EUROPEAN COMMISSION

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Proposal for a

DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

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

{SEC(2011) 750 final}
{SEC(2011) 751 final}

EXPLANATORY MEMORANDUM

1. CONTEXT OF THE PROPOSAL

- **Grounds for and objectives of the proposal**

The aim of this proposal is to amend Directive 2004/40/EC[1] 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).

In 2006, the medical community informed the Commission of its concerns regarding the implementation of this Directive, claiming that the exposure limit values laid down therein would limit to a disproportionate extent the use and development of magnetic resonance imaging (MRI), considered today to be a vital tool for the diagnosis and treatment of several diseases.

Subsequently, other industrial sectors also expressed their concerns about the impact of the Directive on their activities.

In response to these concerns, the Commission has taken a number of measures. For reasons of transparency, it contacted the Member States and the European Parliament to inform them of the measures it planned to take. In this context, it asked the Member States to inform it of any difficulties associated with implementation of the Directive. It also launched a study to assess the actual impact of the Directive on medical procedures using MRI. The results of this study were made available in early 2008.

Meanwhile, in order to:

- allow a full analysis of the studies, including that launched by the Commission, regarding the potential negative impact of the exposure limit values set by the Directive on the medical use of MRI;

- take into account the results of the review of the new ICNIRP recommendations, and other recent recommendations such as the WHO's environmental health criteria for electromagnetic fields based on the latest scientific studies concerning the impact of electromagnetic fields on human health, published since the adoption of Directive 2004/40/EC, and, finally,

- conduct an in-depth impact analysis of the Directive's provisions and propose amendments in order to guarantee both a high level of health and safety protection for workers and the continuation and development of medical and industrial activities using electromagnetic fields,

the deadline for transposition was put back from 30 April 2008 to 30 April 2012 by Directive 2008/46/EC[2] 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).

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1 OJ L 184, 24.5.2004, p. 23.
2 OJ L 114, 26.4.2008, p. 88.

The International Commission for Non-Ionising Radiation Protection (ICNIRP) has now finalised its review of the guidelines on static magnetic fields and low-frequency time-varying fields on which part of the Directive is based. New recommendations were issued in 2009 and 2010, respectively. In most cases, the reference levels and basic restrictions are set at higher levels than in the previous recommendations.

- **General context**

Directive 2004/40/EC is the 18th individual Directive within the meaning of Article 16(1) of Council Directive 89/391/EEC of 12 June 1989 on the introduction of measures to encourage improvements in the safety and health of workers at work. It relates to the short-term adverse health effects on workers exposed to electromagnetic fields during their work.

The provisions of the Directive are minimum requirements, with each Member State free to adopt stricter rules.

The Directive establishes exposure limit values for electric, magnetic and electromagnetic fields varying in time at frequencies of between 0 and 300 GHz[3]. No worker may be exposed to values exceeding these limits, which are based on the health impact and biological considerations.

The Directive also sets action values and orientation values for time-varying and static fields. These values are directly measurable and indicate a threshold above which employers must take one or more of the actions provided for in the Directive. Compliance with these action values will ensure compliance with the relevant exposure limit values.

The limits imposed by the Directive were established on the basis of the recommendations issued by the ICNIRP in 1998, the organisation internally recognised as the authority on assessment of the health impact of this type of radiation. The ICNIRP works closely with all the relevant international organisations, such as the WHO, ILO, IRPA, ISO, CENELEC, IEC, CIE, IEEE, etc.

The Directive is based on the prevention philosophy already set out in more general terms in Framework Directive 89/391/EEC:

– protection of all workers: whatever their sector of activity, whereby workers exposed to the same risks have the same right to be protected;

– obligation on employers to determine and assess risks;

– elimination or, where this is impossible, minimisation of risks identified;

– specific information and training for and consultation of the workers concerned;

– appropriate medical surveillance.

The Directive applies to all sectors of activity without exception and has to be transposed into national legislation no later than 30 April 2012 if no further action is taken**.**

[3] 300 GHz: frequency of 300 billion hertz or cycles per second. The hertz (abbreviation Hz) is the international unit of frequency.

During the discussions preceding its adoption, the specific case of medical resonance imaging was discussed in detail by both the Council and the European Parliament. National experts from institutions such as the National Radiation Protection Board (NRPB, UK), the *Institut national de recherche et de sécurité* (INRS, France), the Finnish Institute of Occupational Health (FIOH, Finland) and the *Bundesamt für Strahlenschutz* (BfS, Germany) provided technical support for the negotiations in the Council. The Council Presidency sought, on several occasions, the opinion of the ICNIRP.

In the absence of any evidence of an undesirable impact, the joint legislators adopted the Directive, with certain amendments to the values originally proposed by the Commission, in particular not setting an exposure limit value for static magnetic fields, an essential component of MRI, because this value was being amended in the light of the latest scientific findings, which appeared as the Directive was being adopted.

This proposal maintains a number of important principles and provisions in the present Directive, such as:

– coverage of all sectors of activity ,

– exposure limit values and action values for electromagnetic fields in the frequency range from 100 kHz to 300 GHz,

– provisions aimed at avoiding or reducing risk,

– information and training of workers,

– consultation and participation of workers,

– sanctions,

– medical surveillance.

The most important changes introduced by the proposal, taking into account the latest scientific findings in this area, are the following:

– clearer definitions, in particular for adverse health effects (Article 2 of Directive 2004/40/EC),

– inclusion of a revised system for limit and reference values different from the current limit values and action values for the range from 0 to 100 kHz (this will affect Articles 2 and 3 of Directive 2004/40/EC plus its annex),

– introduction of indicators to facilitate measurements and calculations (Article 3(3)) and to give guidance on taking measurement uncertainties into account. Product safety legislation set by Directives 1999/5/EC and 2006/95/EC ensures that the public, including workers are not exposed to levels beyond those set by Recommendation 1999/519/EEC, provided that the products are used as intended. Since levels set for the public are lower than those set for workers and include protection against long-term effects, compliance with these Directives provides for sufficient protection under this Directive in these situations.

– introduction of some guidance to ensure simplified but more efficient risk assessments (Article 4) in order to facilitate the evaluation work and also to limit the burden on SMEs, ,

– introduction of limited but appropriate flexibility by proposing a controlled framework for limited derogations for industry,

– inclusion of a rationale for medical surveillance (Article 8),

– special attention to the specific case of medical applications using magnetic resonance and related activities, and

– provision for complementary non-binding measures such as a non-binding practical guide.

- **Consistency with other European Union policies and objectives**

This proposal is consistent with the objectives of other policies of the European Union, in particular those for the improvement of the regulatory framework in order to develop a clear, understandable, up-to-date and user-friendly body of secondary EU legislation, in the interests of citizens and economic operators. It will also enable the provisions of the current Directive to be updated in the light of the latest scientific findings on the impact of electromagnetic radiation on health, which were not yet available at the time of the adoption of Directive 2004/40/EC. It furthermore is intended to be consistent with related legislation that protects users of products that produce EMF in so far that it does not require that EMFs from such products have to be reassessed under this Directive but can be presumed as being below the levels set for the public in Council Recommendation 1999/519/EEC.

2. CONSULTATION OF INTERESTED PARTIES AND IMPACT ASSESSMENT

- **Consultation of interested parties**

- Consultation of the Advisory Committee for Safety and Health at Work, in accordance with the Council Decision of 22 July 2003 setting up an Advisory Committee on Safety and Health at Work. The Committee has been invited to adopt an opinion by the end of March 2011.

- Consultation of scientific experts in this area and the International Commission for Non-Ionising Radiation Protection at bilateral meetings with the Commission.

- Consultation of the social partners in accordance with Articles 154(2) and (3) of the Treaty on the Functioning of the European Union (TFEU). The first consultation (Article 154(2) TFEU) took place between 1 July and 10 September 2009. The second stage of consultation under Article 154(3) took place between 20 May and 5 July 2010 and was carried out independently from the impact assessment.

The results can be summarised as follows:

- In general, both trade unions and employers agree that there is a justified need for a new Directive to protect workers from the health risks caused by exposure to electromagnetic fields. However, certain employer representatives (SMEs and some national organisations) indicate their preference for non-binding instruments instead of a Directive.

- It is commonly accepted that the limit values in the current Directive are too low and based on too conservative assumptions; but while the employers are in favour

of relaxing the limits, the workers' representatives want the long-term health effects to be covered in the future Directive.

