EUROPEAN COMMISSION

Brussels, 14.6.2011
SEC(2011) 751 final

C7-0191/11 EN

COMMISSION STAFF WORKING PAPER

SUMMARY OF THE IMPACT ASSESSMENT

Accompanying document to 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)

{COM(2011) 348 final}
{SEC(2011) 750 final}

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1. POLICY CONTEXT

This impact assessment addresses the protection of workers exposed to high levels of electromagnetic fields (EMF) during their work. This concern forms part of the general EU policy set out in the Treaty on the Functioning of the European Union (TFEU) to provide workers appropriate health and safety protection against risks encountered during their professional activities.

2. CONSULTATION AND EXPERTISE

For legislative initiatives in the social policy field, the Treaty provides for a two-stage consultation of the social partners. The first stage (Article 154(2) TFEU) took place between 1 July and 10 September 2009. The Commission received 16 replies to this consultation.

The second stage of consultation under Article 154(3) TFEU took place between 20 May and 5 July 2010 and was carried out independently from the impact assessment. 27 responses were received.

The results can be summarised as follows:

- In general, both trade unions and employers agree that the current Directive is not the ideal instrument and that there is a basic need for a new EU initiative to protect workers from electromagnetic fields. However, certain employer representatives (SMEs and national organisations) indicate their preference for non-binding instruments instead of a directive.

- It is commonly accepted that the limit values in the current directive are too low and based on too conservative assumptions; but while the employers are in favour of relaxing the limits, the workers' representatives want the long-term health effects to be covered in the future Directive.

- Exempting some categories of workers from the scope of the Directive is not welcomed by industry employers (except MRI equipment manufacturers). Also,

allowing derogations from exposure limits in specific sectors (health care) poses some problems for industry.

- The social partners confirm that no category of workers should be excluded from the benefits of any new legal instrument, provided that the new instrument gives the appropriate flexibility needed to allow activities to be continued.

- While employers are very much in favour of a flexible approach also allowing for exceptions, workers' organisations fear that flexibility may reduce the protection of workers unless there are strict controls.

- Adaptation of the exposure limit values defined in the Directive is acceptable to both employers' and workers' organisations, along with the introduction of a zoning approach to allow for light risk assessments in less problematic situations. There is also a consensus on the importance of operational guidance.

- Medical checks after situations of overexposure above the limit values are welcomed as a default approach by the trade unions. Employers' organisations and the medical profession raise doubts as to whether this is reasonable for the low frequency range, where it might be difficult to detect effects.

- Derogations from the limit values for the medical sector to facilitate MRI treatment are viewed with scepticism by other sectors, whereas trade unions recommend a sunset clause to avoid the erosion of protective legislation.

Representatives from Member States, experts and stakeholders were consulted extensively during the consultation and impact assessment.

3. PROBLEM DEFINITION

What is the problem?

This impact assessment addresses the protection of workers exposed to high levels of electromagnetic fields during their work. This concern forms part of general EU policy set out in the Treaty to provide workers appropriate health and safety protection against risks encountered during their professional activities. That means this document deals only with the (high) exposure of workers during their work and not with the (much lower) exposure encountered by the general public using mobile phones, living close to power lines or passing through metal detectors at airports.

Workers can be exposed to electromagnetic fields in many sectors of activity: industrial processes such as welding, sealing, broadcasting, electricity generation, etc. or medical procedures such as magnetic resonance imaging (MRI). The health consequences of overexposure can differ depending upon the intensity and proximity of the sources on the one hand but also upon the characteristics of the electromagnetic radiation itself, e.g. its frequency. The symptoms of acute effects are well defined. In the high frequency range (e.g. broadcasting, radars), severe burns may occur, while in the low frequency range (e.g. welding, electricity production and distribution), induced currents can affect the functioning of the central or peripheral nervous system and exposed persons can also experience vertigo, nausea, metallic taste feelings, or magnetophosphenes (flashes in the eyes). In very rare cases,

dramatic effects are also encountered when strong magnets attract a ferromagnetic object and cause it to strike a person inadvertently caught between the magnet and the metallic object.

The issue of protecting workers exposed to EMF was already dealt with at EU level in 2004 with the adoption of Directive 2004/40/EC[1] of the EP and the Council.

