Procedure file

Basic information

COD - Ordinary legislative procedure (ex-codecision procedure) Directive	2011/0152(COD)
Minimum health and safety requirements regarding the exposure of workers to the risks arising from physical agents (electromagnetic fields) Repealing Directive 2004/40/EC 1992/0449C(COD) Subject 4.15.15 Health and safety at work, occupational medicine	Procedure completed

Key players

European Parliament

Committee responsible	Rapporteur	Appointed
EMPL Employment and Social Affairs		07/07/2011
	PPE MORIN-CHARTIER Elisabeth	
	Shadow rapporteur	
	S&D RAPTI Sylvana	
	ALDE HARKIN Marian	
	Verts/ALE DELLI Karima	
	ECR MCINTYRE Anthea	

Committee for opinion	Rapporteur for opinion	Appointed
ENVI Environment, Public Health and Food Safety		28/09/2011
	PPE JUVIN Philippe	

Council of the European Union

Council configuration	Meeting	Date
Employment, Social Policy, Health and Consumer Affairs	3247	20/06/2013
Employment, Social Policy, Health and Consumer Affairs	3188	04/10/2012
Employment, Social Policy, Health and Consumer Affairs	3177	21/06/2012
Employment, Social Policy, Health and Consumer Affairs	3131	01/12/2011

European Commission

Commission DG	Commissioner
Employment, Social Affairs and Inclusion	ANDOR László

European Economic and Social Committee

European Committee of the Regions

Key events

14/06/2011	Legislative proposal published	COM(2011)0348	Summary
13/09/2011	Committee referral announced in Parliament, 1st reading		
01/12/2011	Debate in Council	3131	Summary
21/06/2012	Debate in Council	3177	Summary
04/10/2012	Debate in Council	3188	Summary
06/12/2012	Vote in committee, 1st reading		
14/01/2013	Committee report tabled for plenary, 1st reading	A7-0009/2013	
10/06/2013	Debate in Parliament		
11/06/2013	Results of vote in Parliament		
11/06/2013	Decision by Parliament, 1st reading	T7-0243/2013	Summary
20/06/2013	Act adopted by Council after Parliament's 1st reading		
26/06/2013	Final act signed		
26/06/2013	End of procedure in Parliament		
29/06/2013	Final act published in Official Journal		

Technical information

Procedure reference	2011/0152(COD)
Procedure type	COD - Ordinary legislative procedure (ex-codecision procedure)
Procedure subtype	Legislation
Legislative instrument	Directive
	Repealing Directive 2004/40/EC 1992/0449C(COD)
Legal basis	Treaty on the Functioning of the EU TFEU 153-p2
Other legal basis	Rules of Procedure EP 165
Mandatory consultation of other institutions	European Economic and Social Committee European Committee of the Regions
Stage reached in procedure	Procedure completed
Committee dossier	EMPL/7/06523

Documentation gateway

Legislative proposal		COM(2011)0348	14/06/2011	EC	Summary
Document attached to the procedure		SEC(2011)0750	14/06/2011	EC	
Document attached to the procedure		SEC(2011)0751	14/06/2011	EC	
Committee draft report		PE474.084	14/11/2011	EP	
Amendments tabled in committee		PE478.400	16/12/2011	EP	
Committee opinion	ENVI	PE475.801	24/01/2012	EP	

Committee report tabled for plenary, 1st reading/single reading		A7-0009/2013	14/01/2013	EP	
Text adopted by Parliament, 1st reading/single reading		T7-0243/2013	11/06/2013	EP	Summary
Draft final act		00019/2013/LEX	26/06/2013	CSL	
Commission response to text adopted in plenary		SP(2013)520	16/07/2013	EC	

Additional information

National parliaments	IPEX
European Commission	EUR-Lex

Final act

Directive 2013/35
OJ L 179 29.06.2013, p. 0001 Summary

Final legislative act with provisions for delegated acts

Minimum health and safety requirements regarding the exposure of workers to the risks arising from physical agents (electromagnetic fields)

PURPOSE: to amend 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).

PROPOSED ACT: Directive of the European Parliament and of the Council.

BACKGROUND: the aim of this proposal is to amend Directive 2004/40/EC 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). In 2006, the medical community informed the Commission of its concerns regarding the implementation of this Directive, claiming that the exposure limit values laid down therein would limit to a disproportionate extent the use and development of magnetic resonance imaging (MRI), considered today to be a vital tool for the diagnosis and treatment of several diseases. Subsequently, other industrial sectors also expressed their concerns about the impact of the Directive on their activities.

In response to these concerns, the Commission has taken a number of measures. In particular, it asked the Member States to inform it of any difficulties associated with implementation of the Directive and launched a study to assess the actual impact of the Directive on medical procedures using MRI.

