C1	325
C2	325
D1	1825
D2	1825
E	1825

- *Summary*

  - MRI facilities already have a risk-management framework in place.
  - MRI use would be profoundly affected by Option A, and probably B
  - Option A (and probably B) would lead to a health detriment for the society as well as a financial cost.

- *Additional costs for option C1*

This option foresees reinforced qualitative measures (see 4.1.3). This will mainly consist of specific training and refreshing sessions for the personnel working in medical MRI facilities. In this case cleaning, maintenance personnel and nurses likely to bring patients into the MRI room must be considered. Additional training for maintenance personnel is considered close to 0 as they already get extensive training on the subject; specific training for cleaning personnel (min. 3 per

installation) would be 0.5 day and for nurses and dedicated personnel (min. 10 per installation) 1 additional training day per person, during the first year. With a cost estimate of 150 € per day for approx. 110.000 persons brings the additional cost to approx. 14.25 Million Euros (3000 persons from maintenance, 24000 for cleaning, 83000 medical personnel).

Annex 5
Compliance costs for each option

Compliance costs are the costs of actions undertaken by establishments to meet to the requirements of the options. They entail three types of cost:

a) Generic costs

b) Sectoral or activity specific costs

c) Training costs

A) Generic compliance costs

Generic compliance costs are the costs of actions that employers have to undertake in order to understand the requirements and comply with them. This comprises a series of tasks starting with the analysis of the situation, the organisation of the risk assessment and the setting up of the action plan. The tables in Appendix 5a below presents the generic compliance costs for each policy option. For the calculation, a number of assumptions were made:

Number of concerned organisations: The total number of EU-27 enterprises in the non-financial business economy is estimated by Eurostat at around 20,000,000.[56] All of them are concerned by the first action (triage). The number of enterprises that need to undertake the following specific actions is estimated based on the presence of the relevant equipment for a given policy option. As set in Appendix 5b in total 215,140 workplace assessments would take place across sectors. It is estimated that based on these assessments around 60,000 employers after indentifying high exposure would need to develop their own action plan which could include several workplaces.

Tariff: The average EU hourly labour cost used in the study is 18.75 €. For comparison Eurostat's Labour Force Survey for the year 2008 indicates the average EU hourly labour cost of 16.13€ for Industry, construction and services (except activities of households as employers and extra-territorial organisations and bodies). Time needed to perform the actions: Based on the experts opinion as set in FICETTI study.

Appendix 5a - Generic costs summary

Policy option	Costs (Million Euro)
A	111.7
B	111.7
C1	111.7
C2	111.7
D1	39.4

[56] http://epp.eurostat.ec.europa.eu/cache/ITY_OFFPUB/KS-ET-10-001/EN/KS-ET-10-001-EN.PDF

D2	22.5
E	76.3

B) Sectoral or activity specific costs

The costs include the EMF measurement and the introduction of protection measures per sector for each policy option.

The cost per sector is based on the unit cost per establishment (derived from the case studies, Annex 4) multiplied by the number of workplace sites in the sector requiring an assessment.

This could be considered a yearly cost, if there are no substantial changes in the workplace design, equipment used or working procedures.

The table in Appendix 5b includes:

Sectors: Main types of activities where workers are exposed to EMF. For the military sector, the costs could be estimated only on speculative basis and are therefore omitted in the calculations.

Workers exposed and number of workplaces/assessments: Number of potentially affected workers and workplaces in the concerned sectors in the EU is estimated based on the information obtained from the stakeholders from several Member States (Netherlands, Slovenia, UK, Austria, France, Finland, Italy, France, and Sweden). Source: FICETTI report Appendix 6.

Cost per establishment: Compliance cost per establishment is estimated based on case studies conducted in small and medium size enterprises in the concerned sectors.

