

DIRECTIVE 2004/40/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 29 April 2004 on the minimum health and safety requirements regarding the exposure of workers to the risks arising from physical agents (electromagnetic fields) (18th individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 137(2) thereof,

Having regard to the proposal from the Commission, presented after consultation with the Advisory Committee on Safety, Hygiene and Health Protection at Work,

Having regard to the Opinion of the European Economic and Social Committee,

Following consultation of the Committee of the Regions,

Acting in accordance with the procedure laid down in Article 251 of the Treaty,

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) The communication from the Commission concerning its action programme relating to the implementation of the Community Charter of the Fundamental Social Rights of Workers provides for the introduction of minimum health and safety requirements regarding the exposure of workers to the risks caused by physical agents. In September 1990 the European Parliament adopted a resolution concerning this action programme, inviting the Commission in particular to draw up a specific directive on the risks caused by noise and vibration and by any other physical agents at the workplace.

(3) As a first step, the European Parliament and the Council adopted Directive 2002/44/EC of 25 June 2002 on the minimum health and safety requirements regarding the exposure of workers to the risks arising from physical agents (vibration) (16th individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC). Next, on 6 February 2003, the European Parliament and the Council adopted Directive 2003/10/EC on the minimum health and safety requirements regarding the exposure of workers to the risks arising from physical agents (noise) (17th individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC).

(4) It is now considered necessary to introduce measures protecting workers from the risks associated with electromagnetic fields, owing to their effects on the health and safety of workers. However, the long-term effects, including possible carcinogenic effects due to exposure to time-varying electric, magnetic and electromagnetic fields for which there is no conclusive scientific evidence establishing a causal relationship, are not addressed in this Directive. These measures are 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 Community workers, in order to avoid possible distortions of competition.

(5) 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 action values or the exposure limit values for electromagnetic fields. The implementation of this Directive should not serve to justify any regression in relation to the situation which already prevails in each Member State.

(6) 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.

(7) 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.

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

(9) 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, 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.

(10) This Directive constitutes a practical step towards creating the social dimension of the internal market.

(11) The measures necessary for the implementation of this Directive should be adopted in accordance with Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission.

(12) Adherence to the exposure limit and action values should provide a high level of protection as regards the established health effects that may result from exposure to electromagnetic fields but such adherence may not necessarily 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 action values and should therefore be the object of appropriate precautions and protective measures,

HAVE ADOPTED THIS DIRECTIVE:

SECTION I

GENERAL PROVISIONS

Article 1

Aim and scope

1. This Directive, which is the 18th 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 refers to the risk to the health and safety of workers due to known short-term adverse effects in the human body caused by the circulation of induced currents and by energy absorption as well as by contact currents.
3. 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 shall apply:

- (a) «electromagnetic fields» : static magnetic and time-varying electric, magnetic and electromagnetic fields with frequencies up to 300 GHz;
- (b) «exposure limit values» : limits on exposure to electromagnetic fields which are based directly on established health effects and biological considerations. Compliance with

these limits will ensure that workers exposed to electromagnetic fields are protected against all known adverse health effects;

(c) «action values» : the magnitude of directly measurable parameters, provided in terms of electric field strength (E), magnetic field strength (H), magnetic flux density (B) and power density (S), at which one or more of the specified measures in this Directive must be undertaken. Compliance with these values will ensure compliance with the relevant exposure limit values.

Article 3

Exposure limit values and action values

1. The exposure limit values are as set out in the Annex, Table 1.
2. The action values are as set out in the Annex, Table 2.
3. For the assessment, measurement and/or calculation of workers' exposure to electromagnetic fields, until harmonised European standards from the European Committee for Electrotechnical Standardisation (Cenelec) cover all relevant assessment, measurement and calculation situations, Member States may employ other scientifically-based standards or guidelines.

SECTION 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, until harmonised European standards from Cenelec cover all relevant assessment, measurement and calculation situations, be carried out in accordance with the scientifically-based standards and guidelines referred to in Article 3 and, when relevant, by taking into account the emission levels provided by the manufacturers of the equipment when it is covered by the relevant Community Directives.
2. On the basis of the assessment of the levels of electromagnetic fields undertaken in accordance with paragraph 1, if the action values referred to in Article 3 are exceeded, the employer shall assess and, if necessary, calculate whether the exposure limit values 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), and the restrictions as specified therein are respected for workers and safety risks are excluded.

