

ROADMAP
(REV. 30 MARCH 2010)

Title of the initiative: Proposal of the Commission for an amendment of Directive 2004/40/EC of the European Parliament and the Council EC 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).

Lead DG/contact person: EMPL , unit F4

Expected date of adoption of the initiative (month/year): September 2010

Initial IA screening & planning of further work
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A. Context and problem definition

<p>What is the political context of the initiative? How does this initiative relate to past and possible future initiatives, and to other EU policies?</p>
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<p>Directive 2004/40/EC of 29 April 2004 of the European Parliament and the Council on the minimum health and safety requirements regarding the exposure of workers to the risks arising from physical agents (electromagnetic fields (EMF)) is currently in force. Transposition deadline has been postponed in 2008 until 30 April 2012 also because new scientific evidence has become available.</p>
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<p>The Directive relates to the harmful short-term effects of occupational exposure to electromagnetic fields on the health and safety of workers. It requires risks to be eliminated or reduced to a minimum. The action values and exposure limits indicated in the annex of the Directive are tools to help employers to further protect the health of workers who may be exposed to electromagnetic fields at work. They are the only quantitative tool which enables employers to assess exposure and to decide on the prevention and protection measures to set up in order to comply with the objectives of the Directive. In line with the provisions of the Treaty, the Directive lays down minimum requirements. Each Member State may adopt stricter rules.</p>
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<p>Preceding the adoption of Directive 2004/40/EC, the specific case of medical magnetic resonance imaging (MRI) was discussed in detail both in the Council and in the European Parliament. Medical MRI is a powerful cutting edge technique using the properties of magnetic fields and enabling better diagnostics and revolutionary interventional surgery techniques benefiting to the patients. Experts from the competent national authorities provided technical support for the Member States' representatives responsible for negotiations in the Council. The Council Presidency sought, on several occasions, the opinion of the International Commission for Non Ionizing Radiation protection (ICNIRP). As a consequence of these consultations the Directive does not set an exposure limit value for static magnetic fields.</p>
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<p>What are the main problems identified?</p>

<p>Since the adoption of the Directive research has shown that the threshold values could be set considerably higher without causing health problems and the recommendations by ICNIRP have been changed accordingly. Furthermore some industries, in particular the medical sector, have indicated that conforming to the actual threshold values might unduly hamper the performance of MRI in diagnostic and curative medicine as well as in research. Such a development could have serious undesirable effects on public health. Moreover,</p>

stakeholders have claimed that restrictions on MRI could lead to increased use of diagnostic procedures using ionising radiation, which would in turn also have an unintended adverse effect on the protection of workers. New research findings, including a study commissioned by the Commission, appear to confirm at least some of these concerns.

Is EU action justified on grounds of subsidiarity?

Yes - The issue in question is existing EU-legislation which can only be changed by EU action. Furthermore there is a benefit in terms of level playing field and organisational simplification if the same rules apply all over Europe and companies in different MS have to fulfil the same requirements.

B. Objectives of EU initiative

What are the main policy objectives?

Ensure that adequate prevention measures are implemented in the EU for the protection of the health and safety of workers exposed to EMF whilst avoiding to hamper the use and development of medical and industrial activities.

Does the objective imply developing EU policy in new areas or of strategic importance?

No. It is basically about a revision of existing policy. It suggests however to foster research to better understand the mechanisms induced by exposure of persons (workers and public) to electromagnetic fields.

C. Options

What are the policy options?

As directive 2004/40/EC falls under the social chapter of the Treaty, formal consultations of the Social Partners by the Commission are mandatory (Art 154 of the TFEU). In this framework, the following options have been considered by the Commission:

- (1) No new legislation. As a consequence, the European Union would take no new initiative in this field. Directive 2004/40/EC and national regulatory provisions on the subject would remain in force. The Member States would need to adopt national legislation transposing Directive 2004/40/EC by 30 April 2012.
- (2) Amending the existing binding legislative provisions. The Commission would make a proposal that takes due account of specific situations and of the latest international recommendations; it could introduce new exposure limit values based on those recommendations and provide for special conditions or exemptions.
- (3) New, non binding, legislative action. The Commission would take due account of specific situations and of the latest international recommendations by introducing new non-binding recommendations for occupational exposure to electromagnetic fields. This could entail the production of good practice guides, the launching of regular information campaigns, the setting-up of training programmes, and the drawing-up of voluntary agreements between the social partners at EU or sector level.
- (4) Community action is no longer necessary. The Commission could consider it

inappropriate to take any Community legislative initiative in this field. Directive 2004/40/EC would be repealed and the subject matter would be left to national regulatory provisions.