Appendix 5b - Sectoral or activity specific costs summary

Policy Option	Costs (Million Euro)
A	548.0
B	414.6
C1	385.1
C2	385.1
D1	397.1
D2	397.1
E	397.1

C) Training costs

The Framework Directive 89/391/EC sets the obligation for employers to provide the training and information, so the inclusion of EMF aspects into the overall existing OSH training may induce on average the cost of 300€. It is considered that the costs of providing training and information are the same for all the policy options. Training costs as estimated by FICETTI are consolidated on the basis of 300.000 establishments deemed to have one or more EMF sources. However this estimate

does not take into account the cost of workers' salaries during the time they are participating to the training. After correction the total figure of 0.1 become € 0.5 million.

Appendix 5c - Training costs summary

Policy option	Costs (Million euro)
all	0.500

Total compliance costs: A+B+C

Summary of total compliance costs for each option:

Policy Option	Compliance cost (Million Euros)
A: no change to EC/2004/40	660.2
B: new ELVs for all sectors	526.8
C1: possibility for derogation from ELVs	511.6*
C2: some workers out of scope	493.3
D1: non-binding recommendations only	437.0
D2: sectoral agreements only	420.1
E: no EU action	473.9

*including reinforced training for MRI

Appendix 5b. Sectoral costs

Sectors	Workers exposed	Number of workplaces/ assessments	Cost per establishment A	EU total	Cost per establishment B	EU total	Cost per establishment C1	EU total	Cost per establishment C2	EU total	Cost per establishment D1	EU total	Cost per establishment D2	EU total	Cost per establishment E	EU total
Metal industry	**1019000**	**162140**														
Welding	730000	**73000**	1825	133225000	1375	100375000	1375	100375000	1375	100375000	1375	100375000	1375	100375000	1375	100375000
Induction heating	150000	**75000**	4015	301125000	2680	201000000	2680	201000000	2680	201000000	2680	201000000	2680	201000000	2680	201000000
Dielectric heating	90000	**9000**	3000	27000000	3000	27000000	3000	27000000	3000	27000000	3000	27000000	3000	27000000	3000	27000000
Non-destructive magnetic testing	45000	**5000**	1825	9125000	1825	9125000	1825	9125000	1825	9125000	1825	9125000	1825	9125000	1825	9125000
Electrolysis	4000	**140**	4015	562100	1825	255500	1825	255500	1825	255500	1825	255500	1825	255500	1825	255500
Rail transportation	**120000**	**500**	1100	550000	1100	550000	1100	550000	1100	550000	1100	550000	1100	550000	1100	550000
Telecommunications &broadcasting	**39500**	**11000**														
Broadcasting	13500	**1500**	150	225000	150	225000	150	225000	150	225000	150	225000	150	225000	150	225000
Radar systems	20000	**3500**	1100	3850000	1100	3850000	1100	3850000	1100	3850000	1100	3850000	1100	3850000	1100	3850000
Mobile base stations	6000	**6000**	1100	6600000	1100	6600000	1100	6600000	1100	6600000	1100	6600000	1100	6600000	1100	6600000
Electric energy	**200000**	**3000**	1250	3750000	1250	3750000	1250	3750000	1250	3750000	1250	3750000	1250	3750000	1250	3750000
Health care	**211000**	**13000**														
MRI	111000	**8000**	4015	32120000	4015	32120000	325	2600000	325	2600000	1825	14600000	1825	14600000	1825	14600000
Surgical and therapeutic diathermy	100000	**5000**	272	1360000	272	1360000	272	1360000	272	1360000	272	1360000	272	1360000	272	1360000
Research	**1000**	**500**	1825	912500	1825	912500	1825	912500	1825	912500	1825	912500	1825	912500	1825	912500
Other	**50000**	**25000**	1100	27500000	1100	27500000	1100	27500000	1100	27500000	1100	27500000	1100	27500000	1100	27500000
Military	**250000**	**2500**														
Total (Million euro)			A	548.0	B	414.6	C1	385.1	C2	385.1	D1	397.1	D2	397.1	E	397.1

