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REPORT

From :	Permanent Representatives Committee (Part I)
to :	Council (EPSCO)
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Subject :	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) - *General approach*

I. INTRODUCTION

In 2004, Directive 2004/40/EC[1] on the minimum health and safety requirements regarding the exposure of workers to the risks arising from physical agents (electromagnetic fields) was adopted under the framework Directive 89/391/EEC[2].

[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 159, 30.4.2004, p. 1–26.

[2] 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; OJ L 183, 29.6.1989, p. 1–8.

However, soon after its adoption in 2004, the medical community working with the magnetic resonance imaging (MRI) claimed that its activities would be hampered by the strict exposure limit values laid down therein.

Consequently, Parliament and Council decided to delay its transposition until 30 April 2012, due to difficulties in its application and to allow time for the Directive to be amended in the light of new scientific information (among others publication of new International Commission on Non Ionising Radiation (ICNIRP) Guidelines[3] in 2009 and 2010, amending the low frequency range of the ICNIRP 1998 guidelines, incorporated in Directive 2004/40/EC). In 2012, the entry into force of Directive 2004/40/EC was postponed for the second time by 18 moths (until 31 October 2013), as it became clear that the discussion on the new EMF Directive could not be finalised by 30 April 2012.[4]

After long consultations with stakeholders and on the basis of a study conducted by the Commission to assess the actual impact of Directive 2004/40/EC on medical procedures, the Commission presented its proposal for a Council Directive aiming at revising Directive 2004/40/EC on 22 June 2011.

The proposed legal basis being Article 153(2) of the Treaty, the Council is required to act by qualified majority, in accordance with the ordinary legislative procedure with the European Parliament.

The European Parliament has not yet delivered its opinion.

The Committee of Regions has decided not to deliver an opinion.

The European Economic and Social Committee delivered its opinion on 7 December 2011.

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3 ICNIRP - International Commission on Non-Ionizing Radiation Protection.

4 Directive 2012/11/EU of 19 April 2012, OJ L 110/1, 24.4.2012.

II. THE COUNCIL'S WORK

The Social Questions Working Party started examining the proposal in July 2011. Under the Cyprus Presidency, the proposal has been discussed on four occasions, with the last meeting on 18 September.

The Cyprus Presidency based its work on the discussions on the main body of the Directive under the Polish Presidency[5] and on the annexes under the Danish Presidency[6], on the text of which the Working Party reached a broad agreement, subject to further editorial changes of non-substantial nature.

The Presidency's approach to the annexes has been in line with the common understanding in the Progress Report of the Danish Presidency that, based on the broad agreement, the annexes were supposed not to be reopened in substance. The Presidency has also made all efforts to improve the text of the main body of the Directive in order to ensure consistency with the annexes, without changing the philosophy of the proposal as a whole. The main aim has been to keep the balance achieved between the protection of workers, on one side, and the feasibility of implementing the rules by stakeholders in practice, on the other side. Finally, the Presidency stressed at several occasions the absolute necessity of reaching a general approach in early autumn to allow the necessary time for the negotiations with the European Parliament, so that the new Directive could be adopted before the date of transposition of 2004/40/EC Directive, i.e. before 31 October 2013, taking into account also other procedural steps to be made before the entry into force of the Directive.

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5 EPSCO Council from December 2011 (doc. 17019/11).

6 EPSCO Council from June 2012 (docs 10690/12 REV1, COR1 and 2 and 11151/1/12 REV1).

The Working Party has reached broad agreement on the proposal. At the Coreper meeting on 26 October, a large majority of delegations and the Commission reiterated their support to the Presidency proposal, as set out in the Annex. In particular CZ, DK, IE, EL, FR, IT, LT, PL, RO, SK, SE and FI opposed any amendments to the current wording, considering the Presidency proposal to be the best possible, well balanced compromise resulting from extremely difficult and long technical discussions at the expert level. These delegations stressed that, taking account of the time pressure and the planning of the European Parliament, reopening of the annexes would put at risk the opportunity of reaching a timely agreement at first-reading.

With regard to the general support for the Presidency proposal in its current wording, the Committee of Permanent Representatives agreed to submit the text as set out in the Annex to the Council (EPSCO) on 4 October with a view to reaching a general approach. Remaining reservations are indicated in Section III and in the footnotes to the annexed text.

III. REMAINING RESERVATIONS

(1) Reservation of substance

Methods of exposure evaluation in Annex II, Notes A2-3, A3-3, B1-2 and B2-2

DE has maintained its reservation on those parts of Annex II which define the weighted peak method as the main reference method for exposure evaluation to be carried out in accordance with Article 4, while allowing for other methods leading to similar results (Notes A2-3, A3-3, B1-2 and B2-2).

In the Coreper meeting on 26 September, DE reiterated its concerns that, in certain exposure scenarios, the weighted peak method or methods comparable in terms of results produced unnecessarily conservative results, without significant safety gains in terms of protection of workers, which could threaten the continuation of some activities in particular in the German car industry, but also in other industries.

UK shared DE concerns, but could accept the current Presidency proposal. BE, HU and NL, although expressing sympathy with the DE reasoning, could support the Presidency text. MT supported the Presidency text, but could be also flexible taking into account the DE concerns.

(2) Other specific reservations

Delegated acts (Recital 16 and Articles 11, 12 and 13)

MT has maintained a reservation on Article 11, suggesting to exclude Annex I from the delegated acts, as it contained definitions with essential elements and thus should not be subject to delegated acts.

DE has maintained a reservation on Articles 11 to 13, as it felt that the delegated acts were not an appropriate procedure for amending the annexes.

(3) General, parliamentary and linguistic scrutiny reservations

UK has maintained a parliamentary scrutiny reservation.

AT has maintained a linguistic reservation.

The Commission has fully reserved its position on the entire compromise proposal, and in particular on Recital 16 concerning the delegated acts.

V. CONCLUSION

The Council (EPSCO) is invited to reach a general approach on the text of the Directive as set out in the Annex to this Report.

