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## **REPORT**

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From :	The Presidency
to:	Permanent Representatives Committee (Part I) / Council (EPSCO)
No Cion doc.::	11951/11 SOC 598 CODEC 1075 - COM(2011) 348 final
Subject :	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) - <i>Progress report</i>

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## **I. INTRODUCTION**

In 2004, Directive 2004/40/EC<sup>1</sup> on the minimum health and safety requirements regarding the exposure of workers to the risks arising from physical agents (electromagnetic fields) was adopted under the framework Directive 89/391/EEC<sup>2</sup>.

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<sup>1</sup> Directive 2004/40/EC of the European Parliament and of the Council of 29 April 2004 on the minimum health and safety requirements regarding the exposure of workers to the risks arising from physical agents (electromagnetic fields) (18th individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC); OJ L 159, 30.4.2004, p. 1–26.

<sup>2</sup> 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; OJ L 183, 29.6.1989, p. 1–8.

However, soon after its adoption in 2004, the medical community working with the magnetic resonance imaging (MRI) claimed that its activities would be hampered by the strict exposure limit values laid down therein.

Consequently, Parliament and Council decided to delay its transposition until 30 April 2012, due to difficulties in its application and to allow time for the Directive to be amended in light of new scientific information (among others publication of new ICNIRP Guidelines<sup>3</sup> in 2009 and 2010, amending the low frequency range of the ICNIRP 1998 guidelines, incorporated in Directive 2004/40/EC). In 2012, the entry into force of Directive 2004/40/EC was postponed the second time by another 18 months (until 31 October 2013), as soon as it became clear that the discussion on the new EMF Directive could not be finalised until 30 April.<sup>4</sup>

After long consultations with all stakeholders and on the basis of a study conducted by the Commission to assess the actual impact of Directive 2004/40/EC on medical procedures, the Commission presented its proposal for a Council Directive aiming at revising Directive 2004/40/EC on 22 June 2011.

The Social Questions Working Party started examining the proposal in July 2011 under the Polish Presidency. Under the Danish Presidency, the proposal has been discussed on six occasions, the last Working party meeting (attaché only) having place on 8 June.

DK, DE, FR, MT and UK maintained parliamentary scrutiny reservations, AT maintaining a linguistic reservation.

The European Parliament has not yet delivered its opinion. The proposed legal basis being Article 153(2) of the Treaty, the Council is required to act by qualified majority, in accordance with the ordinary legislative procedure with the European Parliament.

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<sup>3</sup> ICNIRP - International Commission on Non-Ionizing Radiation Protection.

<sup>4</sup> Directive 2012/11/EU of 19 April 2012, OJ L 110/1, 24.4.2012.

The Committee of Regions has decided not to deliver an opinion.

The European Economic and Social Committee delivered its opinion on 7 December 2011.

## **II. THE COUNCIL'S WORK UNDER THE DANISH PRESIDENCY**

Under the Danish Presidency, the Working Party on Social Questions examined the proposal at six occasions.<sup>5</sup> The Presidency focused its work on the annexes and the issue of the derogations, the discussions on which had already been launched under the Polish Presidency (see Progress report, doc. 17019/11), with the aim of having a solid basis for the finalisation of the body of the Directive under the CY Presidency.

During the first trimester, the Danish Presidency listened carefully to the views of all delegations' experts as well as of the Commission representatives and studied all proposals submitted by them. On the basis of these highly technical discussions with presentations made by national experts in this field, the Presidency presented, in April 2012, a first Presidency compromise proposal (doc. 9080/12) which has been subsequently slightly amended in the light of comments made by the delegations and by the Commission (docs 9617/12 and 10480/12). The final text of the Presidency compromise proposal is to be found in the Annex to the outcome from the SQWP meeting on 8 June, as set out in doc. 11151/12 REV 1. The Working Party on 8 June (attaché only) reached a broad agreement on text of the annexes and on Article 13 (Commission practical guide), subject to further editorial changes of non-substantial nature (see Sections 1 and 3 below). The Working Party also supported in principle the Presidency draft on Article 3 (derogations), with the understanding that further work still needs to be done on this text under the Cyprus Presidency (see Section 2 below)..