Figures not estimated in annex 4 are taken from the FICETTI report

Appendix 5a. Generic costs

Policy option A

No	Type of obligation	Description of required action	Target group	Estimated number of such organisations	Tariff (per hour)	Time (minutes)	Price (per action)	Total number of actions	Total generic costs (M€)
1	Triage	Understanding instruction from national authority that specific sectors need take no action	Organisations that implicitly do not need to do any assessment at all eg SMEs with no significant EMF sources	20000000	18,75	10	3,125	1	62.500
2	Background	Understanding general Directive requirements & implementation framework (Guide etc) at a basic level	All employers who may need to make an assessment	300000	18,75	30	9,375	1	2.813
3	Determine what assessment is needed	Assess whether the workplace is automatically compliant	All employers who may need to make an assessment	300000	18,75	15	4,6875	1	1.406
4	Detailed background	Understanding detailed Directive requirements & implementation framework (Guide etc) at a basic level	Employers with workplaces that are not automatically compliant	300000	18,75	480	150	1	45.000
								Total (M€)	**111,7**

Policy option B

No	Type of obligation	Description of required action	Target group	Estimated number of such organisations	Tariff (per hour)	Time (minutes)	Price (per action)	Total number of actions	Total generic costs (M€)
1	Triage	Understanding instruction from national authority that specific sectors need take no action	Organisations that implicitly do not need to do any assessment at all eg SMEs with no significant EMF sources	20000000	18,75	10	3,125	1	62.500
2	Background	Understanding detailed Directive requirements & implementation framework (Guide etc) at a basic level	All employers who may need to make an assessment	300000	18,75	30	9,375	1	2.813
3	Determine what assessment is needed	Assess whether the workplace is automatically compliant (Table 1 of EN50499 & Guide)	All employers who may need to make an assessment	300000	18,75	15	4,6875	1	1.406
4	Detailed background	Understanding general Directive requirements & implementation framework (Guide etc) at a basic level	Employers with workplaces that are not automatically compliant	300000	18,75	480	150	1	45.000
								Total (M€)	**111.7**

Policy option C1

No	Type of obligation	Description of required action	Target group	Estimated number of such organisations	Tariff (per hour)	Time (minutes)	Price (per action)	Total number of actions	Total generic costs (M€)
1	Triage	Understanding instruction from national authority that specific sectors need take no action	Organisations that implicitly do not need to do any assessment at all eg SMEs with no significant EMF sources	20000000	18,75	10	3,125	1	62.500
2	Background	Understanding general Directive requirements & implementation framework (Guide etc) at a basic level	All employers who may need to make an assessment	300000	18,75	30	9,375	1	2.813
3	Determine what assessment is needed	Assess whether the workplace is automatically compliant	All employers who may need to make an assessment	300000	18,75	15	4,6875	1	1.406
4	Detailed background	Understanding detailed Directive requirements & implementation framework (Guide etc) at a basic level	Employers with workplaces that are not automatically compliant	300000	18,75	480	150	1	45.000
								Total (M€)	**111.7**

Policy option C2

No	Type of obligation	Description of required action	Target group	Estimated number of such organisations	Tariff (per hour)	Time (minutes)	Price (per action)	Total number of actions	Total generic costs (M€)
1	Triage	Understanding instruction from national authority that specific sectors need take no action	Organisations that implicitly do not need to do any assessment at all eg SMEs with no significant EMF sources	20000000	18,75	10	3,125	1	62.500
2	Background	Understanding general Directive requirements & implementation framework (Guide etc) at a basic level	All employers who may need to make an assessment	300000	18,75	30	9,375	1	2.813
3	Determine what assessment is needed	Assess whether the workplace is automatically compliant	All employers who may need to make an assessment	300000	18,75	15	4,6875	1	1.406
4	Detailed background	Understanding detailed Directive requirements & implementation framework (Guide etc) at a basic level	Employers with workplaces that are not automatically compliant	300000	18,75	480	150	1	45.000
								Total (M€)	**111.7**