ANNEX

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)

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[7],

Having regard to the opinion of the Committee of the Regions[8],

Acting in accordance with the ordinary legislative procedure,

[7] OJ C […], […], p. […].
[8] OJ C […], […], p. […].

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)[9], 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 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 2004/40/EC, on the basis of new scientific information produced by internationally recognised experts.

[9] OJ L 184, 24.5.2004, p. 1.

(5) Directive 2004/40/EC was amended by Directive 2008/46/EC of 23 April 2008[10], with the effect of postponing by four years the deadline for transposition of Directive 2004/40/EC, and subsequently by Directive 2012/11/EU[11], with the effect of postponing the deadline for transposition until 31 October 2013. 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) Minimum requirements should be laid down, 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 action levels (AL) or the exposure limit values (ELV) 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.

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10 OJ L 114, 26.04.2008, p. 88-89.
11 OJ L 110, 24.4.2012, p.1-2.

(9) Protecting workers exposed to electromagnetic fields requires the carrying out of an effective and efficient risks 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 to be provided by practical guidelines 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, therefore exposure limitation systems need to be frequency and exposure pattern dependent to adequetelly 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 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 relevant EU product legislation that establishes stricter safety levels than those provided for by this Directive. 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[12], 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.

12 OJ L 183, 29.6.1989, p. 1.

(14) The physical quantities, limit values and action levels laid down in the annexes of this Directive are based on the recommendations of the International Commission on Non-Ionising Radiation (ICNIRP) and should be considered in accordance with its concept, as long as this directive does not provide for specific provisions".

(15) 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 standards or specifications and new scientific findings concerning electromagnetic fields hazards, as well as to adjust the action levels. 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.

(16) Making amendments to the annexes of purely technical nature might be necessary in the future; whenever such a case occurs, the Commission should work in close cooperation with the Advisory Committee for Safety and Health at Work.[13]

(17) 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.

[13] Cion has reserved its position on Recital 16. See Cover Note, Section III (3).

(18) In accordance with the Joint Political Declaration of 28 September 2011[14] of Member States and the Commission on explanatory documents of [date], Member States have undertaken to accompany, in justified cases, the notification of their transposition measures with one or more documents explaining the relationship between the components of a directive and the corresponding parts of national transposition instruments. With regard to this Directive, the legislator considers the transmission of such documents to be justified.

(19) A system including exposure limit values and action levels, wherever applicable, should be seen as a means to facilitate the provision of a high level of protection against the adverse health or safety risks that may result from exposure to electromagnetic fields. But such a system may conflict with specific conditions in certain activities, such as the use of magnetic resonance technique in medical sector. It is therefore necessary to take these particular conditions into account.

(20) Given the specificities of the armed forces and in order to allow their effective operation and interoperability, including in joint international military exercises, Member States should be able to implement equivalent or more specific protection systems, such as internationally agreed standards like NATO standards, provided that adverse health effects and safety risks are prevented**.**

(21) Employers should be required to ensure that risks arising from electromagnetic fields at work are eliminated or reduced to a minimum. It is nevertheless possible that in specific cases and in duly justified circumstances, these exposure limit values set in this Directive are temporarily exceeded. In such a case, employers are required to take the necessary actions to return to compliance with the exposure limit values as soon as possible**.**

14 OJ C 369, 17.12.2011, p. 14.

(22) A system ensuring a high level of protection as regards the adverse health and safety risks that may result from exposure to electromagnetic fields should take due account of specific groups of workers at particular risk 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 or body worn medical devices. Interference problems especially with pacemakers may occur at levels below the action levels 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 during their work**.**

2. This Directive addresses all known direct biophysical effects and indirect effects provoked by electromagnetic fields**.**

3. The exposure limit values set in this Directive only address scientifically well-established relations between short term direct biophysical effects and exposure to electromagnetic fields. Therefore this Directive does not address suggested 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

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

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

(b) "direct biophysical effects" means effects directly provoked in the human body by the presence in electromagnetic field, in particular:

(i) thermal effects, such as tissue heating through energy absorption from electromagnetic fields in the tissue; and

(ii) non-thermal effects, such as the stimulation of muscles, nerves or sensory organs. These effects might have a detrimental effect on mental and physical health of exposed workers. Moreover, the stimulation of sensory organs may lead to transient symptoms such as vertigo or phosphenes. These might create temporary annoyance or affecting cognition or other brain or muscle functions and may thereby affect the ability of a worker to work safely (safety risks);

(iii) limb currents;

(c) "indirect effects" means effects provoked by the presence of an object in electromagnetic field, which may become the cause of a safety or health hazard, such as:

(i) interference with medical electronic equipment and devices (including cardiac pacemakers and other implanted or body worn devices);

(ii) the projectile risk from ferromagnetic objects in static magnetic fields;

(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; and

(v) contact currents;

(d) "exposure limit values (ELV)" means values established on the basis of biophysical and biological considerations, in particular on scientifically well-established short term and acute direct effects, i.e. thermal effects and electrical stimulation of tissues.

(i) "sensory effects ELV" means exposure limit values above which workers might be subject to transient disturbed sensory perceptions and minor changes in brain functions; and

(ii) "health effects ELV" means exposure limit values above which workers might be subject to adverse health effects, such as thermal heating or stimulation of nerve and muscle tissue;

(e) "action levels (AL)" means operational levels established for the purpose of simplifying the process of demonstrating the compliance with relevant exposure limit values or, where appropriate, to take relevant protection or prevention measures specified in this Directive**.** The terminology used in Annex II is as follows:

(i) for electric fields, “low AL” and “high AL" means levels which relate to the specific protection or prevention measures specified in this Directive; and

(ii) for magnetic fields, "low AL” means levels which relate to the sensory effects ELV and “high AL” to the health effects ELV.

Article 3

Exposure Limit Values and Action Levels

1. Physical quantities regarding the exposure to electromagnetic fields are indicated in Annex I. Health effects ELV, sensory effects ELV and action levels are set out in Annexes II and III..