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<sup>5</sup> The Working Party has discussed the proposal at 6 meetings: 20 January, 9 February, 21 March, 18 April, 24 May and 8 June (attaché only).

Certain delegations maintained (general) reservations and scrutiny reservations on the respective parts of the Presidency compromise proposal. The Commission entered a general reservation on the draft compromise proposal and on some of its specific provisions.

The Presidency compromise proposal contains the following main elements:

## 1) **ANNEXES**

### **The main approach**

It has resulted from the meetings that a majority of delegations support the application of values and limits recommended by ICNIRP (the International Commission of Non-Ionizing Radiation), whenever possible.

### **Structure of the annexes**

In the Commission proposal, the Annex II related to exposure to EMF in the frequency range from 0 to 100 kHz<sup>6</sup>, while the Annex III to the exposure in the frequency range from 100 to 300 kHz, without any overlapping.

Following the discussions and as agreed by the majority of delegations, the structure of the annexes is now based on thermal/non-thermal effects, with an overlap in the transition region 100 kHz to 10 MHz, as agreed by the delegations.

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<sup>6</sup> 100 kHz: frequency of 100000 hertz or cycles per second. The hertz (abbreviation Hz) is the international unit of frequency.

## **Exposure limit values**

The Commission proposal establishes exposure limit values for static magnetic fields and time-varying electric, magnetic and electromagnetic fields at frequencies of between 1 Hz and 300 GHz. No worker may be exposed to values exceeding these limits, which are based on the health impact and biological considerations.

As agreed by the majority of the delegations, the exposure limit values for static fields follow the ICNIRP recommendation for magnetic fields from 2009. For frequencies 1 Hz to 100 kHz, they are based on the ICNIRP basic restrictions from 2010 (i.e. internal parameters with safety factor of 5) and for frequencies 100 kHz to 300 GHz, the values from the 2004/40/EC Directive continue to be applied.

## **Exposure limit values with frequencies between 0 and 1 Hz**

The Commission proposal does not provide for specific exposure limit values for the frequencies from 0 to 1 Hz.

Based on a request by several delegations, the compromise proposal now contains a reference to the ICNIRP recommendations on the frequencies from 0 to 1 Hz, currently being in consultation, which should be inserted in the new Directive on equal terms after having been adopted by ICNIRP.

Some delegations suggested moving the limit from 1 Hz down to 0 Hz, as there was no scientific justification for stopping at 1 Hz, as far as the internal limits are concerned.

## Action values

The Commission proposal sets action values and orientation values for time-varying and static fields which are directly measurable and indicate a threshold, above which employers must take one or more of the actions provided for in the Directive.

With the aim of reducing the costs of enterprises without jeopardising the health and safety of workers, a majority of delegations were in favour action values relaxing the ICNIRP recommendations, however, provided that these action values were based on a good scientific rationale.

Based on a Finnish proposal<sup>7</sup>, the Presidency compromise proposal therefore contains, in Annex II, a double layer of actions values for time varying electrical fields from 1 Hz to 10 MHz and for time varying magnetic fields from 1 Hz to 300 Hz. This is in line with the Commission proposal from June 2012. However, the proposed higher level of action values in the compromise proposal are generally lower than those set in the Commission proposal, and there is no basis for scientifically based higher action values for time varying magnetic fields with frequencies between 300 Hz and 10 MHz. Nevertheless, since standards and other guidelines aimed at specific work situations in due time can be developed, the need for such higher action values for magnetic fields between 300 Hz and 10 MHz are not of major importance for the Directive.

Some delegations raised concerns about the fact that the action values were set lower, compared to the Cion proposal, as it would, according to them, result in a greater impact on businesses, and asked for a risk assessment.

