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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)**

## EXPLANATORY MEMORANDUM

### 1. CONTEXT OF THE PROPOSAL

#### 1.1. Grounds for and objectives of the proposal

The aim of this proposal is to postpone until 30 April 2014 the deadline for the transposition of Directive 2004/40/EC<sup>1</sup> 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).

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

In response to these concerns, the Commission took a number of steps.

To enable the Commission to conduct an in-depth impact analysis and propose amendments, the deadline for transposition of the Directive was put back from 30 April 2008 to 30 April 2012 by Directive 2008/46/EC<sup>2</sup> of the European Parliament and of the Council of 23 April 2008 amending Directive 2004/40/EC on minimum health and safety requirements regarding the exposure of workers to the risks arising from physical agents (electromagnetic fields).

The Commission examined the situation thoroughly, analysing the latest scientific studies, including the one launched by the Commission, on the negative impact the exposure limit values set by the Directive might have on the medical use of imaging technologies using magnetic resonance (MR). After a significant number of consultations of stakeholders and having due regard to the latest scientific recommendations<sup>3</sup>, the Commission adopted, on 14 June 2011, proposal COM (2011) 348 for a new Directive to amend and replace Directive 2004/40/EC, with a view to guaranteeing a high level of health and safety protection for workers while at the same time enabling medical and other industrial activities using electromagnetic fields to continue and develop. Adoption had been delayed mainly by the fact that the new international recommendations for exposure of workers and the public to electromagnetic fields had only been published in December 2010, rather than in 2009, as had been expected.

In addition, proposal COM(2011) 348 aims to update and improve a significant number of other provisions of Directive 2004/40/EC; it also introduces some new elements to make it easier for employers, especially small businesses, to implement the measures.

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<sup>1</sup> OJ L 184, 24.5.2004, p. 23.

<sup>2</sup> OJ L 114, 26.4.2008, p. 88.

<sup>3</sup> In particular the recommendations from the International Commission for Non Ionising Radiation Protection (ICNIRP) for static magnetic fields (April 2009) and for electric and magnetic fields in the 1Hz to 100 kHz range (December 2010).

Once the Commission proposal had been adopted, the European Parliament and the Council immediately started work with a view to amending Directive 2004/40/EC before 30 April 2012.

However, because of

- the technical complexity of the subject-matter, requiring long discussions with national experts,
- the highly divergent views on some key provisions of the proposal,

the European Parliament and the Council will be unlikely to finalise the adoption process before 30 April 2012.

Under these circumstances, we shall need a new Directive postponing for a second time the deadline for transposition of Directive 2004/40/EC. We have to prevent a very uncertain legal situation from arising after 30 April 2012, which is when all the Member States would have to transpose the current Directive 2004/40/EC by, if no further action were taken.

This legal uncertainty would have two consequences:

- the Commission would in principle have to launch infringement proceedings for non-communication of transposition measures against any Member States which have not transposed the Directive yet;
- Directive 2004/40/EC would start to have direct vertical effect in the national legal order of all Member States, and citizens could take their governments to court for their failure to implement the Directive.

We consider it appropriate to postpone the transposition deadline for two years to allow sufficient time for the European Parliament and the Council to discuss and reach a compromise on the basis of the Commission proposal COM (2011) 348 for a new Directive, which would update and improve the provisions of Directive 2004/40/EC while repealing and replacing the earlier Directive.

## **1.2. Directive 2004/40/EC**

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

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

The Directive establishes exposure limit values for electric, magnetic and electromagnetic fields varying in time at frequencies of between 0 and 300 GHz<sup>4</sup>. No worker may be exposed

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<sup>4</sup> 300 GHz: frequency of 300 billion hertz or cycles per second. The hertz (abbreviation Hz) is the international unit of frequency.

to values exceeding these limits, which are based on health impact and biological considerations.

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

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

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

- protection of all workers, whatever their sector of activity, whereby workers exposed to the same risks have the same right to be protected;
- obligation on employers to determine and assess risks;
- elimination or, where this is impossible, minimisation of risks identified;
- specific information and training for and consultation of the workers concerned;
- appropriate medical surveillance.

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

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 European Parliament and the Council adopted the Directive, with certain amendments to the values originally proposed by the Commission. These included 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 became available at the time of the adoption of the Directive.

### **1.3. Proposal COM (2011) 348 for a new Directive**

The above proposal aims to update and improve the provisions of Directive 2004/40/EC while repealing and replacing it. It maintains a number of important principles and provisions in Directive 2004/40/EC.