2. Member Sates shall require that the employer ensures that exposure of workers to electromagnetic fields is limited to the health effects ELV and sensory effects ELV for non-thermal effects set out in Annex II and for thermal effects set out in Annex III. Compliance with health effects ELV and sensory effects ELV must be shown with the use of relevant exposure assessment procedures referred to in Article 4. Should the exposure exceed the exposure limit values, the employer shall take immediate action in accordance with Article 5(8).

3. For the purpose of this Directive, when it is demonstrated that the relevant action levels set out in Annex II and III are not exceeded, the employer complies with the health effects ELV and sensory effects ELV. Should the exposure exceed the action levels, the employer shall take action in accordance with Article 5(2), unless the assessment carried out in accordance with article 4(1), (2) and (3) demonstrates that the relevant ELV are not exceeded and that safety risks can be excluded. Nevertheless, without prejudice to this paragraph, exposure may exceed:

(a) low AL for electric fields (Annex II, Table B1), where justified by the practice or process, provided that the sensory effects ELV (Annex II, Table A3) are not exceeded; or

(i) the health effects ELV (Annex II, Table A2) are not exceeded;

(ii) excessive spark discharges and contact currents (Annex II, Table B3) are prevented by specific protection measures as set out in Article 5(6); and

(iii) information to workers has been given in accordance with Article 6(f);

(b) low AL for magnetic fields (Annex II, Table B2) where justified by the practice or process, also in the head and torso, during the shift, provided that the sensory effects ELV (Annex II, Table A3) are not exceeded; or

(i) the exceedance is temporary;

(ii) the health effects ELV (Annex II, Table A2) are not exceeded;

(iii) action is taken in accordance with Article 5(9), subject to transient symptoms under (a) of that Article; and

(iv) information to workers has been given in accordance with Article 6(f);

4. Without prejudice to paragraphs 2 and 3, exposure may exceed:

(a) the sensory effects ELV (Annex II, Table A1) during the shift, where justified by the practice or process, provided that:

(i) the exceedance is temporary;

(ii) health effects ELV are not exceeded;

(iii) specific preventive measures have been adopted in accordance with Article 5(7);

(iv) action is taken in accordance with Article 5(9), subject to transient symptoms under letter (b) of that Article; and

(v) information has been given to workers in accordance with Article 6(f).

(b) the sensory effects ELV (Annex II, Table A3 and Annex III, Table A2) during the shift, where justified by the practice or process, provided that:

(i) the exceedance is temporary;

(ii) health effects ELV are not exceeded;

(iii) action is taken in accordance with Article 5(9), subject to transient symptoms; and

(iv) information has been given to workers in accordance with Article 6(f).

CHAPTER II
OBLIGATIONS OF EMPLOYERS

Article 4
Assessment of risks and determination of exposure

1. In carrying out the obligations laid down in Articles 6(3) and 9(1) of Directive 89/391/EEC, the employer shall assess all risks for workers arising from electromagnetic fields at the workplace and, if necessary, measure or calculate the levels of electromagnetic fields to which workers are exposed**.**

2. For the purpose of the assessment, the employer shall identify and assess electromagnetic fields at the workplace, taking into account relevant guidance specified in Article 13 or other relevant standards or guidelines provided by the Member State, including exposure databases. Without prejudice to this article and when relevant, the employer shall be also entitled to take into account the emission levels and other appropriate safety-related data provided with the equipment by the manufacturer or distributor in accordance with relevant Union legislation, including assessment of risks, if applicable to the exposure conditions at the workplace or place of installation.

3. If compliance with the exposure limit values cannot be reliably determined on the basis of readily accessible information, the assessment of the exposure shall be carried out on the basis of measurements or calculations. In such a case, the assessment shall take into account the measurements or calculations (e.g. numerical errors, source modelling, phantom geometry, electrical properties of tissues and materials) uncertainties determined in accordance with relevant good practice.

4. The assessment, measurement and/or calculations referred to in paragraph 1, 2 and 3 shall be planned and carried out by competent services or persons at suitable intervals, taking into account the guidance 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 calculations of the level of exposure shall be preserved in a suitable form so as to permit consultation at a later stage, according to national law and practice**.**

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 health effects ELV, the sensory effects ELV and the action levels referred to in Article 3 and Annexes II and III of this Directive;

   (b) the frequency**,** the level, duration and type of exposure**,** including distribution over the workers body and the space of workplace;

   (c) any direct biophysical effects in the human body directly provoked by the presence in electromagnetic field, referred to in Article 2(b).

   (d) any effects concerning the health and safety of workers at particular risk**,** in particular workers who wear an active or passive implanted medical device (such as cardiac pacemakers), workers who wear body worn medical devices (such as insulin pumps)**,** and pregnant workers;

(e) any indirect effects on an object, due to the presence in electromagnetic field, which may become the cause of a safety or health hazard, referred to in Article 2(c);

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

(g) appropriate information obtained from health surveillance;

(h) information provided by the manufacturer of equipment and other relevant available health and safety related information**;**

(i) multiple sources of exposure;

(j) simultaneous exposure to multiple frequency fields;

6. The exposure assessment need not be carried out in workplaces open to the public provided that an evaluation has already been undertaken in accordance with the provisions on the limitation of exposure of the general public to electromagnetic fields, and the restrictions as specified therein are respected for workers and health and safety risks are excluded. Where only equipment, intended for the public use and complying with EU product legislation**,** that establishes stricter safety levels than those provided for by this Directive, are being used as intended for the public these conditions are met.

7. 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 Article 5 of this Directive. 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 employer shall take the necessary actions to ensure that risks arising from electromagnetic fields at the work place are 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 relevant action levels referred to in Article 3 and Annexes II and III are exceeded, unless the assessment carried out in accordance with article 4(1), (2) and (3) demonstrates that the relevant ELV are not exceeded and that safety risks can be excluded, the employer shall devise and implement an action plan comprising technical and/or organisational measures to prevent exposure exceeding the health effects ELV and sensory effects ELV, 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 delimitation and access measures (such as signals, labels, floor markings, fences) in order to limit or control access;

   (e) in case of exposure to electric fields, measures and procedures to manage spark discharges and contact currents through technical means and the training of workers**;**

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

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

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

(i) the availability of adequate personal protection equipment.