- Exempting some categories of workers from the scope of the Directive is not welcomed by employers in the industry sector (except MRI equipment manufacturers). Also, allowing derogations from exposure limits in specific branches (health care) poses some problems for the industry sector.

- The social partners confirm that no category of workers should be excluded from the benefits of any new legal instrument, provided that the new instrument gives the appropriate flexibility needed to allow activities to be continued.

- While employers are very much in favour of a flexible approach also allowing for exceptions, workers' organisations fear that flexibility may reduce the protection of workers unless there are strict controls.

- Adaptation of the exposure limit values defined in the current Directive is acceptable to both employers' and workers' organisations, along with the introduction of a zoning approach to allow for light risk assessments in less problematic situations. There is also a consensus on the importance of operational guidance.

- Medical checks after situations of overexposure above the limit values are welcomed as a default approach by the trade unions. Employers' organisations and the medical profession raise doubts as to whether this is reasonable for the low frequency range, where it might be difficult to detect effects.

- Derogations from the limit values for the medical sector to facilitate MRI treatment are viewed with scepticism by other sectors, whereas trade unions recommend a sunset clause to avoid the erosion of protective legislation.

- **Gathering and use of expertise**

The Commission consulted with internationally recognised scientific experts on the health impact of electromagnetic radiation. The Commission also launched the study referred to above to determine exposure levels for medical staff and their impact on the procedures used for medical MRI.

- **Impact assessment**

From discussions and consultations with stakeholders, the following options emerged:

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.

Policy option B: 'New Directive with revised exposure limits'

Directive 2004/40/EC is replaced by a new Directive with revised exposure limit values that are higher than the previous ones, but are in line with scientific evidence.

Policy option C1: 'New Directive with revised exposure limits and partial exemptions'

Directive 2004/40/EC is replaced by a new Directive with revised exposure limit values higher than the previous ones, but in line with scientific evidence (as in option B). In addition, conditional exemptions are provided for MRI, which will however remain subject to the general EMF risk management requirements and covered by the new Directive.

Policy option C2: 'New Directive with revised exposure limits and complete exemption for MRI'

Directive 2004/40/EC is replaced by a new Directive with revised exposure limit values higher than the previous ones, but in line with scientific evidence (as in option B). Medical MRI will be exempted entirely from all the requirements of the EMF Directive.

Policy option D1: 'Replacement of the Directive by a Recommendation'

Directive 2004/40/EC 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 Council Recommendation on EMF exposure of the general public (1999/519/EEC).

Policy option D2: 'Voluntary agreements between the social partners'

Directive 2004/40/EC is replaced by voluntary agreements at European or sectoral level between social partners in accordance with Article 154(4) TFEU.

Policy option E: 'No EU legislation'

Directive 2004/40/EC is repealed while Directive 89/391/EEC (Framework Directive) and existing national regulatory provisions on the subject remain in force. The absence of national regulations in some Member States will allow unregulated occupational EMF exposures. For this option, it may be assumed that for example those countries which have already (partially) implemented the EMF Directive would not repeal their EMF legislation.

These options were considered as relevant by the stakeholders. Alternative options not analysed in detail include adopting a more sectoral approach, restricting legislation to the provision of safe equipment or exclusively focusing on 'soft' policy instruments such as information campaigns and guidance documents.

The current proposal is in line with Option C1. Option C1 is also acceptable for a large majority of stakeholders. The compliance costs are higher than for option E but lower than for option A, which will be the situation as from 1 May 2012 if Directive 2004/40/EC remains in force.

3. LEGAL ELEMENTS OF THE PROPOSAL

- **Summary of the proposed measures**

The proposal amends the relevant articles and annexes of Directive 2004/40/EC in order to achieve the objectives mentioned under point 1 above. Instead of making a long list of complex amendments to Directive 2004/40/EC, the present Directive repeals and replaces that

Directive in order to achieve a clear, simple and precise text, which is transparent and readily understandable to the public and economic operators.

- **Legal basis**

Article 153(2) of the Treaty on the Functioning of the European Union.

- **Subsidiarity principle**

The subsidiarity principle applies in so far as the proposal concerns a field — the protection of the health and safety of workers at work — which does not fall under the exclusive competence of the European Union.

The objectives of the proposal cannot be achieved sufficiently by the Member States, as the provisions of directives cannot be amended or repealed at national level.

The attainment of the objectives of the proposal can be achieved only by Union action, as this proposal amends an act of EU law which is currently in force, which cannot be done by the Member States themselves.

The principle of subsidiarity is respected in as much as the proposal amends existing Union legislation.

- **Proportionality principle**

The proposal complies with the proportionality principle for the following reason.

It aims to guarantee the protection of workers exposed to EMF while simplifying the burden on employers compared with the situation under Directive 2004/40/EC.

- **Choice of instruments**

Proposed instrument: directive.

No other instruments would have been suitable. The aim is to amend a directive and the only way to do this is to adopt another directive.

4. BUDGETARY IMPLICATIONS

The proposal has no implications for the Union budget except for the meetings of the proposed committees. The appropriations will be taken from the existing budget lines as is usually done for the functioning of the Advisory Committee for Safety and Health at Work (PROGRESS administrative line) and for the invitation of experts (general line).

5. ADDITIONAL INFORMATION

- **Simplification**

The proposal contributes to the simplification of the legislative framework by introducing appropriate proportionality and flexibility.

- **Repeal of existing legislation**

The adoption of the proposal will entail the repeal of Directive 2004/40/EC.

- **European Economic Area**

This draft instrument is concerned with a subject covered by the EEA Agreement and must therefore be extended to cover the European Economic Area.

- **Detailed explanation of the proposal by chapter or by article**

This proposal amends a number of articles and annexes of Directive 2004/40/EC.

Article 1 of the proposal is almost unchanged compared to Directive 2004/40/EC and addresses the aim and scope of the proposal. A new sentence in paragraph 2 explicitly mentions the existence of direct and indirect effects due to exposure to EMF. Both types of effects are covered by the Directive.

Article 2 defines 'electromagnetic fields', 'exposure limit values' and 'action values', as was the case in Directive 2004/40/EC. The new article also defines the 'orientation values' introduced in the proposal and 'adverse health effects' and 'adverse safety effects' for the sake of clarification.

Article 3

This article refers to the exposure limit values and action values as in Directive 2004/40/EC. However, paragraph 1 briefly sets out the roles of the new orientation and action values in order to achieve the proportionality required by stakeholders. This applies to the frequency range from 0 Hz to 100 kHz. From 100 kHz to 300GHz, the levels remain the same as in Directive 2004/40/EC, as no new recommendations have been published since 1998.

Paragraph 3 is similar to the corresponding paragraph of Directive 2004/40/EC but has been adapted to limit extensive measurements to cases where they are really necessary. This will in practice simplify the carrying out of the risk assessment for a large majority of workplaces.

Paragraph 4 is new and provides an exemption from the exposure limits for the medical MRI sector and related activities, which will continue to be subject to all other obligations.

Paragraph 5 is new and provides the right for the military to use a protection system adapted to its specific working situations (e.g. radars). This request was made by NATO, which uses a protection system based on recommendations proposed by IEEE. This system can be considered equivalent to the system set out in this proposal.

Paragraph 6 is new and provides for temporary derogations under controlled conditions where the exposure limits are likely to be exceeded.

Article 4 concerns the 'determination of exposure and assessment of risks' as in Directive 2004/40/EC.

Paragraphs 1 to 3 and 6 remain unchanged. Paragraph 4 has been slightly modified to meet the aim for more flexibility and proportionality.

Paragraph 5 remains unchanged except for point (c), where groups at particular risk are defined more precisely. Also, the limit in (d)(ii) concerning static magnetic fields for the projectile risk from ferromagnetic objects has been raised from 3 to 30 mT, in line with the current updated evidence.

Article 5 'Provisions aimed at avoiding or reducing risks' is substantially unchanged. Only small changes have been made in order to ensure consistency.

Article 6 on 'Worker information and training' has been changed only slightly to ensure consistency.

The same applies to Article 7 on 'Consultation and participation of workers'.

Article 8 on 'Health surveillance' has been amended to introduce a distinction between exposure in the low frequency range (0 Hz to 100 kHz) and exposure in the high frequency range. The change takes into account the fact, confirmed by medical experts, that effects induced by low frequency fields cannot be observed once the worker has left the area of undesired exposure. Any health damage resulting from such exposure therefore cannot be determined by a medical examination.