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<sup>7</sup> Doc. 7860/12.

## **Trigger values**

The Presidency has introduced new designations “trigger values related to safety risks” and “trigger value related to auditory effects”. “Trigger values related to safety risks” reflect the original Commission concept of "exposure limit values for safety effects". These designations have been chosen in order to make clear that these values are not exposure limit values as such, but can be exceeded provided that preventive measures have been taken. Nor are they action levels, as action values are expressed by external fields. However, at the last Working Party meeting, several delegations questioned this new designation and asked for further explanations, some of them suggesting using the term "guidance values".

The Presidency has introduced this designation as a purely editorial amendment, without changing its proposal in substance. Nevertheless, when editing the annexes under the CY Presidency, it can be envisaged to replace this designation by a more suitable one, should the delegations wish so.

## **RMS values/peak values and exposure evaluation method for non-sinusoidal exposures**

In the compromise proposal, the exposure limit values at the low frequencies are, unlike in the Commission proposal, presented as peak values, which is in accordance with the biological rationale. Action levels, however, are for practical reasons still presented as Root-Mean-Squared (RMS) values<sup>8</sup> for the whole frequency range.

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<sup>8</sup> RMS is a statistical measure of the magnitude of a varying quantity.

Based on a request by several delegations, the weighted peak method has been introduced as the principal method for exposure evaluation for non-sinusoidal exposure, but the use of more conservative methods are still allowed (Annex II). Certain delegations felt, however, that action values had also to be expressed as peak values, as measurements of non-sinusoidal signals (in particular pulsed or short signals) may lead to a strong underestimation of the exposure of workers and therefore to a risk if effective values are applied.

### **Safety factor**

In line with ICNIRP recommendations and following the technical discussions, the safety factor of 5 has been applied in Annex II, which corresponds to the safety factor used in the Commission proposal.

Certain delegations have suggested a concept of controlled working conditions with a reduced safety factor of 2, to be used in addition to the ICNIRP concept for normal working conditions with a reduction factor of 5.

### **Projectile hazards threshold**

In the Commission proposal, the limit concerning static magnetic fields for the projectile risk from ferromagnetic (flying) objects has been raised from 3mT (in 2004/404/EC Directive) to 30 mT<sup>9</sup>.

However, a number of delegations felt that this value could result in situations where risk run by persons working with the equipment would be underestimated. Therefore the action value for projectile hazard has been put back to 3 mT, but with an important addition that it only applies for relatively strong magnets where projectile risks exists

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<sup>9</sup> The tesla (symbol T) is the SI (International System of Units) derived unit of magnetic flux density; 1 mT is 10<sup>-3</sup> tesla.



### **Trigger value related to auditory effects**

Following the discussions and comments by the delegations, the recommendation on a limit to avoid auditory effects has been reformulated as a trigger value that can be exceeded provided the right precautions are taken. This scheme is in accordance with the formulation of the protection system for the other sensory organs, e.g. the retina.

Following the last Working Party, there was broad support for the protection level and protection system laid down in the Annexes II and III, as currently drafted (doc. 11151/12 REV 1) but editorial changes of a non-substantial nature might still be required.

## **2) ARTICLE 3 (Derogations)**

The current draft of Article 3 contains a clear description of the system of exposure limit values, trigger values and action values and clearer references to the Annexes on the conditions of using the various values as well as specific conditions related to measurement methods, so that it is aligned with the current draft of the annexes.

### **MRI derogation (Article 3(5) of the Presidency compromise proposal)**

The Commission proposal provides, in Article 3(4), for an exemption from the exposure limits for the medical MRI sector and related activities, which will continue to be subject to all other obligations, in order to ensure that the use and development of MRI equipment, considered today to be a vital tool for the diagnosis and treatment of several diseases, would not be limited to a disproportionate extent.