Policy Option D1

No	Type of obligation	Description of required action	Target group	Estimated number of such organisations	Tariff (per hour)	Time (minutes)	Price (per action)	Total number of actions	Total generic costs (M€)
1	Background	Understanding general EMF requirements & implementation framework in he absence of Diretcive and Guide etc	All employers who may need to make an assessment	300000	18,75	180	56,25	1	16.875
2	Understanding recommendations	Establishing relationship between any recommendation that is made and an employer's legal responsibility	All employers who may need to make an assessment	300000	18,75	120	18,75	1	11.250
3	Determine what assessment is needed	Assess whether the workplace is automatically compliant in the absence of a Directive	All employers who may need to make an assessment	300000	18,75	120	37,5	1	11.250
								Total (M€)	**39.4**

Policy option D2

No	Type of obligation	Description of required action	Target group	Estimated number of such organisations	Tariff (per hour)	Time (minutes)	Price (per action)	Total number of actions	Total generic costs (M€)
1	Background	Understanding general sector-specific requirements	All employers who may need to make an assessment	300000	18,75	120	18.75	1	11.250
2	Determine what assessment is needed	Assess whether the workplace is automatically compliant with sector-specific requirements	All employers who may need to make an assessment	300000	18,75	120	37.50	1	11.250
								Total (M€)	**22.5**

Policy option E

No	Type of obligation	Description of required action	Target group	Estimated number of such organisations	Tariff	Time (minutes)	Price (per action)	Total number of actions	Total generic costs (M€)
1	Triage	Understanding instruction from national authority that specific sectors need take no action	Organisations that implicitly do not need to do any assessment at all eg SMEs with no significant EMF sources	10000000	18.75	10	3.125	1	31.250
2	Background	Understanding general EMF requirements of Framework Directive in absence of guidance associated with EMF Directive	All employers who may need to make an assessment	300000	18.75	480	300	1	45.000
								Total (M€)	**76.3**

Appendix 5c. Training costs (as estimated by FICETTI)

No	Type of obligation	Description of required action	Target group	Estimated number of such organisations	Tariff (per hour)	Time (minutes)	Price (per action)	Freq per year	Total number of actions	**Total generic costs (M€)**
13	Training and informing	Organising training and informing	Employers with workplaces where exposures do not met requirements of Framework Directive	60000	18,75	60	18,75	0,33	1	0,00037125
14		Preparing training and information materials	Employers with workplaces where exposures do not met requirements of Framework Directive	60000	18,75	480	150	0,25	1	0,018
15		Providing training and information	Employers with workplaces where exposures do not met requirements of Directive	60000	18,75	480	150	1	1	0,072
									Total (M€)	**0,09**

Annex 6
Details on costs related to Administrative Burden

Policy option A

No	Type of obligation	Description of required action	Target group	Estimated number of such organisations	Tariff (I per hour)	Time (minutes)	Price (per action)	Freq per year	Total number of actions	Total Administrative Costs
1		Recording of EMF assessment results as required by national legislation	Employers who have made/had made an EMF assessment	30000	18,75	30	9,375	0,33	1	0,0928125
2		Notification to competent authorities (according to national requirements)	Employers in countries where this is required	30000	18,75	10	3,125	0,33	1	0,0309375
			Total					**millions euro**		**0,12375**

Policy option B

No	Type of obligation	Description of required action	Target group	Estimated number of such organisations	Tariff (I per hour)	Time (minutes)	Price (per action)	Freq per year	Total number of actions	Total Administrative Costs
1		Recording of EMF assessment results as required by national legislation	Employers who have made/had made an EMF assessment	30000	18,75	30	9,375	0,33	1	0,0928125
2		Notification to competent authorities (according to national requirements)	Employers in countries where this is required	30000	18,75	10	3,125	0,33	1	0,0309375
			Total					**millions euro**		**0,12375**