3. On the basis of the risk assessment referred to in Article 4**,** the employer shall devise and implement an action plan comprising technical and/or organisational measures to prevent any risks to workers at particular risk and any risks due to indirect effects referred to in Article 4**.**

4. Pursuant to Article 15 of Directive 89/391/EEC, the employer shall adapt the measures referred to in this Article to the requirements of workers at particular risk and individual risks assessments as appropriate**,** in particular for workers who have declared the use of active or passive implanted medical devices (such as cardiac pacemakers), the use of body worn medical devices (such as insulin pumps) or to be pregnant, following the information as set out in Article 6 of this Directive.

5. On the basis of the risk assessment referred to in Article 4, workplaces where workers are likely to be exposed to electromagnetic fields exceeding the action levels 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).[15] 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 and workers informed on the electromagnetic risks**,** then signs and access restrictions specific to electromagnetic fields shall not be required.

15 OJ L 245, 26.8.1992, p. 23.

6. In application of Article 3(3)(a), specific protection measures, cf. training of workers in accordance with Article 6 and the use of technical means and personal protection, such as grounding of work objects, bonding of workers with work objects (equipotential bonding) and, where appropriate and in accordance with Article 4(1)(a) of Directive 89/656/EEC, using insulating shoes, gloves and protective clothing shall be adopted.

7. In application of Article 3(4)(a), specific protection measures, such as controlling movements, shall be adopted.

8. Workers shall not be exposed above the sensory effects ELV and health effects ELV, unless the conditions under Articles 3(3), 3(4), 10(2) or 10(4) are fulfilled. If, despite the measures taken by the employer to comply with this Directive, the health effects ELV and sensory effects ELV are exceeded, the employer shall take immediate action to reduce exposure below these exposure limit values. The employer shall identify the reasons why the health effects limit values and sensory effects limit values have been exceeded, and shall amend the protection and prevention measures accordingly in order to prevent them being exceeded again.

9. In application of Articles 3(3) and 3(4), in case of occurrence of transient symptoms referred to in Article 2(b) reported by the worker, the employer shall update, if necessary, the risk assessment and the prevention measures. Transient symptoms might be related to:

   (a) sensory perceptions and effects in the function of the central nervous system in the head evoked by time varying magnetic fields; and

   (b) static magnetic field effects, such as vertigo and nausea.

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 likely to be 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 of this Directive, concerning in particular:

(a) measures taken to implement this Directive;

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

(c) the possible indirect effects of exposure;

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

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

(f) the possibility of transient symptoms and sensations related to effects in the central or peripheral nervous system;

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

(h) safe working practices to minimise risks from exposure;

(i) workers at particular risk, as refered to in Articles 4(5)(d), 5(3) and (4) of this Directive.

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. Those provisions, shall be introduced with national law and/or practice.

2. In accordance with national law and practice**,** 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

Penalties

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

Article 10

Derogations

1. By derogation from the obligations in Article 3, the provisions set in this Article shall apply**.**

2. Without prejudice to Article 5(1), exposure may exceed the exposure limit values, if the exposure is related to the installation, testing, use, development, maintenance of or research related to MRI-equipment for patients in the health sector, where all the following conditions are met:

   a) where the risk assessment carried out in accordance with Article 4 has shown that limit values are exceeded;

   b) where, given the state of the art, all technical and/or organisational measures have been applied;

   c) in duly justified circumstances;

   d) taking into account the characteristics of the workplace, work equipment, or work practices**;** and

   e) provided that the employer demonstrates that workers are still protected against adverse health effects and safety risks, including ensuring that the instructions for safe use provided by the manufacturer in accordance with Directive 93/42/EEC concerning medical devices are followed.

3. Without prejudice to Article 5(1), Member states may allow for an equivalent or more specific protection system to be implemented for personnel working in operational military installations or involved in military activities, including in joint international military exercises, provided that adverse health effects and safety risks are prevented**.**

4. Without prejudice to Article 5(1), Member States may allow, in duly justified circumstances and only for as long as they remain duly justified**,** for the exposure limit values to be temporarily exceeded in specific sectors or for specific activities outside the scope of paragraphs 2 and 3. Within this context, "duly justified circumstances" shall mean circumstances in which the following criteria are met:

   a) where the risk assessment carried out in accordance with Article 4 has shown that limit values are exceeded**;**

   b) where, given the state of the art, all technical and/or organisational measures have been applied;

   c) where the specific characteristics of the workplace, work equipment, or work practices have been taken into account**;** and

   d) provided that the employer demonstrates that workers are still protected against adverse health effects and safety risks, including using comparable, more specific and internationally recognized standards and guidelines.

5. Member States shall inform the Commission of any derogation under paragraphs 3 and 4 of this Article and the justification for such derogations in the report referred to in Article 17a of Directive 89/391/EEC.

Article 11

Technical amendments of the Annexes[16]

The Commission shall be empowered to adopt delegated acts in accordance with Article 12 in order to make amendments to the Annexes of a purely technical nature[17] 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 standards or specifications, and new scientific findings concerning electromagnetic fields;

(c) make adjustments to the action levels provided that compliance with the existing exposure limit values mentioned in Annex II and III is maintained and where there is new scientific evidence.

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 13 shall apply to delegated acts adopted pursuant to this Article.

Article 12

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.

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16 DE has maintained a reservation on Articles 11 to 13 on delegated acts. See Cover Note, Section III (2).

17 MT has maintained a reservation Article 11. See Cover Note, Section III (2).

2. The delegation of power referred to in Article 11 shall be conferred on the Commission for a period of 5 years from [*the date of entry into force of the present Directive*].