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

- 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 differing from the current limit values and action values for the range from 0 to 100 kHz (this will affect Articles 2 and 3 of Directive 2004/40/EC plus its annex);
- introduction of indicators to facilitate measurements and calculations (Article 3(3)) and to give guidance on taking measurement uncertainties into account. Product safety legislation set by Directives 1999/5/EC and 2006/95/EC ensures that the public, including workers, are not exposed to levels beyond those set by Recommendation 1999/519/EEC, provided that the products are used as intended. Since levels set for the public are lower than those set for workers and include protection against long-term effects, compliance with these Directives will provide for sufficient protection in these situations;
- introduction of some guidance to ensure simplified but more efficient risk assessments (Article 4), in order to facilitate evaluation work and limit the burden on SMEs;
- introduction of limited but appropriate flexibility by proposing a controlled framework for limited derogations for industry from action and limit values. The proposal includes two specific derogations, one for medical magnetic resonance applications (MR), and another for the armed forces. A third derogation is for occasional situations, subject to strict control and authorisation by Member States, followed by evaluation. Member States must report to the Commission on any authorisations granted. These three derogations, which are the result of intense consultations with all stakeholders and are well defined in their scope, guarantee a high level of health and safety protection while ensuring that medical and industrial activities are not unduly hampered;
- inclusion of a rationale for medical surveillance (Article 8);
- special attention to the specific case of medical applications using magnetic resonance and related activities;
- provision for complementary non-binding measures such as a non-binding practical guide.

## **2. CONSULTATION OF INTERESTED PARTIES AND IMPACT ASSESSMENT**

### **2.1. Consultation of interested parties**

#### *Consultation of the Advisory Committee on Safety and Health at Work*

The representatives of the social partners and the government representatives of the 27 Member States in the Advisory Committee on Safety and Health at Work, meeting in plenary

on 1 December 2011, came out in favour of postponing the deadline for the transposition of Directive 2004/40/EC into the national legal order of Member States in order to avoid a situation of legal uncertainty after 30 April 2012, and to allow sufficient time for the European Parliament and the Council to reach a compromise on Commission proposal COM(2011) 348.

### *Consultation of the EU social partners*

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 Commission's Legal Service and Secretariat-General, it was decided that there was no need in this case to consult the social partners formally at European level, pursuant to Article 154 of the Treaty on the Functioning of the European Union. Nevertheless, the EU cross-industry social partners were informed of the proposal by a letter from Commissioner Andor and invited to send their comments.

## **2.2. Transmission of this proposal to the national parliaments**

Draft legislative acts, including proposals from the Commission, sent to the European Parliament and to the Council must be forwarded to national parliaments in accordance with the Protocol (No 1) on the role of national Parliaments in the European Union, annexed to the Treaties.

According to Article 4 of the Protocol, an eight-week period must elapse between a draft legislative act being made available to national parliaments and the date when it is placed on a provisional agenda for the Council for its adoption or for adoption of a position under a legislative procedure.

However, exceptions are possible under Article 4 in cases of urgency, the reasons for which must be stated in the act or position of the Council. The adoption of this proposal by the European Parliament and the Council has to be considered as a case of absolute urgency for the reasons explained above, and which can be summarised as follows.

Commission proposal COM(2011) 348, which is currently being discussed by the European Parliament and the Council, is intended to update and improve the provisions of Directive 2004/40/EC, while repealing and replacing it, before 30 April 2012. Consequently, the great majority of Member States did not transpose Directive 2004/40/EC, waiting for the adoption of the new updated Directive based on the above proposal.

Nevertheless, given the complexity of the subject-matter and the deeply diverging views in the Council, there appears to be no chance of the European Parliament and the Council finalising the adoption process before the 30 April 2012 deadline.

This proposal, whose sole aim is to postpone the deadline for transposition of Directive 2004/40/EC for two years, has therefore to be adopted as a matter of urgency within the very short period remaining. If the proposal is not adopted by the 30 April 2012 deadline, there may be negative legal consequences in the internal legal orders of any Member States that have not yet transposed the Directive (see above section 1.1).

### **2.3. Impact assessment**

Given the urgency of the proposal and its limited impact, the proposal is not accompanied by a separate Impact Assessment.

Doing nothing at this stage would oblige the great majority of Member States which have not yet transposed Directive 2004/40/EC into national law to do so and to enforce it within a very short period of time, i.e. by the current deadline of 30 April 2012, with potentially serious consequences for the continuity of healthcare services using MRI. Certain industrial activities might also be adversely affected.

In any Member States which did not transpose the Directive by the deadline, a very uncertain legal situation would arise. Under the principle of vertical direct effect of EU directives, established by the Court of Justice, their citizens could bring actions against them in national courts for failure to implement the Directive. Furthermore, the Commission would in principle have to launch infringement procedures against those Member States for non-communication of transposition measures.

Postponing the date of transposition will not unduly impede the use of MRI or other industrial activities. At the same time, postponement would give sufficient time for the Directive, in particular the exposure limit values, to be updated and improved, by means of a new Directive based on Commission proposal COM(2011) 348. Reflecting new scientific findings, this would guarantee 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 2012, extending it to 30 April 2014. It does not alter the substance of the Directive in question and does not therefore impose any additional obligations on businesses.