Policy option C1

No	Type of obligation	Description of required action	Target group	Estimated number of such organisations	Tariff (I per hour)	Time (minutes)	Price (per action)	Freq per year	Total number of actions	Total Administrative Costs
1		Recording of EMF assessment results as required by national legislation	Employers who have made/had made an EMF assessment	30000	18,75	30	9,375	0,33	1	0,0928125
2		Notification to competent authorities (according to national requirements)	Employers in countries where this is required	30000	18,75	10	3,125	0,33	1	0,0309375
			Total					**millions euro**		**0,12375**

Policy option C2

No	Type of obligation	Description of required action	Target group	Estimated number of such organisations	Tariff (I per hour)	Time (minutes)	Price (per action)	Freq per year	Total number of actions	Total Administrative Costs
1		Recording of EMF assessment results as required by national legislation	Employers who have made/had made an EMF assessment	30000	18,75	30	9,375	0,33	1	0,0928125
2		Notification to competent authorities (according to national requirements)	Employers in countries where this is required	30000	18,75	10	3,125	0,33	1	0,0309375
			Total					**millions euro**		**0,12375**

Policy option D1

No	Type of obligation	Description of required action	Target group	Estimated number of such organisations	Tariff (I per hour)	Time (minutes)	Price (per action)	Freq per year	Total number of actions	Total Administrative Costs
1		Recording of EMF assessment results as required by national legislation	Employers who have made/had made an EMF assessment	30000	18,75	30	9,375	0,33	1	0,0928125
2		Notification to competent authorities (according to national requirements)	Employers in countries where this is required	30000	18,75	10	3,125	0,25	1	0,0234375
			Total					**millions euro**		**0,11625**

Policy option D2

No	Type of obligation	Description of required action	Target group	Estimated number of such organisations	Tariff (I per hour)	Time (minutes)	Price (per action)	Freq per year	Total number of actions	Total Administrative Costs
1		Recording of EMF assessment results as required by national legislation	Employers who have made/had made an EMF assessment	30000	18,75	30	9,375	0,33	1	0,0928125
2		Notification to competent authorities (according to national requirements)	Employers in countries where this is required	30000	18,75	10	3,125	0,33	1	0,0309375
			Total					**millions euro**		**0,12375**

Policy option E

No	Type of obligation	Description of required action	Target group	Estimated number of such organisations	Tariff (I per hour)	Time (minutes)	Price (per action)	Freq per year	Total number of actions	Total Administrative Costs
1		Recording of EMF assessment results as required by national legislation	Employers who have made/had made an EMF assessment	30000	18,75	30	9,375	0,1	1	0,028125
2		Notification to competent authorities (according to national requirements)	Employers in countries where this is required	30000	18,75	10	3,125	0,2	1	0,01875
			Total					**millions euro**		**0,046875**

Annex 7

Questions (without additional comments and original layout) of the questionnaire on health, socio-economic and environmental impacts in connection with possible amendments to Directive 2004/40/EC

The questions were repeated for all the selected options.

1a. Does the option affect the likelihood of suffering from work-related illness? This may be an effect of EMF itself on a worker, it may be stress due to concerns about EMF (even if these may be unfounded) or it may be and effect or stress caused by any measures taken to comply with the EMF Directive?

1b. Does the option affect the job opportunities?

2a. Does the option affect the health risk of workers with pacemakers or other implanted medical devices (MD)? Please note that the EMF Directive requires that workers with active medical implants, and other sensitive workers, are considered explicitly.

2b. Does the option affect the job opportunities of workers with pacemakers or other implanted MD?

3a. Does the option affect the health risk of pregnant women?

3b. Does the option affect the job opportunities of pregnant women? Please note that this may include either worsened opportunities because EMF exposures are limited, or it may increase opportunities because a risk assessment as required by the EMF Directive may indicate that no particular risk for the pregnant worker or fetus occurs.,

4a. Does the option affect the health risk of fertile-aged women?

4b. Does the option affect the job opportunities of fertile-aged women?

