CEEMET

Council of European Employers for the Metal, Engineering and Technology-based industries

ORGALIME

CEEMET[1] / ORGALIME AMENDMENTS AND COMMENTS

TO THE DRAFT REPORT TABLED BY MR. PEREZ-ALVAREZ

ON THE COMMON POSITION OF THE COUNCIL 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)

BRUSSELS, 19 FEBRUARY 2004

CEEMET[1] is the Council of the European Employers for the Metal, Engineering and Technology-based industries. CEEMET regroups national employer organisations from these industries in 15 European countries. ORGALIME represents the mechanical, electrical, electronic and metal working industries of 23 European countries. Between them CEEMET and ORGALIME represent about 200,000 companies employing some 12 million people, 97% of them are small and medium sized enterprises (SMEs).

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.

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.

CEEMET and ORGALIME would like to share their concerns with the members of the European Parliament and suggest some improvements to the Council common position. These comments take into account the amendments proposed by the Rapporteur, Mr. Perez-Alvarez, in his report of 3 February 2004, which was tabled for the Employment Committee meeting of 17 February 2004.

[1] Since the 1st January 2004, CEEMET is the new name of WEM – The Employers' Organisation for the Metal trades in Europe.

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COMMON POSITION	EP DRAFT REPORT	CEEMET / ORGALIME POSITION
Amendment 1 **Article 4 § 4**		
The assessment, measurement and/or calculations referred to in paragraphs 1 and 2 shall be planned and carried out by competent services or persons at suitable intervals, taking particular account of the provisions of Article 7 of Directive 89/391/EEC concerning the necessary competent services or persons. The data obtained from the assessment, measurement and/or calculation of the level of exposure shall be preserved in a suitable form so as to permit consultation at a later stage.	The assessment, measurement and/or calculations referred to in paragraphs 1 and 2 shall be planned and carried out by competent services or persons at suitable intervals, taking particular account of the provisions of Article 7 of Directive 89/391/EEC ***and the participation of designated workers***. The data obtained from the assessment, measurement and/or calculation of the level of exposure shall be preserved in a suitable form so as to permit consultation at a later stage.	ORGALIME and CEEMET believe that the notion of designated workers is unclear. Furthermore, as a general principle it seems to add a layer of complexity in the way in which an employer chooses to fulfil his obligation to undertake this responsibility.
Amendment 2 **Article 6 point (d)**		
why and how to detect and report signs of injury;	how to detect ***the effects of exposure and the obligation to report them***;	The proposed amendment of Article 6 point d) is too vague: **an "effect" is not necessarily adverse to health** and could not be used by a physician to reach any conclusion: in the vast majority of cases physiological change, signs or symptoms that **exposure to EMF** could trigger **disappear immediately when the exposed person moves away** from the source. **Therefore, ORGALIME and CEEMET recommend amending the Rapporteur's proposed amendment of Article 6 point (d):** "how to detect *the* ***adverse acute*** *effects* ***to health*** *of exposure and the obligation to report them*;"

COMMON POSITION	EP DRAFT REPORT	CEEMET / ORGALIME POSITION
	Amendment 3 **Article 8**	
Appropriate health surveillance shall be carried out according to Articles 14 and 15 of Directive 89/391/CEE for workers who might suffer adverse health or safety effects, especially for workers at particular risk	***In the interests of prevention and to enable any disease that may have been caused by exposure to electromagnetic fields to be detected as soon as possible,*** appropriate health surveillance shall be carried out according to ***Article 14*** of Directive *89/391/EEC*. ***Where it is suspected that a worker has been exposed to a degree exceeding the limit values, the worker and the undertaking shall be subject to the requirement of a medical examination, which the worker shall undergo within a suitable period.*** ***The employer shall take the decisions and steps required to ensure that the doctor or, where applicable, the medical authority responsible for the medical examination has access to the findings of the risk assessment referred to in Article 4. Where the worker's health is found to have been adversely affected in any way as a result of the exposure, a second risk assessment, chargeable to the undertaking, shall be carried out by the necessary competent services or persons, in accordance with Article 4.*** ***The employer shall keep the results of the medical examination for as long as necessary to enable them to be consulted at a later stage and allow comparison over time, on the understanding that the results shall remain confidential in every instance.*** ***Workers who have undergone a medical examination shall be entitled to have access to their personal medical records on request, without prejudice to their right to be given a copy of the report with the results of each examination.***	**ORGALIME and CEEMET** believe that the current wording of **article 8 on health surveillance, as agreed upon by the Council, should be considered as appropriate** and recommend voting against the Rapporteur's proposed amendment for the following reasons: **Mere suspicion could not lead to any obligation.** A **scientifically based exposure assessment only** could determine whether further medical examination would be advisable or not. The right for workers to ask for a medical examination, in order to be reassured that their health has not been endangered, is **already appropriately stated in Articles 14 and 15 of Directive 89/391/CEE**, which is referred to in the Council's Common Position. Therefore, CEEMET and ORGALIME believe that **an automatic obligation, instead of a right for workers *who might suffer adverse health or safety effects*** (such as headaches or nausea), **would generate disproportionate costs for companies**, **without any demonstrable health and safety benefits for workers**. This is in particular true for SMEs in the mechanical engineering sectors, which commonly use, for instance **electrical welding** machines, **surface treatment** or **induction heating processes**, especially since there is to date no examination a doctor can perform in these fields.