3. The delegation of powers referred to in Article 11 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 11 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 13

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 12(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 14

Practical Guide

The Commission shall draw up practical guides before [*date to be inserted*: *the date of transposition in Article 16(1)*] in order to facilitate the implementation of this Directive, in particular on the following issues:

a) determination of exposure taking into account appropriate European or international standards, including:

- calculation methods for limit value exposure assessment,
- spatial averaging of external electric and magnetic fields,
- guidance for dealing with measurements and calculations uncertainties**;**

b) guidance on demonstrating compliance in special types of non-uniform exposure in specific situations, based on well established dosimetry;

c) description of the "weighted peak method" for the low frequency fields and of the "multi-frequency fields summation" for high frequency fields**;**

d) conduct of the risk assessment and, wherever possible, provision of simplified techniques, considering in particular the needs of SMEs;

e) measures aimed at avoiding or reducing risks, including specific prevention measures depending on the level of exposure and the workplace characteristics**;**

f) establishment of documented working procedures as well as specific information and training measures for workers exposed to EMF during MRI related activities falling under Article 10 (2);

g) evaluation for exposure in the range of 100 kHz and 10 MHz where both thermal and non-thermal effects have to be considered**.**

The Commission shall work in close cooperation with the Advisory Committee for Safety and Health at Work.

Article 15

Review and reporting

The report on the practical implementation of this Directive shall be established in accordance to Article 17(a) of Directive 89/391/EEC.

Article 16

Transposition

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by [*date to be inserted: 3 years after the date of entry into force of this Directive*] at the latest.

   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 17

Repeal

1. Directive 2004/40/EC is repealed from [*date to be inserted: the date of entry into force of this Directive*].

2. References to the repealed Directive shall be construed as references to this Directive and shall be read in accordance with the correlation table set out in Annex IV.

Article 18

Entry into force

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

Article 19

Addressees

This Directive is addressed to the Member States.

Done at ,

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:

Electric field strength (E) is a vector quantity that corresponds to the force exerted on a charged particle, regardless of its motion in space. It is expressed in volt per meter (V/m). It has to be distinguished between the environmental electric field E and the electric field present in the body E_i (*in situ*) as a result of exposure to environmental one.

Limb current (I_L) is a current in limbs of a person exposed to electromagnetic fields in the frequency range from 10 MHz to 110 MHz as a result of contact with an object in an electromagnetic field or the flow of capacitive currents induced in exposed body. It is expressed in ampere (A).

Contact current (I_C) is a current that appears when a person gets in contact with an object in an electromagnetic field. It is expressed in ampere (A). A steady state contact current occurs when a person is in a continuous contact with an object in an electromagnetic field. In the process of making such a contact, a spark discharge may occur with associated transient currents.

Electric charge (Q) is an appropriate quantity used for spark discharge and is expressed in coulomb (C).

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

Magnetic flux density (B) is a vector quantity resulting in a force that acts on moving charges, expressed in tesla (T). In free space and in biological materials, magnetic flux density and magnetic field strength can be interchanged using the magnetic field strength of H = 1A/m equivalence to magnetic flux density of $B= 4\pi\ 10^{-7}$ T (it means app. 1.25 microtesla).

Power density (S) is an 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. It is expressed in watt per square meter (W/m^2).

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

Specific energy absorption rate (SAR), averaged over the whole body or over parts of the body, is a rate, at which energy is absorbed per unit mass of body tissue. It is expressed in watt 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: an individual exposed to RF in the low MHz range (eg. from dielectric heaters) and individuals exposed in the near field of an antenna.

Of these quantities, magnetic flux density (B), contact current (I_C), limb current (I_L), electric field strength (E), magnetic field strength (H) and power density (S) can be measured directly.

ANNEX II – NON-THERMAL EFFECTS

EXPOSURE LIMIT VALUES AND ACTION LEVELS IN THE FREQUENCY RANGE FROM 0 HZ TO 10 MHZ

A. EXPOSURE LIMIT VALUES (ELV)

Exposure limit values below 1 Hz (Table A1) are limits for static magnetic field which is not affected by the tissue of the body.

Exposure limits values for frequencies from 1 Hz up to 10 MHz (Table A2) are limits for electric fields induced in the body from exposure to time varying electric and magnetic fields.

Exposure limit values (ELV) for external magnetic flux density up to 1 Hz

The sensory effects ELV is the ELV for normal working conditions (Table A1) and is related to vertigo and other physiological effects related to disturbance of human balance organ resulting mainly from moving in a static magnetic field.

The health effects ELV for controlled working conditions (Table A1) is applicable on a temporary basis during the shift when justified by the practice or process, provided that preventive measures such as controlling movements and providing information to workers have been adopted.

Table A1 Exposure limit values for external magnetic flux density (B_0) from 0 to 1 Hz

	Sensory effects ELV
Normal working conditions	2 T
	Health effects ELV
Controlled working conditions	8 T
Localised limbs exposure	8T

Note A1-1:[18]

Health effects ELV for internal electric field strength from 1 Hz to 10 MHz

Health effects ELV (Table A2) are related to electric stimulation of all peripheral and central nervous system tissues in the body, including head**.**

Table A2 Health effects ELV for internal electric field strength from 1 Hz to 10 MHz

Frequency range	Health effects ELV
1 Hz ≤ f < 3 kHz	1.1 V/m (peak)
3 kHz ≤ f ≤ 10 MHz	3.8×10^{-4} f V/m (peak)

Note A2-1: f is the frequency expressed in hertz (Hz).

Note A2-2: The health effects ELV for internal electric field are spatial peak values in all the body of the exposed subject.

[18] When "*ICNIRP guidelines for limiting exposure to electric fields induced by movement of the human body in a static magnetic field and by time varying magnetic fields below 1 Hz*" will have been finalized, they will be inserted here during the negotiations on this Directive.