Article 9 on 'Sanctions' remains identical to the same article in Directive 2004/40/EC. This article was introduced by the EP during the discussions preceding the adoption of Directive 2004/40/EC.

Article 10 'Technical amendments'. Compared with the same article in Directive 2004/40/EC, significant changes have been introduced. The first paragraph, containing a reference to the legislative procedure laid down in Article 153(2) with regard to the adoption of modifications of the exposure limit values, has been deleted since the proposal itself is based on Article 153(2) of the Treaty and it is not necessary to refer to it again in the enacting terms. The European Parliament and the Council do not empower the Commission to modify the exposure limit values. Any such modifications would therefore not be introduced by the Commission delegated acts but by amendments of the Directive according to the procedure laid down in Article 153(2) TFEU. However, the actual directly measurable reference levels, i.e. the orientation and action values, are considered as amendments of a strictly technical nature in the proposal and are therefore referred to under a new point c) added in the first subparagraph of Article 10. This will facilitate appropriate and timely changes if scientific knowledge and refined modelling methods justify simplifications or adaptations in this area. In the light of the new 'comitology' rules introduced by the Lisbon Treaty, the purely technical amendments to Annexes referred to in Article 10 are measures of general scope that are designed to amend non-essential elements of the Directive. They thus come under 'delegated acts' within the meaning of Article 290 TFEU, and the procedure laid down in that Article (on delegating powers) should be used to adopt those technical amendments. Consequently, the power for the Commission to make use of this procedure is included in this Article 10, along with the possibility to use an urgency procedure referred to in the second subparagraph of this Article.

Article 11 The old 'comitology' procedure referred to in Directive 2004/40/EC has been replaced by new rules on delegating powers introduced by the Lisbon Treaty. Consequently, this article sets out the formal procedure under Article 290 TFEU concerning the exercise of the power conferred on the Commission to adopt delegated acts designed to amend the Directive by making purely technical amendments to its Annexes.

The former Article 12 of Directive 2004/40/EC, 'Reports' has been removed because it was repealed by Article 3(20) of Directive 2007/30/EC. The provisions for implementation reports for all the individual Directives within the meaning of Article 16(1) of Directive 89/391/EEC are now in Article 17a of Directive 89/391/EEC.

Article 12 'Urgency procedure' lays down rules on the exercise of the urgency procedure under the power conferred on the Commission to adopt delegated acts. The possibility to use the urgency procedure is accepted in the field of the protection of health and safety according to the interinstitutional *Common Understanding on delegated acts*. This possibility was already provided by the old EMF directive 2004/40. It will only be used in exceptional cases, where imperative grounds of urgency so require, such as possible imminent risks to workers' health and safety arising from their exposure to electromagnetic fields.

Article 13 is new and refers to the need to establish a practical guide in order to facilitate implementation of the Directive. This practice is already followed in other directives, in particular in the latest Directive 2006/25/EC on physical agents (artificial optical radiation).

Articles 14, 15, 16 and 17 are provisions concerning reporting, transposition, the repeal of Directive 2004/40/EC and entry into force.

Annex I introduces a number of physical quantities not included in the main text (Article 2). This option is considered preferable for better coherence of the text of the proposal.

Annex II is an important part of the proposal because it sets out all the elements required to ensure more flexibility and proportionality in the frequency range from 0 Hz to 100 kHz. It introduces in practice the 'zoning' system supported by most stakeholders together with measures to facilitate risk assessment procedures whenever possible.

Annex III covers the higher end of the frequency spectrum. As there have been no new international recommendations over recent years in this area, the changes are limited to a different presentation and some elements to facilitate the work of employers.

Annex IV is specific to medical magnetic resonance (MR). It is designed to ensure the smooth and harmonised application of appropriate qualitative protection measures in a controlled environment.

Annex V includes a list of legislative acts amending Directive 2004/40/EC (referred to in Article 15) and a correlation table between the provisions of Directive 2004/40/EC, as amended, and this proposal.

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

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the functioning of the European Union, and in particular Article 153(2) thereof,

Having regard to the proposal from the European Commission,

After transmission of the draft legislative act to the national Parliaments,

Having regard to the opinion of the European Economic and Social Committee[4],

Having regard to the opinion of the Committee of the Regions[5],

Acting in accordance with the ordinary legislative procedure,

Whereas:

(1) Under the Treaty the Council may, by means of directives, adopt minimum requirements for encouraging improvements, especially in the working environment, to guarantee a better level of protection of the health and safety of workers. Such directives are to avoid imposing administrative, financial and legal constraints in a way which would hold back the creation and development of small and medium-sized undertakings.

(2) Article 31(1) of the Charter of Fundamental Rights of the European Union provides that every worker has the right to working conditions which respect his or her health, safety and dignity.

(3) After the entry into force of 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)[6], serious concerns were expressed by stakeholders, in particular from the medical community, as to the potential impact of the implementation of that Directive on the use of medical procedures based on medical

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4 OJ C […], […], p. […].
5 OJ C […], […], p. […].
6 OJ L 184, 24.5.2004, p. 1.

imaging. Concerns were also expressed as to the impact of the Directive on certain industrial activities.

(4) The Commission examined attentively the arguments put forward by stakeholders and after several consultations decided to reconsider thoroughly some provisions of Directive 2040/40/EC, on the basis of new scientific information produced by internationally recognised experts.

(5) Directive 2004/40/EC was amended by Directive 2008/46/EC of 23 April 2008[7], with the effect of postponing by four years the deadline for transposition of Directive 2004/40/EC. This would allow the Commission to present a new proposal, and the co-legislators to adopt a new directive based on fresher and sounder evidence.

(6) Directive 2004/40/EC should be repealed and more appropriate and proportionate measures protecting workers from the risks associated with electromagnetic fields should be introduced. However, it does not address the long-term effects, including possible carcinogenic effects of exposure to time-varying electric, magnetic and electromagnetic fields, for which there is currently no conclusive scientific evidence establishing a causal relationship. The present measures should be intended not only to ensure the health and safety of each worker on an individual basis, but also to create a minimum basis of protection for all Union workers, while reducing possible distortions of competition.

(7) This Directive lays down minimum requirements, thus giving Member States the option of maintaining or adopting more favourable provisions for the protection of workers, in particular the fixing of lower values for the orientation values and action values or the exposure limit values for electromagnetic fields. However, the implementation of this Directive should not serve to justify any regression in relation to the situation already prevailing in each Member State.

(8) A system of protection against electromagnetic fields should limit itself to a definition, free of excessive detail, of the objectives to be attained, the principles to be observed and the fundamental values to be applied, in order to enable Member States to apply the minimum requirements in an equivalent manner.

(9) Protecting workers exposed to electromagnetic fields requires the carrying out of an effective and efficient risk assessment. However, this obligation should be proportional to the situation encountered at the workplace. Therefore, it is appropriate to define a protection system that graduates the level of risk in a simple and easily understandable way. Consequently, the reference to a number of indicators and standard situations can usefully assist employers in meeting their obligation.

(10) The undesired effects on the human body are dependent on the frequency of the electromagnetic field or radiation to which it is exposed, from 0 Hz until 100 kHz and above 100 kHz, therefore two different exposure limitation systems need to be considered to protect workers exposed to electromagnetic fields.

(11) The level of exposure to electromagnetic fields can be more effectively reduced by incorporating preventive measures into the design of workstations and by selecting

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[7] OJ L 114, 26.04.2008, p. 88-89.

work equipment, procedures and methods so as to give priority to reducing the risks at source. Provisions relating to work equipment and methods thus contribute to the protection of the workers involved. There is however a need to avoid the duplication of assessments, where work equipment meets the requirements of EU product legislation that establishes more severe safety levels than those provided for by this Directive and especially Directive 1999/5/EC and 2006/95/EC. This allows for simplified assessment in a large group of cases.

(12) Employers should make adjustments in the light of technical progress and scientific knowledge regarding the risks related to exposure to electromagnetic fields, with a view to improving the safety and health protection of workers.

(13) Since this Directive is an individual Directive within the meaning of Article 16(1) of Council Directive 89/391/EEC of 12 June 1989 on the introduction of measures to encourage improvements in the safety and health of workers at work[8], that Directive therefore applies to the exposure of workers to electromagnetic fields, without prejudice to more stringent and/or specific provisions contained in this Directive.