Meanwhile, in order to: allow a full analysis of the studies; take into account the results of the review of the new International Commission on Non-Ionizing Radiation Protection (ICNIRP) recommendations and finally, conduct an in-depth impact analysis of the Directive?s provisions, the deadline for transposition was put back from 30 April 2008 to 30 April 2012.

MRI issue: during the discussions preceding its adoption, the specific case of medical resonance imaging was discussed in detail by both the Council and the European Parliament.

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

This proposal maintains a number of important principles and provisions in the present Directive, such as: the exposure limit values and action values for electromagnetic fields in the frequency range from 100 kHz to 300 GHz; provisions aimed at avoiding or reducing risk; medical surveillance, etc.

The most important changes introduced by the proposal, taking into account the latest scientific findings in this area, are the following: clearer definitions, in particular for adverse health effects (Article 2 of Directive 2004/40/EC); inclusion of a revised system for limit and reference values different from the current limit values and action values for the range from 0 to 100 kHz (this will affect Articles 2 and 3 of Directive 2004/40/EC plus its annex); introduction of indicators to facilitate measurements and calculations; introduction of limited but appropriate flexibility by proposing a controlled framework for limited derogations for industry; special attention to the specific case of medical applications using magnetic resonance and related activities.

IMPACT ASSESSMENT: from discussions and consultations with stakeholders, the following options emerged:

- Policy option A: ?Do nothing?.
- Policy option B: ?New Directive with revised exposure limits?: Directive 2004/40/EC is replaced by a new Directive with revised exposure limit values that are higher than the previous ones, but are in line with scientific evidence.
- Policy option C1: ?New Directive with revised exposure limits and partial exemptions?: Directive 2004/40/EC is replaced by a new Directive with revised exposure limit values higher than the previous ones, but in line with scientific evidence (as in option B). In

addition, conditional exemptions are provided for MRI, which will however remain subject to the general EMF risk management requirements and covered by the new Directive.

- Policy option C2: ?New Directive with revised exposure limits and complete exemption for MRI?: Directive 2004/40/EC is replaced by a new Directive with revised exposure limit values higher than the previous ones, but in line with scientific evidence (as in option B). Medical MRI will be exempted entirely from all the requirements of the EMF Directive.
- Policy option D1: ?Replacement of the Directive by a Recommendation?: Directive 2004/40/EC is replaced by non-binding occupational EMF exposure recommendations, based on the latest international recommendations. The form of these recommendations would be similar to the Council Recommendation on EMF exposure of the general public (1999/519/EEC).
- Policy option D2: ?Voluntary agreements between the social partners?: Directive 2004/40/EC is replaced by voluntary agreements at European or sectoral level between social partners in accordance with Article 154(4) TFEU.
- Policy option E: ?No EU legislation?: Directive 2004/40/EC is repealed while Directive 89/391/EEC (Framework Directive) and existing national regulatory provisions on the subject remain in force. The absence of national regulations in some Member States will allow unregulated occupational EMF exposures. For this option, it may be assumed that for example those countries which have already (partially) implemented the EMF Directive would not repeal their EMF legislation.

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

LEGAL BASIS: Article 153(2) of the Treaty on the Functioning of the European Union (TFEU).

CONTENT: the proposal amends the relevant articles and annexes of Directive 2004/40/EC in order to achieve a clear, simple and precise text, which is transparent and readily understandable to the public and economic operators.

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

- coverage of all sectors of activity ,
- exposure limit values and action values for electromagnetic fields in the frequency range from 100 kHz to 300 GHz,
- provisions aimed at avoiding or reducing risk,
- information and training of workers,
- consultation and participation of workers,
- sanctions,
- medical surveillance.

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

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

Revised system for limit and reference values: the new Directive shall include a revised system for limit and reference values different from the current limit values and action values for the range from 0 to 100 kHz.

In addition:

- Article 3 refers to the exposure limit values and action values as in Directive 2004/40/EC. However, paragraph 1 briefly sets out the roles of the new orientation and action values in order to achieve the proportionality required by stakeholders. This applies to the frequency range from 0 Hz to 100 kHz. From 100 kHz to 300GHz, the levels remain the same as in Directive 2004/40/EC, as no new recommendations have been published since 1998.
- Paragraph 3 is similar to the corresponding paragraph of Directive 2004/40/EC but has been adapted to limit extensive measurements to cases where they are really necessary. This will in practice simplify the carrying out of the risk assessment for a large majority of workplaces.
- Paragraph 4 is new and provides an exemption from the exposure limits for the medical MRI sector and related activities, which will continue to be subject to all other obligations.
- Paragraph 5 is new and provides the right for the military to use a protection system adapted to its specific working situations (e.g. radars). This request was made by NATO, which uses a protection system based on recommendations proposed by IEEE. This system can be considered equivalent to the system set out in this proposal.
- Paragraph 6 is new and provides for temporary derogations under controlled conditions where the exposure limits are likely to be exceeded.