Note A2-3: The exposure limit values are peak values in time which are equal to the Root-Mean-Square (RMS) values multiplied by square root of 2 for sinusoidal fields. In the case of non-sinusoidal fields**,** exposure evaluation carried out in accordance with Article 4shall be based on the weighted peak method (filtering in time domain), explained in the practical guide set out in Article 14, but other scientifically proven and validated exposure evaluation procedures can be applied provided that they lead to approximately equivalent and comparable results.[19]

Sensory effects ELV for internal electric field strength from 1 Hz to 400 Hz

The sensory effects ELV (Table A3) are related to electric field effects on the central nervous system in the head, i.e. retinal phosphenes and minor transient changes in some brain functions.

Table A3. Sensory effects ELV for internal electric field strength from 1 Hz to 400 Hz

Frequency range	Sensory effects ELV
1 Hz ≤ f < 10 Hz	0.7/f V/m (peak)
10 Hz ≤ f < 25 Hz	0.07 V/m (peak)
25 Hz ≤ f ≤ 400 Hz	0.0028 f V/m (peak)

Note A3-1: f is the frequency expressed in hertz (Hz).

Note A3-2: The sensory effects ELV for internal electric field are spatial peak values in the head of the exposed subject.

[19] DE maintained a reservation of substance on this Note (see Cover note, Section III (1)).

Note A3-3: The exposure limit values are peak values in time which are equal to the Root-Mean-Square (RMS) values multiplied by square root of 2 for sinusoidal fields. In the case of non-sinusoidal fields**,** the exposure evaluation carried out in accordance with Article 4 shall be based on the weighted peak method (filtering in time domain), explained in the practical guide set out in Article 14, but other scientifically proven and validated exposure evaluation procedures can be applied provided that they lead to approximately equivalent and comparable results.[20]

B. ACTION LEVELS (AL)

The following physical quantities and values are used to specify the Action Levels (AL), the magnitude of which are established to ensure by simplified assessment the compliance with relevant exposure limit values or at which relevant protection or prevention measures specified in Article 5 of this Directive must be taken:

- Low AL(E) and high AL(E) for electric field strength E of time varying electric fields as specified in Table B1;

- Low AL(B) and high AL(B) for magnetic flux density B of time varying magnetic fields as specified in Table B2;

- AL(I_C) for contact current as specified in Table B3;

- AL(B_0) for magnetic flux density of static magnetic field**s** as specified in Table B4.

Action Levels correspond to calculated or measured electric and magnetic field values at the workplace in the absence of the worker.

[20] DE has maintained a reservation of substance on this Note (see Cover note, Section III (1)).

Action Levels (AL) for exposure to electric fields

Low AL (Table B1) for external electric field are based on limiting the internal electric field below the exposure limit values (Tables A2 and A3) and limiting spark discharges in the working environment.

Below high AL, the internal electric field does not exceed the exposure limit values (Tables A2 and A3) and annoying spark discharges are prevented, provided that the protection measures in 5(3a) are adopted.

Table B1. Action Levels for exposure to electric fields from 1 Hz to 10MHz

Frequency range	Electric field strength Low AL (E) [V/m] (RMS)	Electric field strength High AL (E) [V/m] (RMS)
$1 \leq f < 25$ Hz	2.0×10^4	2.0×10^4
$25 \leq f < 50$ Hz	$5.0 \times 10^5 / f$	2.0×10^4
50 Hz $\leq f <$ 1.64 kHz	$5.0 \times 10^5 / f$	$1.0 \times 10^6 / f$
$1.64 \leq f < 3$ kHz	$5.0 \times 10^5 / f$	6.1×10^2
3 kHz $\leq f \leq$ 10 MHz	1.7×10^2	6.1×10^2

Note B1-1: f is the frequency expressed in hertz (Hz).

Note B1-2: The low AL (E) and high AL (E) are the Root-Mean-Square (RMS) values of the electric field strength which are equal to the peak values divided by √2 for a sinusoidal field. In the case of a non-sinusoidal field, the exposure evaluation carried out in accordance with Article 4 shall be based on the weighted peak method (filtering in time domain), explained in the practical guide as set out in Article 14, but other scientifically proven and validated exposure evaluation procedures can be applied, provided that they lead to approximately equivalent and comparable results.

Note B1-3: AL represent maximum calculated or measured values at workers body position. This results in a conservative exposure assessment and automatic compliance with ELV in all non-uniform exposure conditions. In order to simplify the assessment of compliance with ELV, carried out in accordance with Article 4, in specific non-uniform conditions, criteria of spatial averaging of measured fields based on established dosimetry will be laid down in the practical guide referred to in Article 14. In the case of a very localized source with a distance of a few centimetres from the body, the induced electric field shall be determined dosimetrically, case by case.

Action Levels (AL) for exposure to magnetic fields

Low AL (Table B2) are for frequencies below 400 Hz derived from the sensory effects ELV (Table A3) and action levels above 400 Hz from the health effects ELV for internal electric field (Table A2).

High AL (Table B2) are derived from the health effects ELV for internal electric field related to electric stimulation of peripheral and autonomous nerve tissues in head and trunk (Table A2). Compliance with the high AL ensures that health effects ELV are not exceeded, but the effects related to retinal phosphenes and minor transient changes in brain activity are possible, if the exposure of the head exceeds the low AL for exposures up to 400 Hz. In such a case, Article 5(6) applies**.**

AL for exposure of limbs are derived from the health effects ELV for internal electric field related to electric stimulation of the tissues in limbs by taking into account that magnetic field is coupled weaker to the limbs than to the whole body**.**

Table B2. Action Levels for exposure to magnetic fields from 1 Hz to 10 MHz

Frequency range	Magnetic flux density Low AL(B) [μT] (RMS)	Magnetic flux density High AL(B) [μT] (RMS)	Magnetic flux density AL for exposure of limbs to a localized magnetic field [μT] (RMS)
$1 \leq f < 8$ Hz	$2.0 \times 10^5 / f^2$	$3.0 \times 10^5 / f$	$9.0 \times 10^5 / f$
$8 \leq f < 25$ Hz	$2.5 \times 10^4 / f$	$3.0 \times 10^5 / f$	$9.0 \times 10^5 / f$
$25 \leq f < 300$ Hz	1.0×10^3	$3.0 \times 10^5 / f$	$9.0 \times 10^5 / f$
300 Hz $\leq f < 3$ kHz	$3.0 \times 10^5 / f$	$3.0 \times 10^5 / f$	$9.0 \times 10^5 / f$
3 kHz $\leq f \leq$ [...]10 MHz	1.0×10^2	1.0×10^2	3.0×10^2

Note B2-1: f is the frequency expressed in hertz (Hz).

