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

2011/0152(COD) - 14/06/2011 - Legislative proposal

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.