## **3. LEGAL ELEMENTS OF THE PROPOSAL**

### **3.1. Summary of the proposed measures**

The proposal amends Article 13(1) of Directive 2004/40/EC by postponing the date of transposition to 30 April 2014.

### **3.2. Legal basis**

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

### **3.3. Subsidiarity principle**

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

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

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

The principle of subsidiarity is complied with in that the proposal amends existing EU legislation.

### **3.4. Proportionality principle**

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

It does not alter the substance of the current EU legislation: it is restricted to postponing the date for the transposition of Directive 2004/40/EC until 30 April 2014, in order to avoid a situation of legal uncertainty after the current deadline has expired and to allow sufficient time for the European Parliament and the Council to discuss and to reach a compromise on Commission proposal COM(2011) 348, which seeks to update and improve the provisions of Directive 2004/40/EC while repealing and replacing it.

### **3.5. Choice of instruments**

Proposed instrument(s): directive.

No other instrument would have been suitable. As this is an amended directive, the only way forward is to adopt another directive.

## **4. BUDGETARY IMPLICATION**

– The proposal has no implication for the EU 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 2014.

### **• 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 postpones the date of transposition of Directive 2004/40/EC to 30 April 2014. These extra two years for transposing 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 might have a disproportionate impact on the continuity of

medical procedures which use magnetic resonance imaging. The postponement will give sufficient time for the Directive, and particularly the exposure limit values, to be updated and improved, by means of a new Directive based on Commission proposal COM(2011) 348, which is currently being discussed in the Council and the EP and which aims to guarantee a high level of protection for workers and the continuity of medical procedures and other economic activities. The two-year postponement will also avoid any negative legal consequences in the legal orders of Member States which have not yet transposed the Directive.

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 on the Functioning of the European Union, and in particular Article 153(2) thereof,

Having regard to the proposal from the European Commission,

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

Having regard to the opinion of the European Economic and Social Committee<sup>5</sup>,

Having regard to the opinion of the Committee of the Regions<sup>6</sup>,

Acting in accordance with the ordinary legislative procedure,

Whereas:

- (1) After the entry into force of Directive 2004/40/EC of the European Parliament and of the Council of 29 April 2004 on the minimum health and safety requirements regarding the exposure of workers to the risks arising from physical agents (electromagnetic fields)<sup>7</sup>, serious concerns were expressed by stakeholders, in particular in the medical community, about the potential impact of implementation of that Directive on the use of medical procedures based on medical imaging. Concerns were also expressed as to the impact of the Directive on certain industrial activities.
- (2) The Commission examined the arguments put forward by stakeholders and decided to reconsider some provisions of Directive 2004/40/EC, on the basis of new scientific evidence.

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<sup>5</sup> OJ C [...], [...], p. [...].

<sup>6</sup> OJ C [...], [...], p. [...].

<sup>7</sup> OJ L 184, 24.5.2004, p. 1.

- (3) The deadline for transposition of Directive 2004/40/EC was therefore postponed until 30 April 2012 by Directive 2008/46/EC of 23 April 2008<sup>8</sup>, in order to allow the adoption of a new directive based on the most recent evidence.
- (4) On 14 June 2011 the Commission adopted a proposal for a new Directive to replace Directive 2004/40/EC. The new Directive should ensure both a high level of health and safety protection for workers and the continuation and development of medical and other industrial activities using electromagnetic fields. Consequently, the majority of Member States have not yet transposed Directive 2004/40/EC, pending the adoption of the new Directive.
- (5) However, given the technical complexity of the subject-matter it is unlikely that the new Directive will be adopted before the deadline for transposition of Directive 2004/40/EC.
- (6) Consequently, that deadline should be extended.
- (7) In view of the above and given the very short period of time left before the time limit of 30 April 2012, it must be ensured that this Directive is adopted by the European Parliament and the Council as a matter of urgency and that it enters into force without delay.
- (8) Consequently, as regards the transmission to national Parliaments in accordance with Protocol (No 1) on the role of national Parliaments in the European Union, the exception for urgent cases provided for in Article 4 of this Protocol has been applied in this case with regard to the eight-week period to elapse between a draft legislative act being made available to national Parliaments and the date when it is placed on a provisional agenda for the Council for its adoption or for adoption of a position under a legislative procedure.

HAVE ADOPTED THIS DIRECTIVE:

*Article 1*

In Article 13(1) of Directive 2004/40/EC the date "30 April 2012" is replaced by "30 April 2014."

*Article 2*

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

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<sup>8</sup> OJ L 114, 26.4.2008, p. 88-89.

*Article 3*

This Directive is addressed to the Member States.

Done at Brussels,

*For the European Parliament*  
*The President*

*For the Council*  
*The President*