WEM / ORGALIME Position

on the Common Position of the Council[1] on the

Amended 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)
92/0449/C (COD)

15/12/2003

Introduction

WEM[2] is the employers' organisation of the metal trades[3] in Europe covering the engineering, manufacturing and technology based companies. WEM regroups national employer organisations from these trades in 15 European countries. ORGALIME represents the mechanical, electrical, electronic and metal working industries of 23 European countries. Between them WEM and ORGALIME represent about 200 000 companies employing some 12 million people, 97% of them are small and medium sized enterprises (SMEs).

Employers' organizations in Europe recognize that good health and safety management is an essential feature of profitable and sustainable businesses. Engineering industries in Europe are particularly committed to providing safe electrical and electronic products and machinery to their professional customers.

This position has been worked out in broad consultation with the European trade sector associations, especially in the following fields: electricity operators, lighting industry, machine tools, household appliances, business machines and telecommunications, medical electrical equipment.

[1] Not yet published. This position is based on the draft text of the Directive as set out in Addendum 1 of the political agreement of the COREPER of 8 October 2003.
[2] As from 1st January 2004, WEM will be renamed CEEMET – Council of European Employers for the Metal, Engineering and Technology-based industries.
[3] Metal trades mean the metalworking, mechanical, electrical and electronics engineering, the aerospace, automotive, computer, communications and shipbuilding industries. In some countries it even includes the steel industry.

WEM – The Employers' Organisation of the Metal Trades in Europe
Diamant Building - 80 Bd A. Reyers – B-1030 Brussels
Tel : 0032-2-706.84.67 / Fax : 0032-2-706.84.69
e-mail : secretariat@wem.org / http://www.wem.org

ORGALIME – Liaison Group of the European Mechanical, Electrical, Electronic and Metalworking Industries
Diamant Building - 80 Bd A. Reyers – B-1030 Brussels
Tel : 0032-2-706.82.35 / Fax : 0032-2-706.82.50
e-mail : secretariat@orgalime.org / http://www.orgalime.org

This directive is at odds with the better regulation principles

We regret that the Commission has failed to provide evidence of work accidents or ill-health directly linked to exposure to electromagnetic fields in support of this individual Directive. The proposal, implements the Framework Directive 89/391/EEC within the meaning of its Article 16(1) on the prevention of accidents at work. However, despite being more than 10 years after its launch, the Council has not required any referral of its proposal to the Commission.

The dossier is at odds with the Commission's better regulation principles endorsed earlier this year by the European Parliament. No detailed impact assessment or any proper consultation of stakeholders accompanies the text, its true impact on business is still unknown and any benefits said to accrue from its introduction have not been identified. Therefore the directive places a disproportionate administrative burden and assessment cost on companies without corresponding health benefits. This negative impact will we believe, be felt most keenly in the manufacturing and the health sectors.

The Council's political agreement is believed to be considered as acceptable for some other sectors, especially in the power generation/transmissions and ICT fields, which are able to work within the ICNIRP guidelines. Their views are based on a significant amount of field data whereas in the manufacturing sector there is very little data. That which does exists suggests that there may be very real administrative problems for those companies who have processes such as electric welding, RF welding, dielectric heating, induction furnaces, ferro-magnetic NDT and electroplating. We also believe that this dossier may cause significant problems for businesses, which use electromagnetic security systems. These technologies are widely used in retail and airports.

Thousands of jobs in engineering are at stake

Well-considered legislation provides the foundation for the system and minimum harmonised standards across Member States assists in the development of the single market. However, all health and safety legislative proposals must have a sound scientific basis and be proportionate, in taking into account the interest of all. Without this, society will be faced with additional cost without consequent benefit. In particular, European workers may be faced with a lost of job opportunities due to further relocations of industrial plants outside Europe.