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 particular account of the provisions 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 level, frequency spectrum, duration and type of exposure;
- (b) the exposure limit values and action values referred to in Article 3 of this Directive;
- (c) any effects concerning the health and safety of workers at particular risk;
- (d) any indirect effects, such as:
 - (i) interference with medical electronic equipment and devices (including cardiac pacemakers and other implanted devices);
 - (ii) the projectile risk from ferromagnetic objects in static magnetic fields with a magnetic flux density greater than 3 mT;
 - (iii) initiation of electro-explosive devices (detonators);
 - (iv) fires and explosions resulting from 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 levels of exposure to electromagnetic fields;
- (f) appropriate information obtained from health surveillance, including published information, as far as possible;
- (g) multiple sources of exposure;
- (h) simultaneous exposure to multiple frequency fields.

6. The employer shall be in possession of an assessment of the risk 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 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 it to be necessary.

Article 5

Provisions aimed at avoiding or reducing risks

1. Taking account of technical progress and of the availability of measures to control the risk at source, the risks arising from 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 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 intended 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 action values shall be indicated by appropriate signs in accordance 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, 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. The areas in question shall be identified, and access to them limited where this is technically possible and where there is a risk that the exposure limit values could be exceeded.

4. In any event, workers shall not be exposed above the exposure limit values.

If, despite the measures taken by the employer to comply with this Directive, the exposure limit values are exceeded, the employer shall take immediate action to reduce exposure below the exposure limit values. He shall identify the reasons why the exposure limit values 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 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 and action values and the associated potential risks;
- (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 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.

Article 7

Consultation and participation of workers

Consultation and participation of workers and/or of their representatives shall take place in accordance with Article 11 of Directive 89/391/EEC on the matters covered by this Directive.

SECTION 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.

In any event, where exposure above the 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 the health surveillance has 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 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 infringement of national legislation adopted pursuant to this Directive. These sanctions must be effective, proportionate and dissuasive.

Article 10

Technical amendments

1. Modifications of the exposure limit values and action values set out in the Annex shall be adopted by the European Parliament and the Council in accordance with the procedure laid down in Article 137(2) of the Treaty.

2. Amendments to the Annex of a strictly technical nature in line with:

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

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

shall be adopted in accordance with the regulatory procedure referred to in Article 11(2).

Article 11

Committee

1. The Commission shall be assisted by the Committee referred to in Article 17 of Directive 89/391/EEC.

2. Where reference is made to this paragraph, Articles 5 and 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

The period referred to in Article 5(6) of Decision 1999/468/EC shall be set at three months.

3. The Committee shall adopt its rules of procedure.

SECTION IV

FINAL PROVISIONS

Article 12

Reports

Every five years Member States shall provide a report to the Commission on the practical implementation of this Directive, indicating the points of view of the social partners.

Every five years the Commission shall inform the European Parliament, the Council, the European Economic and Social Committee and the Advisory Committee on Safety and Health Protection at Work of the content of these reports, of its assessment of developments in the field in question and of any initiative, in particular as regards exposure to static magnetic fields, that may be warranted in the light of new scientific knowledge.

Article 13

Transposition

1. The Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive no later than 30 April 2008 . They shall forthwith inform the Commission thereof.

When Member States adopt these measures, they shall contain a reference to this Directive or shall be accompanied by such reference on the occasion of their official publication. The methods of making such reference shall be laid down by Member States.

2. Member States shall communicate to the Commission the provisions of national law which they adopt or have already adopted in the field covered by this Directive.

Article 14

Entry into force

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

Article 15

Addressees

This Directive is addressed to the Member States.

Done at Strasbourg, 29 April 2004 .

For the European Parliament

The President

P. COX

For the Council

The President

M. McDOWELL

ANNEX

EXPOSURE LIMIT AND ACTION VALUES FOR ELECTROMAGNETIC FIELDS

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

Contact current (I_C) between a person and an object is expressed in amperes (A). A conductive object in an electric field can be charged by the field.