Note B2-2: The low AL and the high AL are the Root-Mean-Square (RMS) values which are equal to the peak values divided by √2 for sinusoidal field. In case of non-sinusoidal field the exposure evaluation carried out in accordance with Article 4 shall be based on the weighted peak method (filtering in time domain), explained in the Commissions practical guide as set out in Article 14, but other scientifically proven and validated exposure evaluation procedures can be applied, provided that they lead to approximately equivalent and comparable results.[21]

[21] DE has maintained a reservation of substance on this Note (see Cover note, Section III (1)).

Note B2-3: AL for exposure to magnetic fields represent maximum values at workers body position. This results in a conservative exposure assessment and automatic compliance with ELV in all non-uniform exposure conditions. In order to simplify the assessment of compliance with ELV, carried out in accordance with Article 4, in specific non-uniform conditions, criteria of spatial averaging of measured fields based on established dosimetry will be laid down in the practical guide referred to in Article 14. In the case of a very localized source with a distance of a few centimetres from the body, the induced electric field shall be determined dosimetrically, case by case**.**

Table B3. Action Levels for contact current I_C

Frequency	AL (I_C) steady state contact current [mA] (RMS)
up to 2.5 kHz	1.0
$2.5 \leq f < 100$ kHz	$0.4\,f$
100 kHz $\leq f \leq$ 10 MHz	40

Note B3-1: f is the frequency in kHz.

Action Levels (AL) for magnetic flux density of static magnetic fields

Table B4. Action Levels for magnetic flux density of static magnetic fields

Hazards	AL(B_0)
Active implanted devices, e.g. cardiac pacemakers	0.5 mT
Attraction and projectile risk in the fringed field of high field sources (>100 mT)	3 mT

ANNEX III – THERMAL EFFECTS

EXPOSURE LIMIT VALUES AND ACTION LEVELS IN THE FREQUENCY RANGE FROM 100 KHZ TO 300 GHZ

A. EXPOSURE LIMIT VALUES (ELV)

Health effects ELV for frequencies from 100 kHz up to 6 GHz (Table A1) are limits for energy and power absorbed per unit mass of body tissue generated from exposure to electric and magnetic fields (EMF).

Sensory effects ELV (Table A2) for frequencies from 0.3 to 6 GHz are limits on absorbed energy in a small mass of tissue in the head from exposure to electromagnetic fields.

Health effects ELV for frequencies above 6 GHz (Table A3) are limits for power density of an electromagnetic wave incident on the body surface.

Health effects ELV for frequencies from 100 kHz up to 6 GHz

Table A1 Health effects ELV for exposure to electromagnetic fields from 100 kHz to 6 GHz

Health effects ELV	SAR values averaged over any 6 minutes
ELV related to whole body heat stress expressed as averaged SAR in the body	0.4 W/kg
ELV related to localised heat stress in head and trunk expressed as localised SAR in the body	10 W/kg
ELV related to localised heat stress in the limbs expressed as localised SAR in the limbs	20 W/kg.

Note A1-1: 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 roughly homogeneous electrical properties. In specifying a contiguous mass of tissue, it is recognised that this concept may be used in computational dosimetry but may present difficulties for direct physical measurements. A simple geometry such as cubic or spheric tissue mass can be used.

Sensory effects ELV from 0.3 GHz to 6 GHz

This sensory effects ELV (Table A2) is related to avoiding auditory effects caused by exposures of the head to pulsed microwave radiation.

Table A2 Sensory effects limit ELV for exposure to electromagnetic fields from 0.3 to 6 GHz

Frequency range	Localised Specific Absorption (SA)
$0.3 \leq f \leq 6$ GHz	10 mJ/kg.

Note A2-1**:** Localised SA averaging mass is 10 g of tissue.

Table A3 Health effects ELV for exposure to electromagnetic fields from 6 GHz to 300 GHz

Frequency range	Health effects ELV related to power density
$6 \text{ GHz} \leq f \leq 300$ GHz	50 W/m^2

Note A3-1: The power density shall be averaged over any 20 cm^2 of exposed area. Spatial maximum power densities averaged over 1 cm^2 should not exceed 20 times the value of 50 W/m^2. Power densities from 6 to 10 GHz are to be averaged over any six-minutes period. Above 10 GHz, the power density shall be averaged over any $68/f^{1.05}$ -minute period (where f is the frequency in GHz) to compensate for progressively shorter penetration depth**,** as the frequency increases.

B. ACTION LEVELS (AL)

The following physical quantities and values are used to specify the Action Levels (AL), the magnitude of which are established to ensure by simplified assessment the compliance with the relevant exposure limit values or at which relevant protection or prevention measures specified in Article 5 of this Directive must be taken:

- AL(E) for electric field strength E of time varying electric field as specified in Table B1;

- AL(B) for magnetic flux density B of time varying magnetic field as specified in Table B1;

- AL(S) for power density of electromagnetic waves as specified in Table B1;

- AL(I_C) for contact current as specified in Table B2;

- AL(I_L) for limb current as specified in Table B2;

Action Levels correspond to calculated or measured field values at the workplace in absence of the worker, as maximum value at the position of the body or specified part of the body.

Action Levels (AL) for exposure to electric and magnetic fields

AL(E) and AL(B) are derived from the SAR or power density values (Tables A1 and A3) based on the thresholds related to internal thermal effects caused by exposure to (external) electric and magnetic field.