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

Technical amendments: compared with the same article (Article 10) in Directive 2004/40/EC, significant changes have been introduced. The first paragraph, containing a reference to the legislative procedure laid down in Article 153(2) with regard to the adoption of modifications of the exposure limit values, has been deleted since the proposal itself is based on Article 153(2) of the Treaty and it is not necessary to refer to it again in the enacting terms. The European Parliament and the Council do not empower the Commission to modify the exposure limit values. Any such modifications would therefore not be introduced by the Commission delegated acts but by amendments of the Directive according to the procedure laid down in Article 153(2) TFEU.

However, the actual directly measurable reference levels, i.e. the orientation and action values, are considered as amendments of a strictly technical nature. In the light of the new ?comitology? rules introduced by the Lisbon Treaty, the purely technical amendments to Annexes referred to in Article 10 are measures of general scope that are designed to amend non-essential elements of the Directive. They thus come under ?delegated acts? within the meaning of Article 290 TFEU, and the procedure laid down in that Article (on delegating powers) should be used to adopt those technical amendments.

Provision for complementary non-binding measures such as a non-binding practical guide: Article 13 is new and refers to the need to establish

a practical guide in order to facilitate implementation of the Directive.

Other measures: the proposed revised Directive aims to:

- introduce some guidance to ensure simplified but more efficient risk assessments in order to facilitate the evaluation work and also to limit the burden on SMEs,
- introduce limited but appropriate flexibility by proposing a controlled framework for limited derogations for industry.

Annexes:

- Annex I introduces a number of physical quantities not included in the main text (Article 2). This option is considered preferable for better coherence of the text of the proposal.
- Annex II is an important part of the proposal because it sets out all the elements required to ensure more flexibility and proportionality in the frequency range from 0 Hz to 100 kHz. It introduces in practice the ?zoning? system supported by most stakeholders together with measures to facilitate risk assessment procedures whenever possible.
- Annex III covers the higher end of the frequency spectrum. As there have been no new international recommendations over recent years in this area, the changes are limited to a different presentation and some elements to facilitate the work of employers.
- Annex IV is specific to medical magnetic resonance (MR). It is designed to ensure the smooth and harmonised application of appropriate qualitative protection measures in a controlled environment.
- Annex V includes a list of legislative acts amending Directive 2004/40/EC (referred to in Article 15) and a correlation table between the provisions of Directive 2004/40/EC, as amended, and this proposal.

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

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

Minimum health and safety requirements regarding the exposure of workers to the risks arising from physical agents (electromagnetic fields)

The Council took note of a progress report on a directive on the minimum health and safety requirements regarding the exposure of workers to the risks arising from physical agents (electromagnetic fields).

To recall, the aim of the proposal is to revise directive 2004/40/EC in order to take into account new scientific studies, while ensuring high levels of worker protection and, inter alia, to review the impact of exposure limit values for magnetic resonance imaging (MRI) scanners. Directive 2004/40/EC was adopted together with other measures intended to protect workers from the health effects of noise, vibration and optical radiation. However, soon after its adoption in 2004, the medical community working with magnetic resonance imaging (MRI) claimed that its activities would be hampered by the strict exposure limit values laid down therein.

Due to these difficulties in its application and to allow time for the directive to be amended in the light of new scientific information, Parliament and Council decided at that time to delay its transposition until 30 April 2012.

The activities performed under the Presidency resulted in reducing the area of non-consensus on the proposal, in particular in:

- clarifying the scope of the Directive and clarifying its relation with the Framework Directive;
- clarifying the provisions concerning the obligations of employers, risk assessment and limitations;
- clarifying the meaning of the term workers at particular risk in respect to electromagnetic field exposure and rules of protection applicable to this group;
- elaborating a compromise approach by referring to national law and/or practice, as regards health surveillance;
- redrafting Annexes II and III, while merging them to express exposure limitation over one continuous frequency range, in order to, inter alia: (i) link the figures directly to international science-based safety guidelines, namely those of ICNIRP, following comments expressed by Member States´ representatives; (ii) make the figures measurable and rename some of the values in order to facilitate their use, when translating them into Member States languages and monitoring exposure at the workplace, especially in SMEs; (iii) clarify the meaning of parameters used to express exposure limitation in order to facilitate their interpretation in practical use;
- suggesting a set of possible compromise options which would allow to derogate from binding exposure limits under certain circumstances.