(14) The power to adopt acts in accordance with Article 290 of the Treaty on the Functioning of the European Union should be delegated to the Commission in order to empower it to make purely technical amendments of the Annexes to this Directive, in line with the adoption of directives in the field of technical harmonisation and standardisation and as a result of the technical progress, changes in the most relevant harmonised European standards or specifications and new scientific findings concerning electromagnetic fields, as well as to adjust the orientation and action values and the related lists of activities, workplaces and types of equipments. It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level. The Commission, when preparing and drawing-up delegated acts, should ensure a simultaneous, timely and appropriate transmission of relevant documents to the European Parliament and Council.

(15) In exceptional cases, where imperative grounds of urgency so require, such as possible imminent risks to workers' health and safety arising from their exposure to electromagnetic fields, the possibility should be given to apply the urgency procedure to delegated acts adopted by the Commission.

(16) A system including exposure limit values, orientation values and action values, wherever applicable, should be seen as a means to facilitate the provision of a high level of protection against the established adverse health effects that may result from exposure to electromagnetic fields. But such a system may conflict with specific conditions in certain activities, such as medical procedures using magnetic resonance techniques or military operations where interoperability is required and where internationally accepted standards providing an equivalent protection of workers subject to specific exposure situations are already in place. It is therefore necessary to take these particular conditions into account.

(17) A system ensuring a high level of protection as regards the adverse health effects that may result from exposure to electromagnetic fields should take due account of specific

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

groups of workers and avoid interference problems with, or effects on the functioning of, medical devices such as metallic prostheses, cardiac pacemakers and defibrillators, cochlear implants and other implants. Interference problems especially with pacemakers may occur at levels below the orientation and action values and should therefore be the object of appropriate precautions and protective measures.

HAVE ADOPTED THIS DIRECTIVE:

CHAPTER I

GENERAL PROVISIONS

Article 1
Subject-matter and scope

1. This Directive, which is the 20th individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC, lays down minimum requirements for the protection of workers from risks to their health and safety arising or likely to arise from exposure to electromagnetic fields (0 Hz to 300 GHz) during their work.

2. This Directive relates to the direct risks to the health and safety of workers due to known short-term adverse effects in the human body caused by induced electric or magnetic fields, by energy absorption and by contact currents. It also covers indirect health and safety effects.

3. This Directive does not address long-term effects.

4. This Directive does not address the risks resulting from contact with live conductors.

5. Directive 89/391/EEC shall apply fully to the whole area referred to in paragraph 1, without prejudice to more stringent and/or more specific provisions contained in this Directive.

Article 2
Definitions

1. For the purposes of this Directive, the following definitions apply:

(a) ‘electromagnetic fields’: static electric, static magnetic and time-varying electric, magnetic and electromagnetic fields with frequencies up to 300 GHz;

(b) ‘adverse health effects’: biological effects that have a detrimental effect on mental, physical and/or general well-being of exposed workers. In this Directive, only short-term effects are considered;

(c) "adverse safety effects": effects creating temporary annoyance or affecting cognition or other brain or muscle functions and may thereby affect the ability of a worker to work safely;

(c) ‘direct effect’: effect on the human body directly provoked by the presence of a strong magnetic or electric field, for example the stimulation of muscles, nerves or sensitory organs, tissue heating, vertigo or headaches;

(d) ‘indirect effect’: effect on an object, due to the presence of a strong electric or magnetic field, which may become the cause of a safety or health hazard, for example contact currents, ferromagnetic projectiles or interference with active implantable medical devices;

(e) ‘exposure limit values’: limits on exposure to electromagnetic fields which have been established on the basis of known health effects and biological considerations.Compliance with the exposure limits values for health effects will ensure that workers exposed to electromagnetic fields are protected against all known adverse health effects. Compliance with the exposure limits values for safety effects will ensure that workers exposed to electromagnetic fields are protected against all known adverse health and safety effects;

(f) ‘orientation value’ and ‘action value’: directly measurable — frequency-dependent — parameters, the magnitude of which is established in terms of electric field strength (E), magnetic field strength (H), magnetic flux density (B) and power density (S), and at which one or more of the measures specified in this Directive must be taken,

2. The "orientation value" referred to in point (f) of paragraph 1 corresponds to a field level where no adverse health effect should be noticed under normal working conditions and for persons not being part of a group at particular risk. As a consequence, the depth of the risk assessment procedure can be reduced to a minimum. Compliance with the orientation value will ensure compliance with the relevant exposure limit values for safety and health effects.

The "action value" referred to in point (f) of paragraph 1 corresponds to the maximum directly measurable field for which automatic compliance with the exposure limit value is guaranteed. Any exposure level between the "orientation value" and the "action value" requires more extensive evaluations and preventive measures. Compliance with the action value will ensure compliance with the relevant exposure limit values for health effects.

Article 3

Exposure limit values, orientation values and action values

1. Exposure limit values as well as orientation and action values for both electric and magnetic fields in the frequency range from 0 to 100 kHz shall be as set out in Annex II.

For exposure levels above the action value, appropriate verifications shall demonstrate that the exposure level is not exceeding the relevant exposure limit value for health effects. For exposure levels above the orientation value, appropriate verifications shall demonstrate that the exposure is not exceeding the relevant exposure limit values for safety and health effects or by demonstrating that the exposure level is below the action value. In the latter case, preventive measures and information to workers shall be adapted.

2. Exposure limit values and action values for both electric and magnetic fields in the frequency range from 100 kHz to 300 GHz shall be as set out in Annex III.

For exposure of levels above the action level, appropriate verifications shall demonstrate that the exposure is not exceeding the relevant exposure limit value for health effects.

3. For the assessment, measurement and/or calculation of workers' exposure levels to electromagnetic fields likely to be significantly below the action value, simple methods may be used. For the other cases where the exposure level is likely to be close or above the action value, Member States shall give guidance based on available harmonised European standards established by the European Committee for Electrotechnical Standardisation (CENELEC) or on other scientifically-based standards or guidelines.

4. By way of derogation, paragraphs 1 and 2 shall not apply to medical applications using the magnetic resonance effect and the following related activities: integral system testing before release for shipment, installation, cleaning, maintenance, research and development activities. In these particular cases, specific protection measures shall be put in place. For this purpose the Commission shall consult the existing working groups and proceed according to the measures set out in Annex IV.

5. By way of derogation, paragraphs 1 and 2 shall not apply to the armed forces in Member States where an equivalent and more specific protection system such as NATO standard STANAG 2345 is already in place and implemented. Member States shall inform the Commission of the existence and effective implementation of such protection systems when notifying the transposition of the provisions of this Directive into national legislation in accordance with Article 14.

6. Without prejudice to paragraphs 4 and 5, workers may not be exposed above the exposure limit values for health effects. For specific situations where these values may temporarily be exceeded, Member States may put in place a system authorising work under controlled conditions and on the basis of a comprehensive risk assessment setting out the actual exposure levels and their likelihood and comparing them to the exposure limit values defined inAnnexes II and III. Such specific situations shall be reported to the Commission in the report referred to rin Article 17a of Directive 89/391/EEC.

CHAPTER II

OBLIGATIONS OF EMPLOYERS

Article 4
Determination of exposure and assessment of risks

1. In carrying out the obligations laid down in Articles 6(3) and 9(1) of Directive 89/391/EEC, the employer shall assess and, if necessary, measure and/or calculate the levels of electromagnetic fields to which workers are exposed. Assessment, measurement and calculation may be carried out using the guidance provided in Annexes II and III. For specific cases not referred to in these Annexes, the employer may use harmonised European standards established by CENELEC for relevant assessment, measurement and calculation situations. The employer shall also be entitled to use other scientifically based standards or guidelines if required by the Member State concerned. When relevant, the employer shall also take into account the emission levels and other safety-related data provided by the manufacturers of equipment in accordance with relevant Union legislation.

2. On the basis of the assessment of the levels of electromagnetic fields undertaken in accordance with paragraph 1, if any of the action values referred to in Annexes II or III is

exceeded, the employer shall further assess and, if necessary, calculate whether the exposure limit values for health effects are exceeded.