Very rapidly, it transpired that the Directive as adopted, in particular the binding exposure limit values, would create major implementation problems and would even impede some essential medical procedures and related research in cutting-edge medical applications such as MRI. On the other hand, a lot of new scientific information was becoming available with good evidence that some exposure limits in the Directive were too conservative. The issue became critical as the deadline for transposition of the Directive by the Member States approached. The Commission decided to undertake a full review of the situation.

Who is affected and how?

Overall, according to data from stakeholders, more than 1 500 000 workers (self-employed excluded) in more than 200 000 workplaces are concerned in the EU.

Sector	**Workers**	**Workplaces/assessments**
Electric energy	200 000	3 000
Health care	211 000	13 000
Metal industry	1 019 000	162 140
Telecoms & broadcast	39 500	11 000
Rail	120 000	500
Other	50 000	25 000
Total	1 639 500	214 640

Source: stakeholder information

Workers in both the medical sector and industry can be exposed to much higher levels than those defined for the general public. The general public normally has no access to areas where high exposure levels occur.

The table below shows the possible health effects that can be encountered in a variety of professional activities and the associated frequency range(s).

Frequency range	Related activities	Potential health problems
0 Hz	Magnetic resonance technology Lifting cranes Electrochemical processes	Safety problems: uncontrolled attraction of ferromagnetic metals Health problems: vertigo, metallic taste feeling, headaches
50 Hz	Power lines	Headaches, magnetophosphenes,

[1] 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 184, 24.5.2004, p. 1.*

	Production and distribution of electricity Welding	Unwanted effects on the peripheral nervous system
100 Hz - 10 000 kHz	Magnetic resonance technology (gradient fields)	
9 kHz -	Electric welding	Effects on the nervous system
30 kHz -	Industrial induction heating	
300 kHz -	AM radio Industrial induction heating	
3 MHz -	AM radio Plastic welding Dielectric pressing Induction hardening FM radio Wood processing	Burns Thermal stress
300 MHz -	TV Diathermia GSM Dielectric vulcanising	
3 GHz -	Anti-theft protection systems Radars Satellites (communication with)	
30 GHz -	Transmission of digital and analogue video signals	

Source: AGORIA (BE) good practice guide

The underlying drivers of the problem

Recent research[2] indicates that Directive 2004/40/EC is stricter than necessary on certain points. Since the publication in 1998 of the recommendations of the International Commission for Non-Ionising Radiation (ICNIRP) published, on which the Directive is based, new scientific data have become available on the effects of low-frequency fields. These data suggest that some of the current limits could be too low.

Warnings from the medical sector in particular suggest that Directive 2004/40/EC, even with less strict recommendations, will rule out 5-8 % of medical procedures, because the exposure of medical staff working with MRI equipment might exceed the limits.[3] That would be undesirable, because the use of MRI has many advantages for patients: the technique enables the diagnosis of diseases where this was previously impossible and surgical intervention

[2] Forschungsbericht 400: Elektromagnetische Felder am Arbeitsplatz — Abschlussbericht, ISSN 0174-4992, März 2010 (BMAS report). ICNIRP Guidelines: Guidelines for limiting exposure to time-varying electric and magnetic fields (1 Hz to 100 kHz): published in December 2010.

[3] 1) Project VT/2007/017: 'An Investigation into Occupational Exposure to Electromagnetic Fields for Personnel Working With and Around Medical Magnetic Resonance Imaging Equipment'; final report 4 April 2008.
2) 'Assessment of electromagnetic fields around magnetic resonance (MRI) equipment' (2007) http://www.hse.gov.uk/research/rrpdf/rr570.pdf.

without the use of X-rays, while almost every week new applications are developed for the benefit of patients.

On the other hand, the safety and health of medical personal also needs to be ensured.

State of implementation of the legal framework

The existing legal frameworks in the Member States are very different. A detailed overview can be found in Annex 1 of the report. Very few have already started to transpose Directive 2004/40/EC, sometimes allowing some flexibility to ensure proper use of MRI techniques (although such flexibility is not permitted by Directive 2004/40/EC). Other countries are currently relying on existing non-binding standards or are using the ICNIRP recommendations as a practical reference. Member States have put on ice the introduction of new national legislation to transpose Directive 2004/40/EC, awaiting clarification and a new proposal from the Commission.