Despite considerable efforts deployed by the Presidency and the delegations in drafting compromise proposals and significant progress made in the Working Party, there is still a need for further consultations with experts on two main sets of issues:

(1) To binding exposure limit values (none of the compromise proposals gained sufficient support, nevertheless, many delegations were in favour of a slightly modified Commission proposal containing sectoral derogations, while a number of delegations supported a compromise proposal based on a general derogation);

(2) Exposure limitations and action values as well as methodology used, by deriving it from international science-based safety guidelines, in particular in Annex II of the current draft Directive.

Other issues to be further discussed are: (i) scope of the Directive with regard to long-term effects of electromagnetic field exposure; (ii) delegation of powers to the Commission; (iii) transposition (correlation tables/explanatory documents).

Minimum health and safety requirements regarding the exposure of workers to the risks arising from physical agents (electromagnetic fields)

The Council took note of ongoing work on the minimum health and safety requirements regarding the exposure of workers to the risks arising from the physical agents (electromagnetic fields) directive. This new directive amends the directive from 2004 (2004/40/EC), which has never entered into force due to problems with its implementation.

The current text has been examined by the Council working party for almost a year now and, in principle, a compromise has been reached on the layout of the annexes, subject to further non-substantial editorial amendments. Broad support has been expressed for the derogations, in particular the magnetic resonance imaging (MRI) derogation.

In April 2012, the Danish presidency presented its first compromise proposal on annexes II and III and on article 3. The compromise reached since then concerns annexes II and III containing the values and exposure limits and article 13 on the Commission guide, listing the required information. The member states broadly supported the presidency compromise proposal on article 3 with a special provision for the MRI sector and a general derogation for other industry sectors and the armed forces (NATO), but there was a consensus that article 3 should be further worked on under the Cyprus presidency.

The European Parliament has not yet finalised its internal planning on the procedures; however, it has indicated unofficially that it is awaiting the Council's position, in particular on the technical aspects of the directive.

Minimum health and safety requirements regarding the exposure of workers to the risks arising from physical agents (electromagnetic fields)

The Council reached a general approach (doc. 14020/12) on a new Directive on the minimum health and safety requirements regarding the exposure of workers to the risks arising from electromagnetic fields (14020/12), by which a Directive adopted in 2004 on the same subject will be repealed.

One Member State, however, could not accept the proposed text. While the draft Directive provides for the internationally recognised "weighted peak method" as a reference method for exposure evaluation, that delegation requests more flexibility so as to allow for the use of other methods with less conservative results.

Minimum health and safety requirements regarding the exposure of workers to the risks arising from physical agents (electromagnetic fields)

The Committee on Employment and Social Affairs adopted the report by Elisabeth MORIN-CHARTIER (EPP, FR) on the 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 parliamentary committee recommends that the European Parliaments position adopted at first reading according to the ordinary legislative procedure should amend the Commissions proposal as follows:

Purpose of the Directive: the Directive should address all known direct and indirect biophysical effects caused by electromagnetic fields in order 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.

Long-term effects of exposure to electromagnetic fields: Members call on the Commission and the Member States to increase research and the collection of data on the long-term effects of exposure to electromagnetic fields. As soon as there is conclusive scientific evidence on the exposure to electromagnetic fields, they call on the Commission to then present a new proposal to address the long-term effects of such exposure.

Definitions: Members added a new definition in regard to the direct biophysical effects or direct effects on the human body provoked by the presence in electromagnetic fields. These include, in particular, thermal effects and non-thermal on human tissue but also limb currents.

Members also define the indirect effects which may become the cause of a safety or health hazard for workers, such as fires and explosions resulting from the ignition of flammable materials by sparks caused by induced fields, contact currents or spark discharges.

Exposure limit values (ELVs): according to Members, the exposure limit values set in this Directive should only address the scientifically well-established links between short-term direct biophysical effects and exposure to electromagnetic fields. Several types of ELVs are thus envisaged in the proposed directive, including in regard to sensory effects and effects on health.

Action levels (ALs): Members also envisage action levels or operational levels established for the purpose of simplifying the process of demonstrating the compliance with relevant ELV or, where appropriate, to take relevant protection or prevention measures. To this effect, Members define low AL and high AL" as levels which relate to the specific protection or prevention measures.

Members delete all the old orientation values and action values in the Commissions proposal.

It should be noted that the values laid down in the directive are listed in distinct annexes. The physical quantities, limit values and action levels laid down in the Annexes are based on the recommendations of the International Commission on Non- Ionising Radiation (ICNIRP). Making

amendments to the Annexes of a 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.