3. The assessment, measurement and/or calculations referred to in paragraphs 1 and 2 need not be carried out in workplaces open to the public provided that an evaluation has already been undertaken in accordance with the provisions of Council Recommendation 1999/519/EC of 12 July 1999 on the limitation of exposure of the general public to electromagnetic fields (0 Hz to 300 GHz)[9], and the restrictions as specified therein are respected for workers and safety risks are excluded. Where equipment, intended for the public and complying with EU product legislation and especially Directives 1999/5/EC and 2006/95/EC are being used as intended these conditions are met.

4. The assessment, measurement and/or calculations referred to in paragraphs 1 and 2 shall be planned and carried out by competent services or persons at suitable intervals, taking into account the guidance given in Annexes II and III and taking particular account of Articles 7 and 11 of Directive 89/391/EEC concerning the necessary competent services or persons and the consultation and participation of workers. The data obtained from the assessment, measurement and/or calculation of the level of exposure shall be preserved in a suitable form so as to permit consultation at a later stage.

5. Pursuant to Article 6(3) of Directive 89/391/EEC, the employer shall give particular attention, when carrying out the risk assessment, to the following:

(a) the frequency spectrum and the level, duration and type of exposure;

(b) the exposure limit values and action values referred to in Article 3 and Annexes II and III to this Directive;

(c) any effects concerning the health and safety of workers at particular risk such as workers who have declared to the employer that they wear an Active Implanted Medical Device and women who have declared that they are pregnant;

(d) any indirect effects, such as:

(i) interference with medical electronic equipment and devices (including cardiac pacemakers and other implanted devices as referred to in point (c));

(ii) the projectile risk from ferromagnetic objects in static magnetic fields with a magnetic flux density greater than 30 mT;

(iii) the initiation of electro-explosive devices (detonators);

(iv) fires and explosions resulting from the ignition of flammable materials by sparks caused by induced fields, contact currents or spark discharges;

(e) the existence of replacement equipment designed to reduce the level of exposure to electromagnetic fields;

[9] OJ L 199, 30.7.1999, p. 59.

(f) appropriate information obtained from health surveillance, including published information;

(g) multiple sources of exposure;

(h) simultaneous exposure to multiple frequency fields.

6. The employer shall be in possession of an assessment of the risks in accordance with Article 9(1)(a) of Directive 89/391/EEC and shall identify which measures must be taken in accordance with Articles 5 and 6 of this Directive. The risk assessment shall be recorded on a suitable medium, according to national law and practice. It may include a justification by the employer that the nature and the extent of the risks related to electromagnetic fields make a further detailed risk assessment unnecessary. The risk assessment shall be updated on a regular basis, particularly if there have been significant changes which could render it out of date, or when the results of health surveillance show this to be necessary.

Article 5

Provisions aimed at avoiding or reducing risks

1. Taking account of technical progress and the availability of measures to control the production of electromagnetic fields at the source, the exposure to electromagnetic fields shall be eliminated or reduced to a minimum.

The reduction of risks arising from exposure to electromagnetic fields shall be based on the general principles of prevention set out in Directive 89/391/EEC.

2. On the basis of the risk assessment referred to in Article 4, once the action values referred to in Article 3 and Annexes II and III are exceeded, the employer, unless the assessment carried out in accordance with Article 4(2) demonstrates that the exposure limit values are not exceeded and that safety risks can be excluded, shall devise and implement an action plan comprising technical and/or organisational measures to prevent exposure exceeding the exposure limit values, taking into account in particular:

(a) other working methods that entail less exposure to electromagnetic fields;

(b) the choice of equipment emitting less electromagnetic fields, taking account of the work to be done;

(c) technical measures to reduce the emission of electromagnetic fields, including, where necessary, the use of interlocks, shielding or similar health protection mechanisms;

(d) appropriate maintenance programmes for work equipment, workplaces and workstation systems;

(e) the design and layout of workplaces and workstations;

(f) limitation of the duration and intensity of the exposure;

(g) the availability of adequate personal protection equipment.

3. On the basis of the risk assessment referred to in Article 4, workplaces where workers could be exposed to electromagnetic fields exceeding the orientation or action values shall be indicated by appropriate signs in accordance with Annexes II and III and with Council Directive 92/58/EEC of 24 June 1992 on the minimum requirements for the provision of safety and/or health signs at work (ninth individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC) [10]. The areas in question shall be identified and access to them limited as appropriate. Where access to these areas is suitably restricted for other reasons then signs and access restrictions specific to electropmagnetic fields are not required.

4. In any event, workers shall not be exposed above the exposure limit values for health effects unless the conditions under Article 3(6) are fulfilled. If, despite the measures taken by the employer to comply with this Directive, the exposure limit values for health effects are exceeded, the employer shall take immediate action to reduce exposure below these exposure limit values. The employer shall identify the reasons why the exposure limit values for health effects have been exceeded, and shall amend the protection and prevention measures accordingly in order to prevent them being exceeded again.

5. Pursuant to Article 15 of Directive 89/391/EEC, the employer shall adapt the measures referred to in this Article and in Annexes II and III to the requirements of workers at particular risk.

Article 6

Worker information and training

Without prejudice to Articles 10 and 12 of Directive 89/391/EEC, the employer shall ensure that workers who are exposed to risks from electromagnetic fields at work and/or their representatives receive any necessary information and training relating to the outcome of the risk assessment provided for in Article 4(1) of this Directive, concerning in particular:

(a) measures taken to implement this Directive;

(b) the values and concepts of the exposure limit values, orientation values and action values, the associated potential risks and the preventive measures taken;

(c) the results of the assessment, measurement and/or calculations of the levels of exposure to electromagnetic fields carried out in accordance with Article 4 (1) and (2) of this Directive;

(d) how to detect adverse health effects of exposure and how to report them;

(e) the circumstances in which workers are entitled to health surveillance;

(f) safe working practices to minimise risks from exposure.

[10] OJ L 245, 26.8.1992, p. 23.

Article 7

Consultation and participation of workers

Consultation and participation of workers and/or their representatives shall take place in accordance with Article 11 of Directive 89/391/EEC.

CHAPTER III

MISCELLANEOUS PROVISIONS

Article 8

Health surveillance

1. With the objective of prevention and early diagnosis of any adverse health effects due to exposure to electromagnetic fields, appropriate health surveillance shall be carried out in accordance with Article 14 of Directive 89/391/EEC.

For exposures in the frequency range up to 100 kHz, any undesired or unexpected health effect reported by a worker shall be transmitted to the person in charge of the medical surveillance who will take appropriate action in accordance with national law and practice.

For exposure in the range from 100 kHz up to 300 GHz, and in any event where exposure above the exposure limit values is detected, a medical examination shall be made available to the worker(s) concerned in accordance with national law and practice. If health damage resulting from such exposure is detected, a reassessment of the risks shall be carried out by the employer in accordance with Article 4.

2. The employer shall take appropriate measures to ensure that the doctor and/or the medical authority responsible for health surveillance have access to the results of the risk assessment referred to in Article 4.

3. The results of health surveillance shall be preserved in a suitable form so as to permit consultation at a later date, taking account of confidentiality requirements. Individual workers shall, at their request, have access to their own personal health records.

Article 9

Sanctions

Member States shall provide for adequate sanctions to be applicable in the event of infringements of national legislation adopted pursuant to this Directive. These sanctions must be effective, proportionate and dissuasive.

Article 10

Technical amendments of the Annexes

The Commission shall be empowered to adopt delegated acts in accordance with Article 11 in order to make amendments to the Annexes of a purely technical nature so as to:

(a) take into account the adoption of Directives in the field of technical harmonisation and standardisation with regard to the design, building, manufacture or construction of work equipment or workplaces;

(b) take into account the technical progress, changes in the most relevant harmonised European standards or specifications, and new scientific findings concerning electromagnetic fields;

(c) make adjustments to the orientation and action values provided that compliance with the existing exposure limit values is maintained, and of the related lists of activities, workplaces and types of equipments mentioned in Annexes II and III.

Where, in the case of purely technical amendments of the Annexes referred to in the first subparagraph, imperative grounds of urgency so require, the procedure provided for in Article 12 shall apply to delegated acts adopted pursuant to this Article.

Article 11
Exercise of the delegation

1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.

2. The delegation of power referred to in Article 10 shall be conferred for an indeterminate period of time from [***the date of entry into force of the present Directive***].