If the situation remains as it is, all 27 Member States will have to transpose the provisions of Directive 2004/40/EC by 30 April 2012. This would of course nullify the efforts made by the Commission to find solutions for the implementation problems raised and would definitely not be the outcome expected by governments, social partners and most stakeholders.

Right to act and subsidiarity

Legislative action in the area of occupational health and safety is based on Article 153(1)(a) and (2) TFEU, which explicitly allows for European action in that field.

Upon the adoption of Directive 2004/40/EC, the Commission, Parliament and Council were of the opinion that EU action was the best way to protect workers from risks arising from occupational exposure to electromagnetic fields. Currently, the Commission does not see any new evidence for deviating from the choice made by the Parliament and Council in 2004. The need to protect workers remains essential. Considering the situation pointed out under point 2.5 of the report and the need for review recognised by all parties, it appears that the Commission must act, using its right of initiative.

4. OBJECTIVES

Based on the general objective of protecting workers during their professional activities, the objective here is protection from harmful EMF.

As exposure to EMF is a complex risk, there is a need is to define more specific measures to ensure adequate protection of workers while not unduly impeding the use and development of industrial and medical techniques or imposing disproportionate burdens on enterprises, in particular SMEs.

The operational objective is to ensure the effectiveness of the measures to protect workers exposed to EMF by setting appropriate limit values and providing employers with adequate information on the necessary risk management measures.

5. POLICY OPTIONS

Policy option A: 'Do nothing'

In practical terms, this means that Directive 2004/40/EC has to be transposed by 30 April 2012 into legislation in all the Member States.

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. Details are given in Annex 3 of the report.

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 a general EMF risk management requirement.

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 1999 Council Recommendation on EMF exposure of the general public.

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, which may increase risk, reduce equality, etc. 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.

These options were considered as relevant by the stakeholders. Alternative options not analysed in detail include adopting a more sectoral approach, restricting legislation to the provision of safe equipment or exclusively focusing on 'soft' policy instruments such as information campaigns and guidance documents.

6. ANALYSIS OF IMPACTS

Starting point for the analysis of impacts

The baseline for the analysis is to assume that the Framework Directive has been fully implemented but the specific EMF Directive has not yet been implemented. This corresponds to the actual legal situation.

Discussions with experts and stakeholders have indicated that environmental impacts are not likely, so they have not been assessed.

Social impacts

The main social impacts are the potential health impact on about 1.5 million workers, including in particular a much smaller number of particularly sensitive workers, e.g. those with a medical implant or pregnant women. In this respect, there is a clear preference for options A, B and C1. Option A being most stringent, this might result in stringent protection only on paper. Option C2 ranks behind these three, as the protection of workers in high-exposure areas is clearly weaker than with the other options.

Other prominent social impacts are the benefits of critical medical MRI applications for the public. Options A and B will not provide sufficient flexibility to allow for all such treatments. All other options can provide this flexibility.

Economic impacts

Consistent European rules that allow for mobility and exchange are among the positive economic impacts. These are best guaranteed with options A, B, C1 and C2, whereas options D1, D2 and E are more likely to maintain a high level of insecurity.

Another important economic aspect is the possibility to develop a business with as few restrictions as possible, thus facilitating growth and maintaining or even creating employment in Europe. In that respect, options A and B are seen as rather restrictive and hindering economic development in some areas to an extent not expected with any of the other options.

Compliance and administrative costs

Summary of total compliance and administrative costs for each option:

Policy option	Total costs (million euros)
A: no change to EC/2004/40	660.3
B: new ELVs for all sectors	526.9
C1: possibility for derogation from ELVs	511.7*
C2: some	497.4

workers excluded	
D1: non-binding recommendations only	437.1
D2: sectoral agreements only	420.2
E: no EU action	474.0

*including reinforced training for MRI

Option A is the most expensive to implement. Option B involves lower implementation costs than option A since many activities in the metal industry such as induction heating and electrolysis would fall in most cases below the revised limits. Consequently, employers in the metal industry would not need to take extensive measures to reduce exposure by changing working practices. However, Option B is more expensive than other options because of the costs specifically associated with MRI. The other options will have very similar costs.