Employer obligations: Members call for employers ensure that the 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 IIa and for thermal effects set out in Annex IIIa. Compliance with health effects ELV and sensory effects ELV must be shown with the use of relevant exposure assessment procedures referred to in the proposal. Should the exposure exceed the ELV, the employer shall take immediate action in accordance with measures foreseen in the proposal.

Other measures are envisaged if the relevant action levels are (or are not) exceeded. These measures involve safety protection measures for workers.

On the whole, Members believe that employers should be required to ensure that risks arising from electromagnetic fields are eliminated or reduced as mush as possible. However, it may be, in certain duly justified circumstances, that the ELVs laid down in the Directive may be temporarily exceeded. In such cases, Members call for employers to take the necessary measures to ensure that the ELVs are once again respected as soon as possible. In any event, workers should be kept informed of their level of exposure.

Assessment of risks and determination of exposure: the basic principle is that the employer should assess all the risks for workers arising from electromagnetic fields at the workplace and, if necessary, should measure or calculate the levels of electromagnetic fields to which workers are exposed. This assessment could be made public on request. It should be based on standards or guidelines drawn up by the Member State or on relevant safety data communicated by the equipment manufacturer or distributor.

If, however, compliance with the ELV 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 uncertainties relating to measurements or calculations (e.g. numerical errors, etc.), determined in accordance with relevant good practice. The employer shall pay particular attention, when carrying out the risk assessment, to certain variables such as the frequency, the level, the duration and the type of exposure or the biophysical effects on the human body directly provoked or any effects of the exposure on 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 women who are pregnant.

Exposures in workplaces open to the public: Members stipulate the exposure assessment needs 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. These conditions are considered to be met where only equipment, intended for the public use and complying with EU product legislation is used.

Measures to be taken by the employer in the event of exposure: Members stipulate that, in the event of exposure, the employer shall devise and implement an action plan including technical and/or organisational measures to prevent any risks to workers at particular risk and any risks due to indirect effects. Training of workers is also envisaged in the proposal. Provision is also made for other specific protection measures in the event of the appearance of transient symptoms (ranging from vertigo to nausea).

Health surveillance: with the objective of prevention and early diagnosis of any adverse health effects due to exposure to electromagnetic fields, appropriate health surveillance should be carried out in accordance with national law and/or practice. In any event, where exposure above the ELV is detected, the employer shall ensure that appropriate medical support is provided to the workers concerned, in accordance with national law and practice. Any costs arising from this examination should be borne by the employer.

Exemptions:

Members make provision for a series of derogations to the provisions of the proposal. Exposure may thus exceed the limit values if it is related to the installation, testing, use, development, maintenance of or research related to MRI-equipment for patients in the health sector and on condition that certain conditions are met.

Likewise, 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. Moreover, Members define the justified circumstances when the exemption may apply. Any derogations should be notified to the Commission.

Delegated acts: Members stipulate that the delegation of power to make technical amendments to the directive may be delegated to the Commission for a period of five years. These delegations of power should be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period.

Practical guides: the Commission should draw up practical guides in order to facilitate the implementation of the future Directive and the medical examinations. It should also design simplified techniques to meet the needs of SMEs.

Report: in addition to the report already provided for in the proposal, Members call for the Commission to prepare, within five years of the entry into force of the future Directive, a specific report on the Directives effectiveness in reducing exposure to electromagnetic fields and the percentage of workplaces that required corrective action.

Annexes: lastly, the annexes have been comprehensively reviewed and new annexes have been added providing a technical definition of the values not to be exceeded (both exposure limit values and action levels) as a function of the frequency ranges of electromagnetic fields.

Minimum health and safety requirements regarding the exposure of workers to the risks arising from physical agents (electromagnetic fields)

The European Parliament adopted by 594 votes to 40, with 38 abstentions, a legislative resolution on the 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).

Parliament adopted its position at first reading according to the ordinary legislative procedure. The amendments adopted in plenary are the

result of a compromise negotiated between the European Parliament and the Council. They amend the proposal as follows:

Scope: the Directive covers all known direct biophysical effects and indirect effects caused by electromagnetic fields. The exposure limit values (ELVs) laid down in this Directive cover only scientifically well-established links between short-term direct biophysical effects and exposure to electromagnetic fields. This Directive does not cover suggested long-term effects.

However, if well-established scientific evidence on suggested long-term effects becomes available, the Commission shall consider a suitable policy response, including, if appropriate, the submission of a legislative proposal to address such effects. The Commission shall, by means of a report referred to in the Directive, keep the European Parliament and the Council informed in this regard.

Definitions: a new definition was introduced in regard to direct biophysical effects which are effects in the human body directly caused by its presence in an electromagnetic field, including, in particular, thermal effects, non-thermal effects or limb currents.