A number of delegations expressed support for maintaining the MRI derogation in order to ensure that the use of MRI technology for the benefit of patients would not be jeopardized, several delegations raising, however, concerns regarding equal treatment of the workers and distortion of competition. Certain delegations pointed out that a possibility to derogate from exposure limits should be open also to other industry areas, such as the metal industry, others opposing a sectoral derogation and suggesting that the MRI sector be covered by a general derogation.

Based on the discussions, a revised MRI derogation with a narrower scope, limited to certain MRI activities, has been introduced by the Presidency in the compromise proposal on the basis of an assumption that not the whole MRI sector faces the problem of exceeding the exposure limit values contained in the Presidency compromise proposal. This alternative protective system would be used only in situations, where all possibilities of bringing the exposure under the exposure limit values have been exhausted.

Following the last Working Party, there was a broad support for the MRI derogation, as currently drafted (doc. 11151/12 REV 1).

**General derogation (including for armed forces) (Articles 3(6) and (7) of the Presidency compromise proposal)**

The Commission proposal provides, in Article 3(5), the right for the military to use an equivalent protection system adapted to its specific working situations. This provision has been introduced on a request made by NATO, which uses a protection system based on recommendations proposed by IEEE<sup>10</sup>, in order to ensure the interoperability of EU and non-EU Members of NATO. The Commission proposal also provides for, in Article 3(6), a temporary derogation (of general nature) under controlled conditions where the exposure limits are likely to be exceeded.

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<sup>10</sup> The Institute of Electrical and Electronics Engineers.

A number of delegations opposed a specific derogation for the armed forces, putting forward that it could lead to unequal treatment, in particular between the military and the civilian staff and that the Member States could anyway apply the national law which, usually, provides for special provisions on military cooperation. These delegations also argued that as the currently applicable standard STANAG 2345, referred to in the Commission proposal, did not cover the low frequency and thus did not represent a standard equivalent to the Directive.

In the compromise proposal, the derogation for armed forces and the general derogation have been merged in one provision which only gives access to a derogation on a temporary basis. Such a derogation should address the need for a special scheme for NATO and, at the same time, offer a possibility for other activities than MRI on patients and research to use alternative protective systems, provided that the conditions for this are met.

However, several delegations, asked for reintroducing a separate derogation for the armed forces on a permanent basis, while keeping a general temporary derogation for businesses. In particular, they questioned the temporary character of such derogation in relation to the armed forces, the interoperability of which had to be ensured, according to them, for an unlimited period of time.

Following the last Working Party, paragraph 6 still needs to be further improved. In particular, further considerations should be given to the temporary nature of the derogation in relation to the armed forces.

### 3) **ARTICLE 13 (Commission practical guide)**

Article 13 of the Commission proposal refers to the need to establish a practical guide in order to facilitate implementation of the Directive.

This Article has been aligned with the compromise proposal on Annexes II and III and it now contains a list of issues, on which practical guides should be drawn up by the Commission, in order to avoid the inclusion of very technical matters in the annexes and/or references to standards and norms.

Following the last Working Party, there was broad support for Article 13, as currently drafted (doc. 11151/12 REV 1).

With regard to the urgency of this dossier and the great efforts deployed by the Presidency and all delegations in order to reach an agreement on the technical parts of this complex dossier, the Presidency considers that the Annexes II and III and Article 13 (as regards the aspects covered by the annexes) , as set out in the Annex to doc. 11151/12 REV 1, are not to be reopened, apart from purely editorial changes of a non-substantial nature.

The Presidency also notes that, following the last Working Party , the majority of delegations supported the Presidency proposal on Article 3 as a good basis for a final compromise, but that there is still room for further improvement, in particular as to the nature of the derogation in relation to the armed forces. The compromise proposal supported by a majority of delegations thus represents a good basis for finalising the discussions on the main body of the Directive under the CY Presidency, in order to launch negotiations with the European Parliament before the end of 2012.

#### IV. CONCLUSION

The Committee is invited to take note of this Report and to forward it to the Council (EPSCO) on 21 June 2012.

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