If the outcome of the political agreement reached by the Council on 20/10/2003 is largely improving the initial proposal of the Commission for this physical agent, we firmly believe that this directive may still raise major difficulties for a significant number of our members' companies, especially SMEs in the mechanical and metalworking field. In the years to come, we may fail to meet the needs and challenges of future generations that could be provided by developing innovative solutions using electromagnetic fields, such as we have already seen with Magnetic Resonance Imaging (MRI) in the health sector.

Article 8 should remain as it is in the Council CP

This Directive aims at preventing that EMF exposure may provoke acute effects on workers' health. This risk are in practice extremely low in the overwhelming majority of businesses, even if the limit values based on ICNIRP Guidelines are exceeded, for the following reasons:

1. The scientific basis for the action and limit values of this Directive are the ICNIRP Guidelines, which are endorsed by WHO (World Health Organisation's EMF Project) and the Scientific Advisory Committee of the European Commission. However, these guidelines are established in a precautionary manner in the face of scientific uncertainty about any cause-effect relationship which may exist, and are in no way based on clinical reports of ill-health occurrences, which would have actually been linked to EMF exposure.
   In this respect, **exposure to EMF is not comparable with exposure to other physical agents such as noise or hand-arm vibrations**, where assessable damages could be medically observed if the limit values are exceeded;

2. The physiological effects that exposure to EMF could trigger, even from natural sources such as the sun, are in the overwhelming majority of working conditions not adverse to health and **disappear immediately when the exposed person moves away** from the source. This has been confirmed by the WHO, DG SANCO, and many national reports such as the NRPB's or the "Stewart report" in the UK, the Zmirou report in France.

Therefore we believe that the current wording of article 8 on health surveillance, as agreed upon by the Council, should be considered as appropriate. In particular, it would be an unjustified responsibility for the medical inspection to assess health damages under its discretionary suspicion that it may have been caused by over-exposure to EMF. In the vast majority of cases there is no physiological change, signs or symptoms which a physician could use to reach any conclusion. Therefore medical examination would add further cost with no benefit to worker or employer.

ORGALIME and WEM have some comments and are of the opinion that the formulation of some provisions could be improved, in order to make them clearer to users of the future Directive. These are specified hereafter.

Brussels, 15 December 2003

Exclusion of workers using medical equipment

① Amendment suggested by COCIR[4]
Article 1, Paragraph 5 (new)

Council Common Position	Proposed Amendment
-	This Directive does not address the health and safety requirements of workers in the field of medical devices, which are covered by Council Directive 93/42/EC of 14 June 1993 concerning medical devices.

Justification

The Medical Device Directive (MDD) requires manufacturers to fulfill the essential requirements for medical devices. The reference for these requirements is set by the harmonized safety standards. These safety standards are based on worldwide internationally accepted standards for medical equipment and are continuously kept up-to-date.
They include general safety requirements specific for medical devices (on electrical, mechanical, thermal, etc., aspects) for patients, workers and the general public. Also included is the requirement for a risk management process that forces the manufacturer to apply risk management even for those parameters not specifically addressed in the harmonized standards.
IEC has published a general safety standard for medical equipment and a series of collateral standards for horizontal aspects. In addition, the second edition of a particular safety standard, IEC 60601-2-33, on MRI for patients (including EMF exposure limits for all relevant frequencies including the static magnetic field), was published in 2002. Currently an IEC working group is developing a standard for performance characteristics of MRI systems. A particular standard for EMF exposure is to be expected in the coming years, EMF exposure for the workers and general public is therefore covered currently via the risk management process of the manufacturer.
Since effective international safety regulations are already in place for medical devices it is not necessary and –therefore- not advisable to regulate the safety of this type of equipment also via other national or European directives

[4] COCIR is the European Co-ordination Committee of the Radiological, Electro medical and Medical IT Industries, of which all major manufacturers of medical electrical equipment are member or associate member

Simplified risk assessment procedure for work equipment covered by internal market directives