5. Does the option increase or decrease the knowledge of employers and employees related to health risks arising from EMF?

6. During a risk assessment involving a lot of different health and safety risk factors, does the option increase or decrease the attention to exposure to EMF?

7. Does the option affect the number of EMF exposure assessments in your sector? The requirements to undertake EMF exposure assessments, and the circumstances in which they should or should not be made, are described in the Non-binding Guide to the EMF Directive which is available in draft form at www.indigo-emf.eu (password: ECIndigoLock).

8. Does the option affect the quality of EMF exposure assessments in your sector?

9. Does the option increase knowledge of employers on how to adequately manage occupational exposure to EMF?

10. How does the option affect preventive technical actions and organizational changes which will lead to a decrease of the risk level or/and to a decrease in number of workers exposed to health risks arising from EMF?

11a. Does the option increase or decrease the likelihood of incurring costs? These costs include immediate costs such as the costs of EMF assessments and remedial measures, and also deferred costs which might arise from changes in worker job satisfaction or concern that a health risk continues to exist in the workplace

11b. Does the option affect the costs of risk assessments in a company? Please note that the Non-binding Guide to the EMF Directive describes the circumstances in which risk assessment might be required and explains how this should be done

11c. Does the option affect the costs of training for workers at risk in a company? Please note that the Non-binding Guide to the EMF Directive describes the circumstances in which training might be required

11d. Does the option affect the costs of trainings for OSH specialists in a company?

11e. Does the option affect the costs of providing information in a company? Please note that the Non-binding Guide to the EMF Directive describes the circumstances, in which the provision of information might be required

11f. Does the option affect the costs of changes in work equipment at workplaces in a company? Please note that the Non-binding Guide to the EMF Directive describes the circumstances, in which changes in work equipment might be required

11g. Does the option affect the costs of changes in work organization in a company (including costs of ensuring limited access to areas where exposures exceed the exposure limit values)? Please note that the Non-binding Guide to the EMF Directive describes the circumstances in which changes in work organization might be required

11h. Does the option affect the costs of medical examinations of workers exposed in a company? Please note that the Non-binding Guide to the EMF Directive describes the circumstances in which medical examinations might be required.

12. Does the option impose additional administrative requirements for companies?

13. Does the option require companies in your sector to make significant changes in the way they conduct their operations?

14a. Do you foresee considerable difficulties in implementing the option in your sector or in your country?

15. Does the option affect the social safety of employers?

16. Does the option affect the well-being of employees?

17. Does the option affect the level of absenteeism?

18. Does the option affect productivity?

19. Does the option affect the work ability of workers?

20. The costs due to implementing EMF regulations will outweigh benefits?

21. Does the policy option affect training activities?

22. Does the option increase or decrease the inequality between different sized enterprises (large-scale enterprises, SMEs, micro-sized organizations) regarding their ability to obtain information about health risks arising from EMF?

23. Does the option increase or decrease the inequality between different sized enterprises (large-scale enterprises, SMEs, micro-sized organizations) regarding their ability to protect their employees against health risks arising from EMF?

24. Does the option increase or decrease the competitiveness of EU enterprises compared to non-EU rivals?

25. Do you think that the options presented here guarantee the same level of protection of the workers among the various sectors (health care, telecommunications, metal industry, rail transportation, etc.) or does any of them introduce a level of inequality?

26. Does the option stimulate or hinder the needs for research and development?

27. Does the option facilitate the introduction and dissemination of new production methods, technologies and products?

28a. Does the option facilitate or restrict the use of technological innovations in your sector?

29a. Please rank the different options regarding their suitability for the health care of the employees. Use "7" for the option with the strongest effect to "1" for the option with the lowest effect.

29b. Please rank the different options regarding their ability to make legislation easier to apply.

29c. Please rank the different options regarding their ability to decrease the administrative burden to employers.

29d. Please rank the different options regarding their efficiency in implementation and enforcement of prevention of health risks from EMF.