Also included within the indirect effects or effects caused by the presence of an object in an electromagnetic field which may become the cause of a safety or health hazard, such as interference with medical electronic equipment and devices, including cardiac pacemakers and other implants, or that can cause fires and explosions

Exposure limit values (ELVs): ELVs are values established on the basis of biophysical and biological considerations, in particular on the basis of scientifically well-established short-term and acute direct effects, i.e. thermal effects and electrical stimulation of tissues. Health effects ELVs means those ELVs above which workers might be subject to adverse health effects and sensory effects ELVs means those ELVs above which workers might be subject to transient disturbed sensory perceptions.

Action levels (ALs): these are defined as operational levels established for the purpose of simplifying the process of demonstrating the compliance with relevant ELVs or, where appropriate, to take relevant protection or prevention measures specified in the Directive. To this effect, provision is made for low ALs and high ALs implying differentiated levels of protection or prevention.

It should be noted that the values provided for in the Directive are listed in disctinct annexes.

The physical quantities, ELVs and ALs, laid down in this Directive are based on the recommendations of the International Commission on Non-Ionizing Radiation Protection (ICNIRP) and should be considered in accordance with ICNIRP concepts.

Obligations of employers: it is stipulated that employers ensure that exposure of workers to electromagnetic fields is limited to the health effects ELVs and sensory effects ELVs set out in Annex II and in Annex III. Compliance with health effects ELVs and sensory effects ELVs must be established by the use of relevant exposure assessment procedures referred to in the Directive. Where the exposure of workers to electromagnetic fields exceeds the ELVs, the employer shall take immediate preventive action in accordance with the provisions of the Directive.

Provision is made for other measures if the relevant ALs are (or are not) exceeded. These provisions include measures to protect the safety of workers unless the assessment carried out in accordance with the Directive demonstrates that the relevant ELVs are not exceeded and that safety risks can be excluded.

Provision is made, however, for a series of derogations so that, under certain very strict conditions, the ALs for the electromagnetic fields may be exceeded.

Generally speaking, employers would be required to ensure that risks arising from electromagnetic fields in the workplace are eliminated or reduced as much as possible. If these values are exceeded, they may only be so on a temporary basis and, in such cases, employers would have to take the necessary measures to ensure that the ELVs are once again respected as soon as possible.

Assessment of risks and determination of exposure: the basic principle is that the employer shall assess all the risks for workers arising from electromagnetic fields at the workplace and, if necessary, shall measure or calculate the levels of electromagnetic fields to which workers are exposed.

- Publication of the assessment: the assessment can be made public on request in accordance with relevant Union and national laws applicable to the processing of the personal data of employees. Unless there is an overriding public interest in disclosure, public authorities that are in possession of a copy of the assessment may refuse a request for access to it or a request to make it public, where disclosure would undermine the protection of commercial interests of the employer, including those relating to intellectual property.

- Practical guides: for the purpose of the assessment, the employer shall identify and assess electromagnetic fields at the workplace, taking into account the relevant practical guides and other relevant standards or guidelines provided by the Member State concerned, including exposure databases. The content of these non-binding practical guides is laid down in the Directive. They shall be made available at the beginning of 2016. The employer shall also be entitled to take into account the emission levels and other appropriate safety-related data provided, by the manufacturer or distributor, for the equipment, in accordance with relevant Union law.

If compliance with the ELVs 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 taking into account certain variables such as the frequency, the duration and type of exposure or the direct biophysical effects on the human body or the effects of exposure of workers with cardiac pacemakers or with medical devices (e.g. insulin pump), as well as pregnant women.

Exposures in workplaces open to the public: the exposure assessment will not need to 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, if the restrictions as specified in those provisions are respected for the workers and if all health and safety risks are excluded. These conditions are considered to be met where only equipment, intended for the public use is used as intended and complies with EU product legislation.

Measures to be taken by employers to avoid or reduce the risk of exposure: employers shall apply a series of protection and preventive measures in the form of an action plan to be implemented in the event of exposure. This plan would include technical and/or organisational measures to prevent any risks to workers at particular risk and any risks due to indirect effects (e.g. appropriate delimitation and access measures, such as signals, labels, floor markings, barriers). Training of workers is also envisaged, as are other specific protection measures such as the grounding of work objects or the use of insulating shoes. Measures to trace the actions taken and applied are also laid down. Lastly, risk management measures are stipulated for cases where a worker reports transient symptoms (which can range from vertigo to nausea).