3. The delegation of powers referred to in Article 10 may be revoked at any time by the European Parliament or by the Council. A revocation decision shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the *Official Journal of the European Union* or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.

4. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.

5. A delegated act adopted pursuant to Article 10 shall enter into force only if no objection has been expressed by either the European Parliament or the Council within a period of 2 months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by 2 months at the initiative of the European Parliament or the Council.

Article 12
Urgency procedure

1. Delegated acts adopted under this Article shall enter into force without delay and shall apply as long as no objection is expressed in accordance with paragraph 2. The notification of a delegated act to the European Parliament and to the Council shall state the reasons for the use of the urgency procedure.

2. Either the European Parliament or the Council may object to a delegated act in accordance with the procedure referred to in Article 11(5). In such a case, the Commission shall repeal the act without delay following the notification of the decision to object by the European Parliament or the Council.

CHAPTER IV

FINAL PROVISIONS

Article 13
Practical guide

In order to facilitate implementation of this Directive, in particular the conduct of the risk assessment, the Commission shall draw up practical guides to the provisions of Articles 4 and 5 and Annexes II to IV. The Commission shall work in close cooperation with the Advisory Committee for Safety and Health at Work.

Article 14
Review and reporting

The report to be established in accordance to Article 17(a) of Directive 89/391/EEC shall notably report on the effectiveness of the Directive in reducing exposure to electromagnetic fields and the percentage of workplaces that required corrective action.

.Article 14
Transposition

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by [30 April 2014] at the latest.. They shall forthwith communicate to the Commission the text of those provisions and a correlation table between those provisions and this Directive.

When Member States adopt those provisions, they shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. Member States shall determine how such a reference is to be made.

2. Member States shall communicate to the Commission the text of the main provisions of national law which they adopt in the field covered by this Directive.

Article 15
Repeal

Directive 2004/40/EC is repealed.

Article 16
Entry into force

This Directive shall enter into force on the day of its publication in the *Official Journal of the European Union.*

Article 17
Addressees

This Directive is addressed to the Member States.

Done at Brussels,

For the European Parliament	*For the Council*
The President	*The President*

ANNEX I
PHYSICAL QUANTITIES REGARDING THE EXPOSURE TO ELECTROMAGNETIC FIELDS

The following physical quantities are used to describe the exposure to electromagnetic fields:

Contact current (I_C) between a person and an object is expressed in amperes (A). A steady state contact current occurs when a person is in contact with a conductive object in an electric field. In the process of making such a contact, a spark discharge may occur with associated transient currents.

Electric field strength is a vector quantity (E) that corresponds to the force exerted on a charged particle regardless of its motion in space. It is expressed in volts per metre (V/m).

Magnetic field strength is a vector quantity (H) that, together with the magnetic flux density, specifies a magnetic field at any point in space. It is expressed in amperes per metre (A/m).

Magnetic flux density is a vector quantity (B) resulting in a force that acts on moving charges, expressed in teslas (T). In free space and in biological materials, magnetic flux density and magnetic field strength can be interchanged using the equivalence 1 A/m = $4\pi\ 10^{-7}$ T.

Power density (S) is the appropriate quantity used for very high frequencies, where the depth of penetration in the body is low. It is the radiant power incident perpendicular to a surface, divided by the area of the surface, and is expressed in watts per square metre (W/m^2).

Specific energy absorption (SA) is the energy absorbed per unit mass of biological tissue, expressed in joules per kilogram (J/kg). In this Directive, it is used for establishing limits for non-thermal effects from pulsed microwave radiation.

Specific energy absorption rate (SAR), averaged over the whole body or over parts of the body, is the rate at which energy is absorbed per unit mass of body tissue and is expressed in watts per kilogram (W/kg). Whole-body SAR is a widely accepted quantity for relating adverse thermal effects to radio frequency (RF) exposure. Besides the whole-body average SAR, local SAR values are necessary to evaluate and limit excessive energy deposition in small parts of the body resulting from special exposure conditions. Examples of such conditions are: a grounded individual exposed to RF in the low MHz range and individuals exposed in the near field of an antenna.

Of these quantities, magnetic flux density, contact current, electric and magnetic field strengths and power density can be measured directly.

ANNEX II
EXPOSURE TO ELECTROMAGNETIC FIELDS IN THE FREQUENCY RANGE FROM 0 HZ TO 100 KHZ

A. EXPOSURE LIMITATION SYSTEM

The main principles underlying the protection system adopted for the range of frequencies up to 100 kHz (100 thousand cycles per second) are as follows:

- taking due account of the latest international recommendations published by the specialised organisations recognised worldwide

- introducing appropriate and 'limited to purpose' simplifications in order to facilitate the understanding and 'in field' implementation of the protection system

- introducing in practice a 'zoning system' in which each activity can be classified, whereby the location of an activity in a determined zone has a direct impact on the extent of the risk assessment to be carried out by the employer and on the recommended preventive measures

- limiting the number of cases where compliance with the actual exposure limits must be ensured because the measured exposure level is higher than the upper limit of the highest permitted zone (action level).

B. EXPOSURE LEVELS AND EXPOSURE LIMITS

In line with the most recent recommendations the following options have been taken:

- Actions values and Orientation values correspond to estimated or measured field values at the workplace in absence of the worker.

- Exposure limit values for health effects and exposure limit values for safety effects are expressed as electric fields generated in nervous tissue *in the body* (in V/m)

- For a worker at particular risk, as defined in Article 4 (5c), an individual assessment must be made in accordance with Annex II point E.

Note 1: any situation where the measured value is higher than the action value, a thorough verification must be made according to Article 4(2).

Note 2: for any situation where the shape of the signal differs sufficiently from a sinusoid to affect the outcome, then peak values should be used as follows. For exposure limit values the peak value should be compared with the peak value of the induced electric field obtained by multiplying the values of table 2.1 by 1.41. For magnetic and electric field levels outside the body, peak values of their rate of change with time should be compared with the values of table 2.2 or 2.3 multiplied by 8.9f (which is $\sqrt{2}\ 2\pi f$).

For complex pulsed signals a thorough verification must be made according to Article 3(3).

Table 2.1 Exposure Limit Values (expressed in RMS values)

Frequency (Hz)	Exposure Limit Value (V/m)	
	For safety effects	For health effects
1 - 10	0.5/f	0.8
10 - 25	0.05	0.8
25 - 400	0.002 f	0.8
400 - 3000	0.8	0.8
3000 - 100000	2.7×10^{-4} f	2.7×10^{-4} f

f is the frequency expressed in Hertz (Hz)

The exposure limit value for safety effects is derived from the effect threshold for effects on the central nervous system in the head (CNS).

The exposure limit value for health effects is derived from the effect threshold for effects on the peripheral nervous system (PNS) and it also prevents stimulation of nerve fibres in the central nervous system.

Exposure limit values for static magnetic fields are given in table 2.3

Table 2.2 Orientation and action values for exposure to an **electric field** (RMS values)

Frequency (Hz)	Orientation value (V/m)	Action value (V/m)
1 – 25	20×10^3	20×10^3
25 – 90	$500 \times 10^3/f$	20×10^3
90 – 3000	$500 \times 10^3/f$	$1800 \times 10^3/f$
3000 - 100000	170	600

Note 1: The action value for electric fields for the frequency range 1-90 Hz is limited to 20 kV/m to limit the risk of indirect effects which are spark discharges which may occur when a worker comes into contact with a conducting object at a different electrical potential. Where the risk of spark discharges is managed using technical means and the training of workers, exposures in excess of action values can be accepted provided that the exposure limit values are not exceeded, in accordance with Article 4(2).

Table 2.3 Orientation and action values for exposure to a **magnetic field** (RMS)

Frequency (Hz)	Orientation value (μT)	Action value (μT)
0	2×10^6	8×10^6
>0 – 1	$(2\text{-}1.8\ f) \times 10^6$	$(5.67 - 5f) \times 10^6$
1 – 8	$2\ 10^5/f^2$	$0.666 \times 10^6/f$
8 – 25	25000/f	$0.666 \times 10^6/f$
25 – 300	1000	$0.666 \times 10^6/f$
300 - 3000	$3 \times 10^5/f$	$0.666 \times 10^6/f$
3000 - 9000	100	222
9000 - 20000	100	$2 \times 10^6 / f$
20000 – 100000	$2 \times 10^6 / f$	$2 \times 10^6 / f$

Note 1: Values for 0 Hz in this table are exposure limit values. Above 8 T Article 3(6) shall apply.