Does the action proposed in the options cut across several policy areas or impact on action taken/planned by other Commission departments?

No

Do the options respect the proportionality principle?

The proportionality of different options in terms of the objectives will be assessed in the impact assessment report.

D. Initial assessment of impacts

What are the significant impacts likely to result from each policy option (cf. list of impacts in the impact assessment guidelines), even if these impacts would materialise only after subsequent Commission initiatives?

Revising the threshold limits and bringing them in line with the new recommendations (option 2) is – following the new scientific knowledge – not expected to cause significant negative effects in terms of occupational health and safety while it is expected to have benefits compared to the options which do not include legislative action (options 1 and 3): less jobs would conflict with the new threshold values (in so far the compliance-requirements for industry would be reduced) and also because of the improved congruence with scientific standards acceptance of the new Directive should be higher. The assessment of further modifications (exemptions under specific conditions) will have to be provided in the IA on a case by case basis.

Option 3 (non-legislative action) focuses on improving the implementation of the existing legislation by recommendations and other soft instruments such as good practice guides, voluntary agreements and awareness rising. The particular strength of this option would be to draw the attention of employers to (simple) ways of how to prevent trespassing the thresholds. The other options might not sufficiently support this potential.

The withdrawal of the EU from any legislation in this field (option 4) is likely to increase the range of legislative actions in the EU as many Member States may be inclined to maintain their current legislation or to develop their own legislation to protect their workers subject to exposure to EMF. . This lack of common approach is already seen as problematic by some representatives from industry who advocate the necessity for some harmonisation.

Could the options have impacts on the EU-Budget (above 5 Mio €) and/or should the IA also serve as the ex-ante evaluation, required by the Financial Regulation? No

Could the options have significant impacts on simplification/administrative burden or on relations with third countries?

The regulation will bring along certain administrative burdens, however only at a limited number of workplaces. n

Employers providing workplaces with high exposure to EMF might, depending on the option chosen and on the actual situation in the enterprise, benefit from less restrictive threshold and/or be requested to support their employees by several measures to protect against EMF for instance an obligation to work in a controlled environment.

Consequently the new initiative should propose a more proportionate approach and will thereby *de facto* reduce the administrative burden. The new initiative should also be designed to facilitate the understanding and the implementation of the requirements and/or recommendations

Given the complexity of the policy area, the new proposal will entail accompanying measures/recommendations in order to propose to Member States suggestions to facilitate timely and correct implementation.

The new initiative is expected to bring the situation in the EU in line with the situation in other industrialised countries (like the US, Australia, Canada, Japan where systems combining binding and non binding measures are in place.

Who is affected?

Although the Directive applies for all workplaces, the changes will only affect a limited number of workplaces. It has relevance for workplaces which can involve strong electromagnetic fields such as: working at MRI, welding, industrial electrolysis.

E. Planning of further impact assessment work

What information and data is already available?

There is recent research on health effects of electromagnetic fields on the human body and research on the exposure values of personal operating MRI and how exposure could be reduced.

What further information needs to be gathered? How will this be done (e.g. internally or by an external contractor) and by when? Need to have an in-depth knowledge of the real situation.

The available information focuses on the technical aspects. While these aspects are important they have to be linked to economic aspects and to the issue of administrative costs. To do so a contract has been signed with an external contractor in December 2008. The final report has been received at the end of September 2009. The contract explored the situation in the most critical sectors of activity as far as exposure of workers to EMF is concerned, giving due account to the situation in the SMEs. The study showed that a binding legal framework introducing appropriate flexibility and associating a number of more practicable binding measures to reinforced non binding measures (controlled areas or working conditions where necessary, more adequate information and training, dissemination of good practices) would improve the overall situation without introducing unacceptable costs or burden. The study also showed that this novel approach would definitely improve the situation compared to the eventual situation under current directive 2004/40/EC.

What type and level of analysis will be carried out (cf. principle of proportionate analysis)?

Health, socioeconomic and environmental aspects will be considered.

Which stakeholders & experts have been/will be consulted, how and at what stage?

European social partners under article 154 of the TFEU (first stage took place from July 2009 until September 2009; second stage due to start in March 2010). Also involvement of MS. The discussion in the steering group suggested that also stakeholders from the most concerned sectors of activity in the medical and industrial domains are directly involved: MRI practitioners, branches of the industry employing large number of welders, using induction furnaces, large electrolyses facilities... This process of direct involvement is already taking place since 2005 and many informal contacts have and are still being organised with stakeholders from the medical and industrial sectors of activity. Moreover, a dedicated tripartite working party mandated by the Advisory Committee for Safety and Health at Work is contemplating the issue and will make recommendations for the Commission.