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

2011/0152(COD) - 26/06/2013 - Final act

PURPOSE: 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).

LEGISLATIVE ACT: Directive 2013/35/EU 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) (20th individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC) and repealing Directive 2004/40/EC.

CONTENT: this Directive amends Directive 2004/40/EC by repealing and replacing the 2004 text which never entered into force because of problems relating to its implementation.

The main objectives of this revision are technical and relate to:

- the definition of exposure limitations on the basis of new scientific evidence;
- provisions for derogations, under certain strict conditions, in particular for workers involved with medical applications using magnetic resonance imaging (MRI).

Subject matter and scope: the Directive lays down minimum requirements for the protection of workers from risks to their health and safety arising, or likely to arise, from exposure to electromagnetic fields during their work. It covers all known **direct biophysical effects and indirect effects** caused by electromagnetic fields. The exposure limit values (ELVs) laid down in this Directive cover only **scientifically well-established links** between short-term direct biophysical effects and exposure to electromagnetic fields. It **does not cover suggested long-term effects**.

However, if well-established scientific evidence on suggested long-term effects becomes available, the Commission shall consider a **suitable policy response**, including, if appropriate, the submission of a legislative proposal to address such effects. The Commission shall, by means of a report, keep the European Parliament and the Council informed in this regard.

It should also be noted that this Directive does not cover the risks resulting from contact with live conductors.

Definitions: the Directive defines what is meant by “electromagnetic fields” (whose frequencies are up to 300 GHz), as well as what is meant by “direct biophysical effects” which are the effects in the human body directly caused **by its presence** in an electromagnetic field, including thermal effects, non-thermal effects and limb currents.

"Indirect effects", effects, caused by the **presence of an object** in an electromagnetic field, which may become the cause of a safety or health hazard, such as interference with medical electronic equipment and devices, including cardiac pacemakers and other implants or medical devices worn on the body or, for example, resulting in fires and explosions, are also defined.

The Directive also defines the following:

- **"exposure limit values (ELVs)"** which are values established on the basis of biophysical and biological considerations, in particular on the basis of scientifically well-established short-term and **acute direct effects**, i.e. thermal effects and electrical stimulation of tissues. These include 'health effects ELVs' means those ELVs above which workers might be subject to adverse health effects, such as thermal heating or stimulation of nerve and muscle tissue and 'sensory effects ELVs' means those ELVs above which workers might be subject to transient disturbed sensory perceptions and minor changes in brain functions;
- **"action levels (ALs)"** which are operational levels established for the purpose of simplifying the process of demonstrating the compliance with relevant ELVs or, where appropriate, to take relevant protection or prevention measures specified in this Directive. To this end, provision is made for "low ALs" and "high ALs" implying different levels of protection or prevention.

It should be noted that the values foreseen in the Directive are laid down in its annexes.

The physical quantities, ELVs and ALs, laid down in this Directive are based on the recommendations of the International Commission on Non-Ionizing Radiation Protection (ICNIRP).

Obligations of employers: the general principle laid down by the Directive is that the employer shall assess **all risks for workers arising from electromagnetic fields at the workplace** and, if necessary, measure or calculate the levels of electromagnetic fields to which workers are exposed.

Assessment of risks and determination of exposure: for the purposes of assessing the risks of exposure, the employer shall make use of a series of technical tools laid down in the Directive and, in particular:

- **practical guides: non-binding** practical guides made available by the Commission which shall be made available in 2016;
- other relevant standards or guidelines provided by the Member State concerned, including exposure databases;
- the emission levels and other appropriate safety-related data, provided by the manufacturer or distributor, for the equipment, in accordance with relevant Union law.

If compliance with the ELVs cannot be reliably determined on the basis of readily accessible information, the assessment of the exposure shall be carried out on the basis of **measurements or calculations**. In such a case, the assessment shall take into account uncertainties concerning the measurements or calculations, such as numerical errors.

The assessment can be made public in accordance with relevant Union and national laws applicable to the processing the personal data of employees. Unless there is an overriding public interest in disclosure, public authorities that are in possession of a copy of the assessment may refuse a request for access to it or a request to make it public, where disclosure would undermine the protection of commercial interests of the employer, including those relating to **intellectual property**.