Note 2: The action value above 9 kHz and the orientation value above 20 kHz result from the exposure limit values for whole-body average SAR as defined in Annex III.

In addition to the values given in Tables 2.1, 2.2 and 2.3, steady-state contact currents resulting from a worker being in contact with conductive objects shall be limited to.

From 0 Hz up to 2.5 kHz: 1.0 mA;

From 2.5 kHz up to 100 kHz: $0.4\ 10^{-3} f$ mA (frequency, f in Hz).

C. CATEGORIES OF WORK EQUIPMENT OR ACTIVITIES

1) The following work equipment or activities are, in normal conditions, considered to expose the worker under the *orientation value.*

- Activities using equipment complying with Directives 1999/5/EC and 2006/95/EC when used as intended and notably:
    - 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)

- offices (incl. computer equipment, cable networks, radio communication equipment; exc. tape erasers)
- operation of 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
- detection of articles and people
    - RFID 1 Hz - 100 kHz
- tape erasers (if instructions of manufacturer available and followed).
- induction heating
    - automated systems (if instructions of manufacturer available and followed)
- detection of articles and people
    - EAS 0.01 - 20 kHz (magnetic)
    - EAS 20 - 100 kHz (resonant inductive)
    - metal detectors
- induction hobs in hotel & catering industry (food preparation)

- hand-held motor-operated electric tools

- transportable motor operated electric tools (incl. electrically operated garden appliances)
- testing instruments (exc. non-destructive magnetic testing)
- installation and maintenance
    - electrical hand-held tools (exc. welding equipment)
- electricity production and distribution
    - bus bars/conductor rails in substations
    - above ground high voltage cables
    - electricity substations
    - switch gear
- welding
    - automated systems (if instructions of manufacturer available and followed)
    - arc welding – cable (if instructions of manufacturer available and followed)
- medical applications
    - shallow hyperthermia (if instructions of manufacturer available and followed)
    - pain control, stimulation of bone growth etc.
    - incubators, lamps for phototherapy, wireless communication systems etc.
    - deep hyperthermia (if instructions of manufacturer available and followed)
    - electrosurgery (if instructions of manufacturer available and followed)
- 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)
- electricity production and distribution

- electrochemical processes (except specific places)

2) The following activities may expose the worker above the *orientation value* but in normal conditions are considered to expose them under the *action value.*

– plastic sealers

– induction heating

– 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

– use of - 'open magnetron'

– non-destructive magnetic testing

3) The following activities may exceed the action value and require special assessment to ensure that the exposure limit values for health effects are not exceeded:

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

D. PREVENTION MEASURES and other conditions

1) For persons at particular risk referred to in Article 4(5)(c), individual assessments must be made in accordance to point E.

2) Zone of exposures under the orientation value:

- Signage as appropriate

3) Zone of exposures above the orientation value but under the action value

- Signage as appropriate

- Delimitation measures (e.g. floor markings, fences) in order to limit or control access, as appropriate

- Information and specific training of relevant workers

- Verification of compliance with exposure limit values for safety effects or alternatively procedures to ensure adverse safety effects are managed.

4) Exposures above the action value:

- Signage as appropriate

- Delimitation measures (e.g. floor markings, fences) in order to limit or control access, as appropriate

- Verification of compliance with exposure limit values for health effects.

- Procedure to manage spark discharges through technical means and the training of workers. (Applies only where electric field exposures are in this zone.)

- Appropriate delimitation and access measures

- Information and specific training of relevant workers.

E. PERSONS AT PARTICULAR RISK

Workers having declared themselves as wearing an Active Implantable Medical Device (AIMD) and women having declared themselves to be pregnant are considered to be persons at particular risk, as stated in Article 4(5)(c).

Where a worker has declared to their employer that he or she wears an AIMD the employer shall carry out an assessment to determine what restriction on where they can work is needed to avoid interference to their implanted device. Advice on how to do this is provided by CENELEC (see EN 50527 and associate parts). It may be noted that principle underlying the CENELEC guidance is that interference will not occur when the fields is below the Reference Levels given in Council Recommendation 1999/519/EC on the limitation of exposure of the general public to electromagnetic fields (0 Hz to 300 GHz)[11].

Where a worker has declared to her employer that she is pregnant then the requirements of Council Directive 92/85/EEC on the introduction of measures to encourage improvements in the safety and health at work of pregnant workers and workers who have recently given birth or are breastfeeding[12] apply. The employer shall enable the worker to avoid having to enter areas where exposures exceeding the exposure limits for the general public given in Council Recommendation 1999/519/EC, or its subsequent revisions.

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[11] OJ L 199, 30.7.1999, p. 59.

[12] OJ L 348, 28.11.1992, p. 1.

ANNEX III

EXPOSURE TO ELECTROMAGNETIC FIELDS IN THE FREQUENCY RANGE FROM 100 KHZ TO 300 GHZ

A. EXPOSURE LIMITATION SYSTEM

Depending on the frequency of the field or radiation to which the worker is exposed, the following physical quantities are used to specify the exposure limit values for electromagnetic fields:

– between 100 kHz and 10 MHz exposure limit values are provided both on SAR to prevent heat stress and on induced electric fields to prevent effects on central and peripheral nervous system functions;

– between 10 MHz and 10 GHz exposure limit values are provided on SAR to prevent whole-body heat stress and excessive localised heating of tissues;

– between 10 GHz and 300 GHz an exposure limit value on power density is provided to prevent excessive tissue heating at or near the body surface;

- in the frequency range of this annex, 100 kHz to 300 GHz, only exposure limit values for health effects need to be considered and consequently

B. EXPOSURE LEVELS AND EXPOSURE LIMITS

Table 3.1 Action values and exposure limit values for exposure to high frequency **electric field** (RMS values)

Frequency (Hz)	Action value (V/m)	Exposure Limit Value for induced electric field (V/m)	Exposu-re Limit Value forWhole Body: Average SAR (in W/kg) ‡	Exposu-re Limit Value forHead and Trunk: Localised SAR (in W/kg)‡	Exposu-re Limit Value for limbs: Localised SAR (in W/kg)‡	Exposu-re Limit Value: Power Density S (in W/m^2)
$10^5 – 10^6$ (*)	600	2.7×10^{-4} f*	0.4	10	20	-
$10^6 – 10^7$ (*)	600 10^6/f	2.7×10^{-4} f*	0.4	10	20	-
10^7 - – 4 10^8	60	-	0.4	10	20	-

$4\ 10^8$ - $2\ 10^9$	$3 \times 10^{-3} \times f^{0.5}$	-	0.4	10	20	-
$2\ 10^9$ - 10^{10}	137	-	0.4	10	20	-
10^{10} - $3\ 10^{11}$	137	-	-	-	-	50

(*)f is the frequency expressed in Hertz (Hz)

(‡) See ANNEX III point F

Table 3.2 Action values and exposure limit values for exposure to high frequency **magnetic field** (RMS values)

Frequency (Hz)	Action value (μT)	Exposure Limit Value for the induced electric field (V/m)	Exposure Limit Value for Whole Body: average SAR (in W/kg) ‡	Exposure Limit Value for Head and Trunk: Localised SAR (in W/kg)‡	Exposure Limit Value for limbs: Localised SAR (in W/kg)‡	Exposure Limit Value: Power Density S (in W/m^2)
$10^5 – 10^7$	$2\ 10^6/f$	2.7×10^{-4} f	0.4	10	20	-
10^7 - $4\ 10^8$	0.2	-	0.4	10	20	-
$4\ 10^8$ - $2\ 10^9$	$10^{-5} \times f^{0.5}$	-	0.4	10	20	-
$2\ 10^9$ - 10^{10}	0.45	-	0.4	10	20	-
10^{10} - $3\ 10^{11}$	0.45	-	-	-	-	50

(‡) See Annex III point F

In addition to the values given in Tables 3.1 and 3.2, contact currents resulting from a worker being in contact with conductive objects shall be limited to:

From 100 kHz to 10 MHz:: · 40 mA.