Policy options C2 and E are evaluated under the assumption that employers will need to carry out a risk assessment additional to that required by the Framework Directive. Residual costs will occur for instance in the telecommunications and power generation/transmission sectors, which would continue to work to ICNIRP recommendations as provided for in Directive 2004/40/EC because they do not represent a problem for them.

SMEs want simplified information at EU level. Simple and short sector-specific guidance documents (checklist type) will hence be needed whichever option is chosen. Equipment labelling and better manufacturer information might help identify those situations where no detailed assessment is required.

7. COMPARING THE OPTIONS

Whatever the option, the benefits cannot be described without difficulty. Health benefits can only be indicated to the extent that no adverse effect will occur below the current or future limits. This should favour options A to C2.

Given new scientific evidence indicating that exposure limits under option B will ensure protection against overexposure, option A only adds the disadvantages of restricting some activities and overall less willingness to comply.

At the other end of the spectrum of possibilities, options D1 (Recommendation), D2 (Voluntary agreement) and E (No EU legislation) can be rejected. Stakeholders and experts expressed a strong preference for consistent European legislation giving employers and employees legal and physical security. Although EMF on its own is not a major issue, consistent European legislation in the field is seen as contributing to the single European market. Furthermore, abstaining from any European action on EMF would significantly reduce the attention paid to the risks of EMF and could have negative health impacts.

The three remaining options are B (revised exposure limits), C1 (revised exposure limits and conditional exemptions limited to some provisions for medical MRI) and C2 (revised exposure limits and complete exemptions of some activities from the Directive).

Option B has the advantage of consistent rules on EMF with exposure limits that are already high enough for a considerable number of workplaces, so that there is no longer a threat of overexposure. Compared to option A, the number of situations with potential overexposure is significantly lower. Option B is in line with recent scientific evidence. The disadvantage of this option is that there are some activities (like some MRI treatments) where temporary overexposure is possible. Completely stopping these activities — which are in some cases closely linked to technological progress and directly contribute to the health and well-being of the public — is problematic.

Option C1 has the advantage of consistent rules on EMF in most areas, as for Option B, while allowing derogations from exposure limits for medical MRI with reinforced preventive measures in situations where there is a threat of overexposure. As in the case of option B, this relies on recent scientific evidence. However, it would be more flexible than option B. The disadvantage of option C1 is that in the case of derogations it requires a more stringent and more controlled working environment.

Option C2 also has the advantages of consistent rules on EMF in most areas, and allows for flexible solutions in situations where there is a threat of overexposure. The obligations in terms of risk assessment are lower for the exempted sector. This also reduces compliance costs. The disadvantage of this option is the risk of it leading to lower levels of worker protection. Furthermore, it would encourage greater variation in the protection of employees, going against both the letter and spirit of the Framework Directive.

Conclusion on costs: The cost of Option C1 is higher than for the less stringent options C2 to E. However, for a rather limited increase in cost, Option C1 scores much better than the latter options for other, more qualitative impacts, and guarantees a high level of protection for workers. The cost of Option C1 is significantly lower than for Option A and almost equivalent to Option B, while offering to the MRI sector and industry the flexibility they need.

Consequently, based on these considerations and in line with the survey results, the Commission therefore prefers **option C1**.

Survey assessment

During preparation of the impact assessment, a survey was carried out and received 166 replies. Overall, the survey results consistently show that option C1 is preferred by stakeholders.

8. MONITORING AND EVALUATION

Framework Directive 89/391/EEC and the subsequent 19 individual directives under its Article 16(1) provide for regular review of the effectiveness of their implementation. Since 2007, this systematic review has been harmonised and is performed every 5 years by all the Member States for all risks covered by the directives. A report is then prepared by the Commission.

Also, committees bringing together national experts from EU Member States are an important part of the process of evaluating and monitoring EU legislation on health and safety at work. In particular, these include the tripartite Advisory Committee for Safety and Health at Work, set up by Council Decision 2003/C 218/01, and the Senior Labour Inspectors Committee (SLIC), set up by Commission Decision 95/319/EC.