② Amendment suggested by WEM/ORGALIME
Article 4, Paragraph 3

Council Common Position	Proposed Amendment
The assessment, measurement and/or calculations referred to in paragraphs 1 and 1a need not be carried out in workplaces open to the public provided that an evaluation has already been undertaken in accordance with the provisions of Council Recommendation 1999/519/EC on the limitation of exposure of the general public to electromagnetic fields, and the restrictions as specified therein are respected for workers and safety risks are excluded.	The assessment, measurement and/or calculations referred to in paragraphs 1 and 1a need not be carried out **in particular** in workplaces open to the public provided that an evaluation has already been undertaken in accordance **with the essential requirements of the relevant Community directives and** with the provisions of Council Recommendation 1999/519/EC on the limitation of exposure of the general public to electromagnetic fields, and the restrictions as specified therein are respected for workers ~~**and safety risks are excluded**~~.

Justification

Some directives based on Article 95 of the Treaty (operation of the Internal Market), and in particular the "Low Voltage" directive (LVD) 73/23/EEC on electrical safety, the "Radio and Telecom Terminal Equipment" Directive (RTTED) 1999/5/EC, the Machine Safety Directive (MSD) 98/37/EC, the Medical Device Directive 93/42/EC, already requires manufacturers to limit exposure of users to EMF, according to the current state of the art. This state of the art is reflected to date by the Guidelines of the International Commission on Non Ionising Radiation Protection (ICNIRP) and has been acknowledged by the WHO and the European Commission.
Therefore professional equipment falling under the scope of "relevant directives" should be placed on the market in conformity with the essential requirements. A risk assessment has consequently already been undertaken by the manufacturer of this equipment with regard to the exposure to EMF. The European Commission has already mandated CENELEC to draft measurements standards for some equipment categories on the legal basis of the LVD and RTTED, with due consideration with the ICNIRP Guidelines for the protection of the general public, as referred to in the Council Recommendation 1999/519/EC.

We believe that it would considerably facilitate the task of hundred of thousands European employers, especially SMEs, if they could benefit from a simplified risk assessment obligation with regard to EMF, provided that they could demonstrate that the equipment used at the work place is in conformity with the relevant Community Directives (as stated in Art. 4, §1), and in accordance with manufacturer's instructions. This would be a proportionate response to a complex problem. Consequently, the amendment proposed would, without changing the spirit of the provision, enable employers of all office environments or small workshops, for instance, to benefit from this simplified risk assessment.

For clarity, we also suggest to delete the last part of the sentence of paragraph 3, since equipment, which is in conformity with Internal Market directives, could not be considered as putting the worker's safety at risk.

Provision for a report on the implementation of the Directive and its revision in case of impossibility for some business sectors to comply

③ Amendment suggested by WEM/ORGALIME
Article 11, Paragraph 2 (new)

Council Common Position	Proposed Amendment
-	"Within a deadline of one year from the adoption of the Directive, the European Commission shall present a report to the Council on the production processes used in the European Union which can not meet the limit values foreseen by the Directive and for which no substitution processes exist at an economically acceptable cost. The report shall present measures which would allow continuing use of these processes in the European Union. The report shall analyse more specifically the impact of the Directive on the following processes: welding; electrolysis, induction heating process; demagnetizers; ferromagnetic crack detection and security systems. If necessary, the European Commission shall present a draft proposal amending the Directive to take into account the conclusions of the report."

Justification

The technical impact of the Directive on certain everyday production processes which use electricity has not been duly evaluated. This covers for example spot (resistance)/Manual Metal Arc/TIG/MIG welding, electroplating process used in the metal industry for surface treatment, the production of chlorine through electrolysis and the use of electric-arc furnaces. Furthermore, it is more than likely that there are other processes which have not been identified yet and the implementation of which is not compatible with the limit values of the Directive at this stage of technical knowledge. In order to avoid unwarranted relocations outside the European Union, it is proposed to adopt measures on the basis of a report prepared by the European Commission.