COMMISSION OF THE EUROPEAN COMMUNITIES

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Proposal for a

DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

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

(presented by the Commission)

EXPLANATORY MEMORANDUM

1) CONTEXT OF THE PROPOSAL

• Grounds for and objectives of the proposal

The aim of this proposal is to postpone until 30 April 2012 the deadline for the transposition of Directive 2004/40/EC[1] of the European Parliament and of the Council of 29 April 2004 on the minimum health and safety requirements regarding the exposure of workers to the risks arising from physical agents (electromagnetic fields).

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

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

Meanwhile, the results of a British Government study on the "Assessment of electromagnetic fields around magnetic resonance imaging (MRI) equipment" and "Comments concerning possible MRI restrictions due to implementation of an EU Directive" formulated by the Health Council (*Gezondheidsraad*) of the Netherlands, in cooperation with its Belgian counterpart, have recently been published. These two high-level scientific documents confirm the possibility that the limit values established in the Directive may interfere with medical procedures using MRI.

Moreover, the International Commission for Non-ionising Radiation Protection (ICNIRP) is currently reviewing the guidelines on static magnetic fields and low-frequency time-varying fields on which the Directive is based. In both cases, new recommendations will probably provide for less strict limit values for low-frequency fields than those laid down in the Directive. These changes are likely to be backed up by the new scientific studies conducted since the adoption of the Directive. The new recommendations of the ICNIRP are expected in November 2007 and autumn 2008 respectively.

The World Health Organisation (WHO) is also currently revising its environmental health criteria for electromagnetic fields in order to reflect the latest scientific studies available.

The deadline for transposition of Directive 2004/40/EC into the law of the Member

[1] OJ L 184, 24.5.2004, p. 23.

States is 30 April 2008. In view of the above-mentioned developments, this deadline should be postponed for four years:

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

- pending the results of the review of the ICNIRP recommendations, to take into account the WHO's environmental health criteria for electromagnetic fields based on the latest scientific studies concerning the impact of electromagnetic fields on human health published since the adoption of the directive and, finally,

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

- **General context**

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

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

The Directive establishes exposure limit values for electric, magnetic and electromagnetic fields, varying in time with frequencies of between 0 and 300 GHz[2]. No worker may be exposed to values exceeding these limits, which are based on the health impact and biological considerations.

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

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

The Directive is based on the prevention philosophy already provided for in more general terms in framework Directive 89/391/EEC:

[2] 300 GHz: frequency of 300 billion hertz. The hertz (abbreviation Hz) is the international unit of frequency.

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

– obligation on employers to determine and assess risks;

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

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

– appropriate medical surveillance.

The Directive applies to all sectors of activity without exception and has to be transposed into national legislation no later than 30 April 2008**.**

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

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

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

This proposal is consistent with the objectives of the other policies of the European Union, in particular those concerning the improvement of the regulatory framework in order to develop a clear, understandable, up-to-date and user-friendly body of secondary Community legislation, in the interests of citizens and economic operators. The report on the implementation of Directive 2004/40/EC at national level will allow a better assessment of its impact on the protection of workers and on medical procedures using MRI and certain industrial procedures. It will also allow the provisions of the Directive to be updated in the light of the latest scientific findings on the impact of electromagnetic radiation on health, which were not yet available at the time of its adoption.

2) CONSULTATION OF INTERESTED PARTIES AND IMPACT ASSESSMENT

- **Consultation of interested parties**

Consultation methods, main sectors targeted and general profile of respondents

Consultation of the Advisory Committee for Safety, Hygiene and Health Protection at Work, in accordance with the Council Decision of 22 July 2003 on the setting-up of an Advisory Committee on Safety, Hygiene and Health Protection at Work, which issued a favourable opinion.

Consultation of the national authorities in the Member States by way of letters to the Permanent Representations.

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

Given the nature of the proposal, which affects only the date of transposition of the Directive without amending the provisions themselves, and after consultation with the Legal Service and the Secretariat-General of the Commission, it was decided that it was not necessary in this case to consult the social partners at European level, pursuant to Article 138 of the EC Treaty.

Summary of responses received

The representatives of the social partners and the government representatives of the 27 Member States in the Advisory Committee for Safety, Hygiene and Health Protection at Work confirmed, at the plenary meeting on 21 June 2007, the position presented by the Working Group on Electromagnetic Radiation responsible for assisting the Commission on the issue of MRI. The Committee came out in favour of an overall solution for all categories of workers and a postponement of the deadline for transposing the Directive into national legislation. More time is needed to clarify the interpretation of exposure to static magnetic fields and the currents they generate and for the ICNIRP to definitely issue its new recommendations. Postponing the deadline for transposition would also mean that the levels of exposure could be evaluated and calculated on the basis of harmonised European standards, currently being drawn up by Cenelec and due in the spring of 2008.

In their responses to the letters sent by the Commission, the Member States confirmed their concerns about the difficulty of applying the current text of the Directive in the health sector and were in favour of postponing the deadline for transposition so that the Commission, during this period, can present amendments which allow MRI to be maintained and developed whilst ensuring the health protection of workers.

The consultations with the scientific experts and the ICNIRP confirm the view that certain limit values defined in the Directive could be considered too binding in the light of new scientific findings and thus have a negative impact on the use of magnetic resonance equipment and certain industrial procedures. It was also found during the consultations that the recommendations of the ICNIRP, which form the basis of the Directive, are being reviewed and that new recommendations and a new version of the WHO's environmental health criteria for electromagnetic radiation will be available towards the end of 2008.