Annex 8
Estimated cost for cases of overexposure

According to current directive 2004/40/EC, in the case of overexposure a medical examination shall be made available to the worker(s). Accidental overexposure causes costs are generated from the diagnostics, treatment and health insurance (work inability, long- term disability) and from organizational managing of the case. If the risk assessment has been performed appropriately, the managing of the subject is more rapid and the costs are lower.

The investigation procedure depends on how well the exposure situation is known and on the symptoms and signs presented from the subject. The usual clinical symptoms of the acute overexposure that are investigated are skin or eye reactions. Symptoms to the nervous system, both central nervous systems (CNS) and/or peripheral nervous system (PNS) are also considered. More advanced methods in diagnostics might include neurological and laboratory studies.

The estimations of costs are presented in the following tables. The estimated total cost for any case of overexposure without any serious complications would be approximately 8 k€ (reference Finland). The cost increases considerably in case of complications. The use of the present international safety limits in the prevention of the overexposure has minimized the number of accidental overexposures in the working environment.

Table 1. Estimated medical examination costs in overexposure case.

Item	Details	Cost
Occupational physician	Two visits: evaluation of the present situation and planning of following steps	200 €
Consultation of medical specialists (neurology, dermatology, ophthalmology)	Visits and special examination techniques	1300 €
Dermatologist	One visit	300 €
Sick leave days	Wash out after the incident, 5 days á 300 € (The Social Insurance Institution of Finland has estimated the costs of one sick leave day to be 300 € on average)	1500 €
	TOTAL	**3200 €**
MRI examination (brain)	If required according to previous medical examinations	1000 €
Neurophysiologic tests	If required according to previous medical examinations	1000 €

Table 2. Estimated organisational costs in overexposure case.

The current information on exposure situation	Gathering and analysing existing information on the exposure situation. (Engineer 0.5 workdays)	147 €
Legal requirements	Communication with the authorities. (Engineer 0.5 workdays)	147 €
Office work	General office work related to overexposure situation (Office staff, 2 work days)	300 €
Mitigation	Technical measures to prevent recurring of the event (based on the induction heating case study, 'worst-case scenario')	4015 €
	TOTAL	**4609 €**

The costs per workday for an engineer are based on annual salary of 45 000 € and 50 % overhead. With 230 working days per year this leads to 293 € per working day. The costs per workday for office staff are based on annual salary of 23 000 € and 50 % overhead. With 230 working days per year this leads to 150 € per working day.

NB: These costs have been estimated for Finland, where the salaries are at the higher end of the spectrum. A quick extrapolation shows that in EU, this cost may vary from approx. €2000 to €4700 depending on the Member State (see sections 5.1.3 and 5.1.8).

Annex 9
Survey based assessment of the options

The social impacts do most prominently concern workers' health and potential losses of jobs. The economic impacts are: on the one side the actual costs of implementation and potential negative consequences of restricting some economic activities (i.e. not realising growth potential or technological progress), and on the other side they are the benefits of consistent rules all over Europe, less legal insecurity for the employers, and lower probability of certain accidents or work-related injuries.

When looking at the potential consequences of the different options, most impacts are difficult to quantify in a consistent way. Therefore it was chosen to consolidate the validity of the outcomes of the analysis of impacts by conducting an extensive stakeholder survey. This survey was organized in the framework of the FICETTI study, taking advantage of the presence at the Ljubljana workshop in February 2009 of a large number of stakeholders representing a significant number of important sectors.

166 stakeholders' representatives replied to the questionnaire wherefrom:

Government/regulator	11 %
Sectoral organization representing employers	15 %
Trade union organization	7 %
Research Centre/university	10 %
OSH specialists/consultants	5 %
Health care	18 %
Large-scale enterprise (> 250 employees)	24 %
SME (10 < employees < 250)	3 %
Micro-sized enterprise (< 10 employees)	0 %
Self-employed	0 %
Other	6 %

Expressed by sector, the partition is as follows:

Rail transportation	4 %
Metal industry	15 %
Health care sector	34 %
Telecommunications or broadcast	8 %
Electric energy production/distribution/transmission	7 %
Other	32 %

156 (94%) of the respondents were aware of the requirements set in Directive 2004/40/EC. In so far it can be said that the respondents were well informed about the ongoing debate.