C. CATEGORIES OF WORK EQUIPMENT OR ACTIVITIES

1) The following activities are, in normal conditions, considered to expose the worker under the *action value.*

- Workplaces in which only equipment complying with Directives 1999/5/EC and 2006/95/EC is used as intended and notably:
    - transmitters (small, at GSM base stations, < 1 W)
    - Telephones and hand portables
    - Radar systems (speed checks, weather radars)
    - RFID above 100 kHz
    - Microwave drying
    - TETRA transmitters in masts
    - TETRA transmitters on vehicles, power max. 10 W
    - Tape erasers
    - Base stations for mobile telephony (GSM, UMTS)

2) The following activities are, in normal conditions, considered to expose the worker above the *action value.*

- Equipment that is being installed or maintained (trouble shooting on)
- Non-automated induction heating working in this frequency range
- Radiofrequency and microwave lighting
- Non destructive magnetic testing
- Activities within the exclusion zone for the public around:
    - Large broadcasting transmitters
    - Radar systems (navigational)
    - Other EMF producing equipment

D. PREVENTION MEASURES

1) For persons at particular risk, referred to in Article 4.5(c), individual assessments must be made in accordance with Annex III point E.

2) Zone of exposure under the *action value*:

- Signage as appropriate

- Information of workers

3) Exposures above the action value:

- Verify compliance with exposure limit values

- Appropriate delimitation and access measures

- Information and specific training of relevant workers.

E. PERSONS AT PARTICULAR RISK

Workers having declared themselves as wearing an AIMD and women having declared themselves to be pregnant are considered to be persons at particular risk, as stated in Article 4(5)(c).

Where a worker has declared to their employer that he or she wears an AIMD the employer shall carry out an assessment to determine what restriction on where they can work is needed to avoid interference to their implanted device. Advice on how to do this is provided by CENELEC (EN 50527 and associate parts). It may be noted that principle underlying the CENELEC guidance is that interference will not occur when the fields is below the Reference Levels given in Recommendation 1999/519/EC.

Where a worker has declared to her employer that she is pregnant then the requirements of the Directive 92/85/EEC apply. The employer shall enable to worker to avoid having to enter areas where exposures exceeding the exposure limits for the general public given in Recommendation 1999/519/EC, or its subsequent revisions.

F MEASUREMENTS

The main frequency(ies) to which the worker may be exposed must be determined. Manufacturers' or installer's data must be used whenever available. It is also necessary to assess whether the fields are sinusoidal or pulsed. Moreover:

- all SAR values are to be averaged over any six-minute period;

- localised SAR averaging mass is any 10 g of contiguous tissue; the maximum SAR so obtained should be the value used for estimating exposure. These 10 g of tissue are intended to be a mass of contiguous tissue with nearly homogeneous electrical properties. In specifying a contiguous mass of tissue, it is recognised that this concept can be used in computational dosimetry but may present difficulties for direct physical measurements. A simple geometry such as cubic tissue mass can be used provided that the calculated dosimetric quantities have conservative values relative to the exposure guidelines;

- for pulsed exposures in the frequency range 0.3 to 10 GHz and for localised exposure of the head in order to limit and avoid auditory effects caused by thermo elastic expansion, an additional exposure limit value is recommended. This is that the SA should not exceed 10 mJ/kg averaged over 10 g of tissue;

- power densities are to be averaged over any 20 cm^2 of exposed area and any $68/f^{1,05}$-minute period (where f is in GHz) to compensate for progressively shorter penetration depth as the frequency increases. Spatial maximum power densities averaged over 1 cm^2 should not exceed 20 times the value of 50 W/m^2;

- with regard to pulsed or transient electromagnetic fields, or generally with regard to simultaneous exposure to multiple frequency fields, appropriate methods of assessment, measurement and/or calculation capable of analysing the characteristics of the waveforms and nature of biological interactions have to be applied, taking account of European harmonised standards developed by CENELEC.

ANNEX IV
SPECIFIC MEASURES FOR ACTIVITIES FALLING UNDER ARTICLE 3(4)

In accordance with Article 3(4), and in order to ensure harmonised and adequate protection of workers and whilsttaking due account of existing precautionary and protective measures, the following principles will be followed and tasks carried out.

1. Objectives

a) The first objective is to develop, with the parties concerned, a consistent and practicable methodology to protect workers exposed to EMF during activities falling under Article 3(4).

b) The second objective is to include, in the developed methodology and related tools, aspects such as:

– effective information measures and dynamic consultation mechanisms

– efficient training measures, also for external personnel having access to the MR area (MR installation room, control room, any related adjacent room)

– documented working procedures (and review mechanism)

– strict rules for access to MR rooms

– monitoring of the quality of implementation.

c) The third objective is to involve all the representative organisations in the dissemination of information to their members to ensure effective implementation of the good practices in a harmonised manner in all the MR installations of the Union.

2. Tasks

The tasks will be to:

- collect good practices already in place in Member States or in specific installations;
- examine existing guides and working procedures;
- identify and describe risks (EMF, noise, flying objects, cryogenic liquids);
- identify the maximum-exposure scenarios
- define typical working situations;
- define appropriate rules of conduct for each typical working situation;
- establish a standard training programme and its content;
- establish any other means to fulfil the objectives;

- for future establishments, produce recommendations to improve safety (design of department, access management to MR room, design of rooms, etc.).

3. Duration of work and reporting

a) The work will start immediately after adoption of this Directive and will be finalised no later than the date mentioned under Article 14(1);

b) The Commission will prepare a report explaining the outcomes achieved. The report will be transmitted to the Council and European Parliament not later than 9 months after the date mentioned under Article 14(1).

ANNEX V

CORRELATION TABLE

Directive 2004/40/EC	This Directive
Article 1(1)	Article 1(1)
Article 1(2)	Article 1(2)
Article 1(3)	Article 1(3)
Article 1(4)	Article 1(4) (unchanged)
Article 1(5)	Article 1(5) (unchanged)
Article 2(a)	Article 2(a)
-	Article 2(b)
-	Article 2(c)
-	Article 2(d)
Article 2(b)	Article 2(e)
Article 2(c)	Article 2(f)
Article 3(1)	Article 3(1)
Article 3(2)	Article 3(2)
Article 3(3)	Article 3(3)
-	Article 3(4)
-	Article 3(5)
-	Article 3(6)
Article 4(1)	Article 4(1)
Article 4(2)	Article 4(2)
Article 4(3)	Article 4(3)
Article 4(4)	Article 4(4)
Article 4(5)(a)	Article 4(5)(a)

Article 4(5)(b)	Article 4(5)(b)
Article 4(5)(c)	Article 4(5)(c)
Article 4(5)(a)(i)	Article 4(5)(a)(i)
Article 4(5)(a)(ii)	Article 4(5)(a)(ii)
Article 4(5)(a)(iii)	Article 4(5)(a)(iii) (unchanged)
Article 4(5)(a)(iv)	Article 4(5)(a)(iv) (unchanged)
Article 4(5)(f) to (h)	Article 4(5)(f) to (h) (unchanged)
Article 4(6)	Article 4(6)
Article 5(1)	Article 5(1)
Article 5(2), introductory wording	Article 5(2), introductory wording
Article 5(2)(a) to (g)	Article 5(2)(a) to (g) (unchanged)
Article 5(3)	Article 5(3)
Article 5(4)	Article 5(4)
Article 6, introductory wording	Article 6, introductory wording
Article 6(a)	Article 6(a) (unchanged)
Article 6(b)	Article 6(b)
Article 6(c) to (f)	Article 6(c) to (f) (unchanged)
Article 7	Article 7 (unchanged)
Article 8(1)	Article 8(1)
Article 8(2)	Article 8(2) (unchanged)
Article 8(3)	Article 8(3) (unchanged)
Article 9 (unchanged)	Article 9 (unchanged)
Article 10(1)	Article 10(1)
Article 10(2), introductory text	Article 10(2), introductory text
Article 10(2)(a)	Article 10(2)(a) (unchanged)

Article 10(2)(b)	Article 10(2)(b) (unchanged)
-	Article 10(2)(c)
Article 10(2), last sentence	Article 10(2), last sentence
Article 11(1)	-
Article 11(2)	Article 11
Article 11(3)	Article 12
Article 12 (Article repealed by Directive 2007/30/EC)	-
-	Article 13
Article 13(1)	Article 14(1)
Article 13(2)	Article 14(2) (unchanged)
-	Article 15
Article 14	Article 16
Article 15	Article 17
Annex	-
-	Annex 1
-	Annex 2
-	Annex 3
-	Annex 4
-	Annex 5