- **Gathering and use of expertise**

The Commission consulted with scientific experts regarding the impact on health of electromagnetic radiation, recognised at international level, and drew on the results of a study launched by the British Government to assess the electromagnetic fields around MRI equipment, and on the opinion of the Netherlands Health Council. The outcome was a recommendation to postpone the date of transposition of the Directive. The Commission has also launched a study to determine exposure levels for medical staff and their impact on the procedures used for medical MRI, the results of which are due in early 2008.

- **Impact assessment**

Option 1: Do nothing at this stage. This would oblige the Member States to transpose the Directive into national law by the date set and to enforce it, with potentially serious consequences on the continuity of healthcare services using MRI. Certain industrial activities could also be adversely affected.

Option 2: Postponing the date of transposition would not unduly impede either the use of MRI or other industrial activities. At the same time, the exposure limit values for those who work with electromagnetic fields are being reviewed by the scientific community. Postponement would thus give sufficient time for the Directive, in particular the limit values contained therein, to be updated, in the light of new scientific findings, in order to guarantee both a high level of protection for workers and the continuity of economic activities.

The proposed amendment affects only the obligation on Member States to transpose the Directive by 30 April 2008. It does not impose additional obligations on enterprises.

Given its nature, this proposal has not been subjected to a more detailed impact analysis.

3) LEGAL ELEMENTS OF THE PROPOSAL

- **Summary of the proposed measures**

The proposal amends Article 13(1) of Directive 2004/40/EC in order to postpone the date of transposition until 30 April 2012.

- **Legal basis**

Article 137(2) of the EC Treaty.

- **Subsidiarity principle**

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

The objectives of the proposal cannot be achieved sufficiently by the Member States,

as the provisions of directives cannot be amended or repealed at national level.

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

The principle of subsidiarity is respected in as much as the proposal amends existing Community provisions.

- **Proportionality principle**

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

It is restricted to postponing the date for transposing the Directive until 30 April 2012, in order to give the necessary time to analyse its impact, *inter alia* on the use of MRI, and to update it in line with new scientific knowledge.

- **Choice of instruments**

Proposed instrument(s): directive.

No other instruments would have been suitable. As this is an amendment of a directive, the only way forward is to adopt a directive.

4) BUDGETARY IMPLICATION

The proposal has no implication for the Community budget.

5) ADDITIONAL INFORMATION

- **Simplification**

The proposal does not simplify the legislative framework. It is aimed solely at postponing the date for transposition of Directive 2004/40/EC to 30 April 2012.

- **Repeal of existing legislation**

The adoption of the proposal will not entail the repeal of existing legislation.

- **European Economic Area**

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

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

This proposal amends the date of transposition of Directive 2004/40/EC to 30 April 2012. These four extra years to transpose the provisions of the Directive into national law are justified by the concerns expressed, and in some cases confirmed, that the exposure limit values laid down in the Directive could have a disproportionate impact

on the continuity of medical procedures using magnetic resonance imaging, and by the need to give the scientific community sufficient time to evaluate the latest scientific studies on the health impact of electromagnetic radiation, on which the limit values and the provisions of the Directive are based.

Article 1 of the proposal amends Article 13(1) "Transposition" of Directive 2004/40/EC accordingly.

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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[3],

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

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

Acting in accordance with the procedure laid down in Article 251 of the Treaty[6],

Whereas:

(1) Directive 2004/40/EC of the European Parliament and of the Council[7] establishes minimum health and safety requirements to protect workers against the risks arising from exposure to electromagnetic fields. Article 13(1) of the said Directive provides that Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with the Directive no later than 30 April 2008.

(2) Directive 2004/40/EC provides for action values and limit values based on the recommendations of the International Commission for Non-ionising Radiation Protection. New scientific studies on the impact on health of exposure to electromagnetic radiation, made public after the Directive was adopted, have been brought to the attention of the European Parliament, the Council and the Commission; the results of these scientific studies are currently being examined by the International Commission for Non-ionising Radiation Protection as part of the ongoing review of its recommendations, on the one hand, and by the World Health Organisation as part of the review of its environmental health criteria, on the other. These new

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3 OJ C […], […], p. […].
4 OJ C […], […], p. […].
5 OJ C […], […], p. […].
6 OJ C […], […], p. […].
7 OJ L 184, 24.5.2004, p. 23.

recommendations, due to be published by the end of 2008, are likely to contain elements which could lead to substantial amendments to the action and limit values.

(3) In this context, the potential impact of the implementation of Directive 2004/40/EC on the use of medical procedures based on medical imaging and certain industrial activities should be reconsidered thoroughly. A study has been launched by the Commission to assess directly and quantitatively the situation regarding medical imaging. The results of this study, which are expected in early 2008, should therefore be taken on board, in addition to the results of similar studies launched in the Member States, in order to ensure a balance between the prevention of potential risks to the health of workers and access to the benefits available from the effective use of the medical technologies in question.

(4) Article 3(3) of the Directive provides that the assessment, measurement and/or calculation of workers' exposure to electromagnetic fields are governed by harmonised European standards of the European Committee for Electrotechnical Standardisation (Cenelec). These harmonised standards, which are essential for ensuring smooth application of the Directive, must be taken into account and are expected in 2008.

(5) The time required to obtain and analyse this new information and to draw up and adopt a new proposal for a directive justifies the four-year postponement of the deadline for transposition of Directive 2004/40/EC,

HAVE ADOPTED THIS DIRECTIVE:

Article 1

Article 13(1) of Directive 2004/40/EC is hereby amended as follows:

"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 2012. 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."

Article 2

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

Article 3

This Directive is addressed to the Member States.

Done at Brussels,

For the European Parliament
The President

For the Council
The President