Current density (J) is defined as the current flowing through a unit cross section perpendicular to its direction in a volume conductor such as the human body or part of it, expressed in amperes per square metre (A/m^2).

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), which, 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 $1 A/m = 4\pi \cdot 10^{-7} T$.

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

Specific energy absorption rate (SAR) averaged over the whole body or over parts of the body, is defined as 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 measure 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.

A. EXPOSURE LIMIT VALUES

Depending on frequency, the following physical quantities are used to specify the exposure limit values of electromagnetic fields:

exposure limit values are provided for current density for time-varying fields up to 1 Hz, to prevent effects on the cardiovascular and central nervous system,

between 1 Hz and 10 MHz exposure limit values are provided on current density to prevent effects on central nervous system functions,

between 100 kHz and 10 GHz exposure limit values on SAR are provided to prevent whole-body heat stress and excessive localised heating of tissues. In the range 100 kHz to 10 MHz, exposure limit values on both current density and SAR are provided,

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.

>TABLE>

Notes :

1. f is the frequency in Hertz.
2. The exposure limit values on the current density are intended to protect against acute exposure effects on central nervous system tissues in the head and trunk of the body. The exposure limit values in the frequency range 1 Hz to 10 MHz are based on established adverse effects on the central nervous system. Such acute effects are essentially instantaneous and there is no scientific justification to modify the exposure limit values for exposure of short duration. However, since the exposure limit values refer to adverse effects on the central nervous system, these exposure limit values may permit higher current densities in body tissues other than the central nervous system under the same exposure conditions.
3. Because of the electrical inhomogeneity of the body, current densities should be calculated as averages over a cross-section of 1 cm^2 perpendicular to the current direction.
4. For frequencies up to 100 kHz, peak current density values can be obtained by multiplying the rms value by $(2)^{1/2}$.
5. For frequencies up to 100 kHz and for pulsed magnetic fields, the maximum current density associated with the pulses can be calculated from the rise/fall times and the maximum rate of change of magnetic flux density. The induced current density can then be compared with the appropriate exposure limit value. For pulses of duration t_p , the equivalent frequency to apply for the exposure limit values should be calculated as $f = 1/(2t_p)$.

6. All SAR values are to be averaged over any six-minute period.
7. 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.
8. 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 thermoelastic 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.
9. Power densities are to be averaged over any 20 cm² 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 cm² should not exceed 20 times the value of 50 W/m².
10. 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.

B. ACTION VALUES

The action values referred to in Table 2 are obtained from the exposure limit values according to the rationale used by the International Commission on Non-ionising Radiation Protection (ICNIRP) in its guidelines on limiting exposure to non-ionising radiation (ICNIRP 7/99).

>TABLE>

Notes :

1. f is the frequency in the units indicated in the frequency range column.
2. For frequencies between 100 kHz and 10 GHz, Seq , E, H, Band IL are to be averaged over any six-minute period.
3. For frequencies exceeding 10 GHz, Seq , E, Hand Bare to be averaged over any 68/f^{1.05}-minute period (f in GHz).

4. For frequencies up to 100 kHz, peak action values for the field strengths can be obtained by multiplying the rms value by $(2)^{1/2}$. For pulses of duration t_p , the equivalent frequency to apply for the action values should be calculated as $f = 1/(2t_p)$.

For frequencies between 100 kHz and 10 MHz, peak action values for the field strengths are calculated by multiplying the relevant rms values by 10^a , where $a = (0,665 \log (f/10) + 0,176)$, f in Hz.

For frequencies between 10 MHz and 300 GHz, peak action values are calculated by multiplying the corresponding rms values by 32 for the field strengths and by 1000 for the equivalent plane wave power density.

5. 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 harmonised European standards developed by Cenelec.

6. For peak values of pulsed modulated electromagnetic fields, it is also suggested that, for carrier frequencies exceeding 10 MHz, S_{eq} as averaged over the pulse width should not exceed 1000 times the S_{eq} action values or that the field strength should not exceed 32 times the field strength action values for the carrier frequency.