Health surveillance: with the objective of prevention and early diagnosis of any adverse health effects due to exposure to electromagnetic fields, appropriate health surveillance should be carried out in accordance with Directive 89/391/EEC. Health records and their availability shall be provided for in accordance with national law and/or practice. In any event, where exposure above the ELVs is detected, the employer shall ensure that appropriate medical examinations or individual health surveillance is provided to the worker(s) concerned, in accordance with national law and practice. The costs of such examinations shall be borne by the employer.

Exemptions: provision is made for a series of derogations. Exposure may thus exceed the limit values if it is related to the installation, testing, use, development, maintenance of or research related to MRI-equipment for patients in the health sector and on condition that certain conditions are met.

Likewise, 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. The provisions, furthermore, stipulate the justified circumstances when the exemption shall apply. All derogations shall be notified to the Commission.

Delegated acts: the Commission shall be empowered to adopt delegated acts amending, in a purely technical way, the Annexes, so as to take into account the adoption of regulations and directives in the field of technical harmonisation and standardisation and new scientific findings concerning electromagnetic fields, as well as to make adjustments to the ALs. Where purely technical amendments need to be made to the annexes, the Commission shall work in close cooperation with the Advisory Committee for Safety and Health at Work.

Annexes: the annexes have been reviewed and new annexes have been added providing a technical definition of the values not to be exceeded as a function of the frequency ranges of electromagnetic fields.

Transposition: the Directive shall be transposed in the Member States by 1 July 2016 at the latest.

Minimum health and safety requirements regarding the exposure of workers to the risks arising from physical agents (electromagnetic fields)

PURPOSE: to amend Directive 2004/40/EC 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).

LEGISLATIVE ACT: Directive 2013/35/EU 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) (20th individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC) and repealing Directive 2004/40/EC.

CONTENT: this Directive amends Directive 2004/40/EC by repealing and replacing the 2004 text which never entered into force because of problems relating to its implementation.

The main objectives of this revision are technical and relate to:

- the definition of exposure limitations on the basis of new scientific evidence;
- provisions for derogations, under certain strict conditions, in particular for workers involved with medical applications using magnetic resonance imaging (MRI).

Subject matter and scope: the Directive 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. It covers all known direct biophysical effects and indirect effects caused by electromagnetic fields. The exposure limit values (ELVs) laid down in this Directive cover only scientifically well-established links between short-term direct biophysical effects and exposure to electromagnetic fields. It does not cover suggested long-term effects.

However, if well-established scientific evidence on suggested long-term effects becomes available, the Commission shall consider a suitable policy response, including, if appropriate, the submission of a legislative proposal to address such effects. The Commission shall, by means of a report, keep the European Parliament and the Council informed in this regard.

It should also be noted that this Directive does not cover the risks resulting from contact with live conductors.

Definitions: the Directive defines what is meant by electromagnetic fields (whose frequencies are up to 300 GHz), as well as what is meant by direct biophysical effects which are the effects in the human body directly caused by its presence in an electromagnetic field, including thermal effects, non-thermal effects and limb currents.

Indirect effects, effects, caused by the presence of an object in an electromagnetic field, which may become the cause of a safety or health hazard, such as interference with medical electronic equipment and devices, including cardiac pacemakers and other implants or medical devices worn on the body or, for example, resulting in fires and explosions, are also defined.

The Directive also defines the following:

- exposure limit values (ELVs) which are values established on the basis of biophysical and biological considerations, in particular on the basis of scientifically well-established short-term and acute direct effects, i.e. thermal effects and electrical stimulation of tissues. These include health effects ELVs means those ELVs above which workers might be subject to adverse health effects, such as thermal heating or stimulation of nerve and muscle tissue and sensory effects ELVs means those ELVs above which workers might be subject to transient disturbed sensory perceptions and minor changes in brain functions;
- action levels (ALs) which are operational levels established for the purpose of simplifying the process of demonstrating the compliance with relevant ELVs or, where appropriate, to take relevant protection or prevention measures specified in this Directive. To this end, provision is made for low ALs and high ALs implying different levels of protection or prevention.

It should be noted that the values foreseen in the Directive are laid down in its annexes.

The physical quantities, ELVs and ALs, laid down in this Directive are based on the recommendations of the International Commission on Non-Ionizing Radiation Protection (ICNIRP).

Obligations of employers: the general principle laid down by the Directive is that 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.

Assessment of risks and determination of exposure: for the purposes of assessing the risks of exposure, the employer shall make use of a series of technical tools laid down in the Directive and, in particular:

- practical guides: non-binding practical guides made available by the Commission which shall be made available in 2016;
- other relevant standards or guidelines provided by the Member State concerned, including exposure databases;
- the emission levels and other appropriate safety-related data, provided by the manufacturer or distributor, for the equipment, in accordance with relevant Union law.