Scope of the assessment: the assessment, measurement and calculations shall be planned and carried out by competent services or persons at suitable intervals. It shall give particular attention to the following: (i) the health effects ELVs, (ii) the sensory effects ELVs and (iii) the ALs referred to in the Directive and in Annexes II and III of the Directive but also (among other things) to:

- the frequency, the level, duration and type of exposure, including the distribution over the worker's body and over the volume of the workplace;
- any direct biophysical effects;
- any effects on the health and safety of workers at particular risk, in particular workers who wear active or passive implanted medical devices, such as **cardiac pacemakers**, workers with medical devices worn on the body, such as insulin pumps, and pregnant workers; …

Provisions aimed at avoiding or reducing risks: employers shall ensure that the exposure of workers to electromagnetic fields is **limited to the health effects ELVs and sensory effects ELVs** set out in Annex II, for non-thermal effects, and in Annex III, for thermal effects. Where the exposure of workers to electromagnetic fields exceeds the ELVs, the employer shall take immediate preventive action in accordance with the Directive, i.e. **an action plan** to be implemented in the event of exposure. This plan would include **technical and/or organisational measures** to prevent any risks to workers at particular risk and any risks due to indirect effects (e.g. appropriate delimitation and access measures, such as signals, labels, floor markings, barriers).

Information and training of workers is also provided for, as is the appropriate consultation and participation of workers and/or their representatives.

Other specific protective measures are also foreseen such as **the grounding of work objects or the use of insulating shoes**, measures to **trace the actions taken** and applied and, lastly, risk management measures are stipulated for cases where a worker reports **transient symptoms** (which can range from vertigo to nausea).

Specific provisions are foreseen **where the relevant ALs are (or are not) exceeded**. These provisions include worker protection measures unless the assessment carried out in accordance with the Directive demonstrates that the relevant ELVs are not exceeded and that safety risks can be excluded.

Provision is, however, made for a series of exceptions so that, under certain strict conditions, ALs for electromagnetic fields may be exceeded.

Generally, speaking, employers are required to ensure that risks arising from electromagnetic fields at work are **eliminated or reduced to a minimum**. If these values are exceeded, this may only be **on a temporary basis** and, where this arises, employers shall be required to take the necessary actions in order to return to compliance with the ELVs as soon as possible.

Measures are also foreseen to take account of the exposure of workers in **workplaces open to the public**.

Health surveillance: with the objective of prevention and early diagnosis of any adverse health effects due to exposure to electromagnetic fields, appropriate health surveillance shall be carried out in accordance with Directive 89/391/EEC. **Health records** and their availability shall be provided for in accordance with national law and/or practice. In any event, where exposure above the ELVs is detected, the employer shall ensure that appropriate medical examinations or individual health surveillance is provided to the worker(s) concerned, in accordance with national law and practice. The costs of such examinations shall be borne by the employer.

Exemptions: provision is made for a series of derogations. Exposure may exceed the limit values if it is related to the installation, testing, use, development, **maintenance of or research related to MRI-equipment** for patients in the health sector and on condition that certain conditions are met.

Likewise, Member States may allow for an equivalent or more specific protection system to be implemented for personnel working in operational military installations or involved in **military activities**, including in joint international military exercises, provided that adverse health effects and safety risks are prevented.

The Directive, furthermore, stipulates the 'justified circumstances' when the exemption shall apply. All derogations shall be notified to the Commission.

Penalties: Member States shall provide for adequate penalties applicable in the event of infringements of national legislation adopted pursuant to this Directive. These penalties must be effective, proportionate and dissuasive.

Annexes: the annexes have been reviewed and new annexes have been added providing a technical definition of the values not to be exceeded as a function of the frequency ranges of electromagnetic fields.

DELEGATED ACTS: the Commission shall be empowered to adopt delegated acts with a view to amending the annexes from a technical point of view so as to:

- take into account the adoption of regulations and directives in the field of technical harmonisation and standardisation with regard to the design, building, manufacture or construction of work equipment or workplaces;
- take into account technical progress, changes in the most relevant standards or specifications, and new scientific findings concerning electromagnetic fields;
- make **adjustments to the ALs** where there is new scientific evidence, provided that employers continue to be bound by the existing ELVs set out in Annexes II and III.

The power to adopt delegated acts will be conferred on the Commission for a period of **five years from 29 June 2013.**

The European Parliament or the Council may object to the delegated act within a period of **two months** of notification of that act (which may be extended by two months). If either the European Parliament or Council objects, the delegated act shall not enter into force.

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 shall be given to apply the urgency procedure to delegated acts adopted by the Commission.

ENTRY INTO FORCE: the Directive enters into force on 29.06.2013. Directive 2004/40/EC is repealed from that date.

TRANSPOSITION: the Directive shall be transposed in the Member States no later than **01.07.2016**.