Table B1. Action Levels for exposure to electric and magnetic fields for exposure to electromagnetic fields from 100 kHz to 300 GHz.

Frequency range	Electric field strength AL(E) [V/m] (RMS)	Magnetic flux density AL(B) [μT] (RMS)	Power density AL(S) [W/m^2]
100 kHz ≤ f < 1 MHz	6.1×10^2	$2.0 \times 10^6 / f$	-
1 ≤ f < 10 MHz	$6.1 \times 10^8 / f$	$2.0 \times 10^6 / f$	-
10 ≤ f < 400 MHz	61	0.2	-
400 MHz ≤ f < 2 GHz	$3 \times 10^{-3} f^{½}$	$1.0 \times 10^{-5} f^{1/2}$	-
2 ≤ f < 6 GHz	1.4×10^2	4.5×10^{-1}	-
6 ≤ f≤ 300 GHz	1.4×10^2	4.5×10^{-1}	50

Note B1-1: f is the frequency expressed in hertz (Hz).

Note B1-2: $[AL(E)]^2$ and $[AL(B)]^2$ are to be averaged over 6 min period. For RF pulses, the peak power density averaged over the pulse width shall not exceed 1000 times the respective AL(S) value. For multi-frequency fields the analysis shall be based on summation, as explained in the practical guide set out in Article 14.

Note B1-3: AL(E) and AL(B) represent maximum calculated or measured values at workers body position. This results in a conservative exposure assessment and automatic compliance with ELV in all non-uniform exposure conditions. In order to simplify the assessment of compliance with ELV, carried out in accordance with Article 4, in specific non-uniform conditions, criteria of spatial averaging of measured fields based on established dosimetry will be laid down in the practical guide referred to in Article 14. In the case of a very localized source with a distance of a few centimetres from the body, the induced electric field shall be determined dosimetrically, case by case.

Note B1-4: The power density shall be averaged over any 20 cm^2 of exposed area. Spatial maximum power densities averaged over 1 cm^2 should not exceed 20 times the value of 50 W/m^2. Power densities from 6 to 10 GHz are to be averaged over any six-minutes period. Above 10 GHz the power density shall be averaged over any $68/f^{1.05}$ -minute period (where f is the frequency in GHz) to compensate for progressively shorter penetration depth as the frequency increases.

Table B2. Action Levels for steady state time varying contact currents and induced limb currents

Frequency range	Steady state contact current, $AL(I_C)$ [mA] (RMS)	Induced limb current in any limb, $AL(I_L)$ [mA] (RMS)
100 kHz ≤ f < 10 MHz	40	-
10 MHz ≤ f ≤ 110 MHz	40	100

Note B2-1: $[AL(I_L)]^2$ is to be averaged over 6 min period.

ANNEX IV

ANNEX IV - 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(b)	Article 2(d)
Article 2(c)	Article 2(e)
Article 3(1)	Article 3(1)
Article 3(2)	- […]
Article 3(3)	- […]
-	Article 3(2)
-	Article 3(3)
-	Article 3(4)
Article 4(1)	Article 4(1) and 4(2)
Article 4(2)	- […]
-	Article 4(3)
Article 4(3)	Article 4(6)
Article 4(4)	Article 4(4)
Article 4(5)(a)	Article 4(5)(b)
-	Article 4(5)(c)
Article 4(5)(b)	Article 4(5)(a)

Article 4(5)(c)	Article 4(5)(d)
Article 4(5)(d)	Article 4(5)(e)
Article 4(5)(d)(i)	- […]
Article 4(5)(d)(ii)	- […]
Article 4(5)(d)(iii)	- […]
Article 4(5)(d)(iv)	- […]
Article 4(5)(e)	Article 4(5)(f)
Article 4(5)(f)	Article 4(5)(g)
-	Article 4(5)(h)
Article 4(5)(g) to (h)	Article 4(5)(i) to (j) (unchanged)
Article 4(6)	Article 4(7)
Article 5(1)	Article 5(1)
Article 5(2), introductory wording	Article 5(2), introductory wording
Article 5(2)(a) to (c)	Article 5(2)(a) to (c) […]
-	Article 5(2)(d)
	Article 5(2)(e)
Article 5(2)(d)	Article 5(2)(f)
Article 5(2)(e)	Article 5(2)(g)
Article 5(2)(f)	Article 5(2)(h)
Article 5(2)(g)	Article 5(2)(i)
-	Article 5(3)
Article 5(3)	Article 5(5)
-	Article 5(6)
-	Article 5(7)
Article 5(4)	Article 5(8)
Article 5(5)	Article 5(4)
-	Article 5(9)

Article 6, introductory wording	Article 6, introductory wording
Article 6(a)	Article 6(a) (unchanged)
Article 6(b)	Article 6(b)
-	Article 6(c)
Article 6(c) to (d)	Article 6(d) to (e) (unchanged)
-	Article 6(f)
Article 6(e) to (f)	Article 6(g) to (h) (unchanged)
-	Article 6(i)
Article 7	Article 7 (unchanged)
Article 8(1) first paragraph	Article 8(1) first paragraph
Article 8(1) second paragraph	-
Article 8(2)	- […]
Article 8(3)	Article 8(2) […]
Article 9 (unchanged)	Article 9 […]
-	Article 10(1)
-	Article 10(2)
-	Article 10(3)
-	Article 10(4)
-	Article 10(5)
Article 10(1)	Article 11(1)
Article 10(2), introductory text	Article 11(2), introductory text
Article 10(2)(a)	Article 11 […] (a)
Article 10(2)(b)	Article 11[…] (b)
-	Article 11(2)(c)
Article 10(2), last sentence	Article 11(2), last sentence
Article 11(1)	-
Article 11(2)	Article 12
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Article 12 (Article repealed by Directive 2007/30/EC)	-
-	Article 14
-	Article 15
Article 13(1)	Article 16(1)
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-	Article 16
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-	Annex 1
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