If compliance with the ELVs 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 uncertainties concerning the measurements or calculations, such as numerical errors.

The assessment can be made public in accordance with relevant Union and national laws applicable to the processing the personal data of employees. Unless there is an overriding public interest in disclosure, public authorities that are in possession of a copy of the assessment may refuse a request for access to it or a request to make it public, where disclosure would undermine the protection of commercial interests of the employer, including those relating to intellectual property.

Scope of the assessment: the assessment, measurement and calculations shall be planned and carried out by competent services or persons at suitable intervals. It shall give particular attention to the following: (i) the health effects ELVs, (ii) the sensory effects ELVs and (iii) the ALs referred to in the Directive and in Annexes II and III of the Directive but also (among other things) to:

- the frequency, the level, duration and type of exposure, including the distribution over the workers body and over the volume of the workplace;
- any direct biophysical effects;
- any effects on the health and safety of workers at particular risk, in particular workers who wear active or passive implanted medical devices, such as cardiac pacemakers, workers with medical devices worn on the body, such as insulin pumps, and pregnant workers;

Provisions aimed at avoiding or reducing risks: employers shall ensure that the exposure of workers to electromagnetic fields is limited to the health effects ELVs and sensory effects ELVs set out in Annex II, for non-thermal effects, and in Annex III, for thermal effects. Where the exposure of workers to electromagnetic fields exceeds the ELVs, the employer shall take immediate preventive action in accordance with the Directive, i.e. an action plan to be implemented in the event of exposure. This plan would include technical and/or organisational measures to prevent any risks to workers at particular risk and any risks due to indirect effects (e.g. appropriate delimitation and access measures, such as signals, labels, floor markings, barriers).

Information and training of workers is also provided for, as is the appropriate consultation and participation of workers and/or their representatives.

Other specific protective measures are also foreseen such as the grounding of work objects or the use of insulating shoes, measures to trace the actions taken and applied and, lastly, risk management measures are stipulated for cases where a worker reports transient symptoms (which can range from vertigo to nausea).

Specific provisions are foreseen where the relevant ALs are (or are not) exceeded. These provisions include worker protection measures unless the assessment carried out in accordance with the Directive demonstrates that the relevant ELVs are not exceeded and that safety risks can be excluded.

Provision is, however, made for a series of exceptions so that, under certain strict conditions, ALs for electromagnetic fields may be exceeded.

Generally, speaking, employers are required to ensure that risks arising from electromagnetic fields at work are eliminated or reduced to a minimum. If these values are exceeded, this may only be on a temporary basis and, where this arises, employers shall be required to take the necessary actions in order to return to compliance with the ELVs as soon as possible.

Measures are also foreseen to take account of the exposure of workers in workplaces open to the public.

Health surveillance: 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 Directive 89/391/EEC. Health records and their availability shall be provided for in accordance with national law and/or practice. In any event, where exposure above the ELVs is detected, the employer shall ensure that appropriate medical examinations or individual health surveillance is provided to the worker(s) concerned, in accordance with national law and practice. The costs of such examinations shall be borne by the employer.

Exemptions: provision is made for a series of derogations. Exposure may exceed the limit values if it is related to the installation, testing, use, development, maintenance of or research related to MRI-equipment for patients in the health sector and on condition that certain conditions are met.

Likewise, 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.

The Directive, furthermore, stipulates the justified circumstances when the exemption shall apply. All derogations shall be notified to the Commission.

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

Annexes: the annexes have been reviewed and new annexes have been added providing a technical definition of the values not to be exceeded as a function of the frequency ranges of electromagnetic fields.

DELEGATED ACTS: the Commission shall be empowered to adopt delegated acts with a view to amending the annexes from a technical point of view so as to:

- take into account the adoption of regulations and directives in the field of technical harmonisation and standardisation with regard to the design, building, manufacture or construction of work equipment or workplaces;
- take into account technical progress, changes in the most relevant standards or specifications, and new scientific findings concerning electromagnetic fields;
- make adjustments to the ALs where there is new scientific evidence, provided that employers continue to be bound by the existing ELVs set out in Annexes II and III.

The power to adopt delegated acts will be conferred on the Commission for a period of five years from 29 June 2013.

The European Parliament or the Council may object to the delegated act within a period of two months of notification of that act (which may be extended by two months). If either the European Parliament or Council objects, the delegated act shall not enter into force.

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 shall be given to apply the urgency procedure to delegated acts adopted by the Commission.

ENTRY INTO FORCE: the Directive enters into force on 29.06.2013. Directive 2004/40/EC is repealed from that date.

TRANSPOSITION: the Directive shall be transposed in the Member States no later than 01.07.2016.