There were 30 questions (some with sub questions) in the questionnaire (see questions in annex 6). The latter addressed health aspects, competiveness, social, administrative aspects in

a very comprehensive way. The results were duly affected by the appropriate weighting factors.

The conclusions of the survey reflect the opinions of the participating stakeholders and can be summarized as follows:

- Option A is generally considered to have disproportionate economic costs, especially for SMEs

- Option B was difficult to assess in the absence of new exposure guidelines from ICNIRP at the time of the survey. Stakeholders believe Option B has rather high economic consequences but it scores well on social and health impacts

- Option C1 is the only option to score consistently positively in this survey based analysis, despite the fact that the new exposure guidelines were not known at the time just like for Option B. It seems that the announced flexibility and proportionality gave the breakthrough.

- Option C2 scores badly on economic and neutrally on health and social impact grounds, leading to an overall negative score.

- Options D and E score badly on health and social impact grounds. Option E especially is unpopular with stakeholders.

Annex 10
Glossary

Action values (AVs): in the current directive 2004/40/EC, the magnitude of directly measurable parameters, provided in terms of electric field strength (E), magnetic field strength (H), magnetic flux density (B) and power density (S), at which one or more of the specified measures in the directive must be undertaken. Compliance with these values will ensure compliance with the relevant exposure limit values.

Electromagnetic fields: static magnetic and time-varying electric, magnetic and electromagnetic fields with frequencies up to 300 GHz;

Equipment: any device or hardware concerned by the EMF issue and producing electromagnetic fields when operating.

Exposure level: intensity of the radiation to which a person is exposed. The exposure level is expressed in Volt per meter (V/m) for the electric field strength and in Amperes per meter (A/m) for the magnetic field strength. For the magnetic field, this value is often replaced by the magnetic flux density expressed in Tesla (T). The relation between both is $B=\mu H$, where μ is the magnetic permeability of the material involved.

Exposure limits (Els): same as Exposure Limit Values (below)

Exposure limit values (ELVs): limits on exposure to electromagnetic fields which are based directly on established health effects and biological considerations. Compliance with these limits will ensure that workers exposed to electromagnetic fields are protected against all known adverse health effects.

Risk assessment: As a component of risk analysis, it involves identification, evaluation, and estimation of the levels of risks involved in a situation, their comparison against rules or standards, and determination of appropriate preventive and/or corrective measures to eliminate or reduce the risk.

Acronyms and abbreviations

AV(s) – Action Values

AIMD – Active Implantable Medical Devices

ALARA – As Low as Reasonably Achievable

ALARP – As Low as Reasonably Practicable

CENELEC – European Committee for Electrotechnical Standardisation

COCIR - European Coordination Committee of the Radiological, Electromedical and Healthcare IT Industry

EAS – Electronic Article Surveillance

ELF(s) – Extremely Low frequencies

ELV(s) – Exposure Limit Values

EMF – Electromagnetic Fields

ESR – European Society of Radiology

HF(s) - High Frequencies

HPA – Health Protection Agency (UK)

HSE – Health and Safety Executive (UK)

ICNIRP – International Commission on Non-Ionizing Radiation Protection

IEC – International Electrotechnical Committee

IEEE - Institute of Electrical and Electronics Engineers

IF(s) - Intermediate Frequencies

LF(s) – Low Frequencies

MRI – (medical) Magnetic Resonance Imaging

NRPB – National Radiological Protection Body (nowadays **HPA**)

RF – Radiofrequencies

RFID – Radiofrequency Identification

TFEU – treaty on the Functioning of the European Union