COMMON POSITION	EP DRAFT REPORT	CEEMET / ORGALIME POSITION
	Amendment 4 **Article 8 bis New**	
–	***Member States shall lay down appropriate penalties to apply in the event of infringement of the national legislation adopted pursuant to this Directive. Penalties must be effective, proportionate, and dissuasive.***	We believe that such penalties would be unjustified, when it is in practice impossible to assess the prejudice to the worker's health in the overwhelming majority of cases. Such a provision is inappropriate and would only further deter companies from maintaining operating plants within the European Union and would, on the contrary, constitute an incentive to further relocations to third countries. Furthermore, the terms 'proportionate' & 'dissuasive' in the context of this dossier appear to be contradictory.
	Amendment 5 **Article 11 § 3 New**	
–	***The Commission shall propose exposure limit values in relation to static magnetic fields on the basis of the review of guidance by the International Commission on Non-Ionising Radiation and will report on progress in this regard within five years of the adoption of this Directive.***	**ORGALIME and CEEMET recommend voting against the Rapporteur's proposed amendment of Article 11 paragraph 3 (new) for the following reasons:** In the years to come, we may fail to meet the needs and challenges of future generations that could be met by developing innovative solutions using electromagnetic fields, such as we have already seen with Magnetic Resonance Imaging (MRI) in the health sector. In the absence of any detailed regulatory impact assessment, the proposed amendment is unjustifiable. Threats over the future use by hospitals of MRI scanners that may not comply in the future with the provisions of this Directive lead to unacceptable legal uncertainties. This will consequently deter industry from undertaking research and developing costly equipment and hospitals from investing in such equipment, with **disastrous consequences for the diagnosis of cancer and other diseases for millions of patients** (5 per day and per scanner).

Besides these comments, ORGALIME and CEEMET would like to add the following amendments to the EP Report for 2nd reading:

Exclusion of workers using medical equipment

① Amendment suggested by COCIR [2]
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 fulfil 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

[2] 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 CEEMET/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

Many existing "product" directives already require the protection of users, including workers, **against exposure to** [ionising and non ionising] **radiation**, according to the current state of the art, which is reflected to date by the Guidelines of the International Commission on Non Ionising Radiation Protection (ICNIRP). There are at least 3 "relevant community directives", which apply to a broad range of professional products, such as:

- the "Low Voltage" directive 73/23/EEC for **all electrical and electronic equipment operating in a voltage range between 50 V. AC / 75 V.DC and 1000 V. AC / 1500 V.DC**:[3];
- the **Machinery Directive** 98/37/EC[4]
- the **Medical Device Directive** 93/42/EC [5]

For all professional equipment for which the employer could show compliance with these relevant Community **directives** (as stated in Art. 4, §1)**, an evaluation of the EMF risk** has already been undertaken. Therefore, we believe that introducing the expression "in particular" before "workplaces open to the public", would **extend the scope of the article to all other workplaces,** such as the back office of a corner shop, for them **to also benefit from a simplified risk assessment**.

We believe that this amendment would considerably facilitate the task of hundred of thousands of European employers, especially SMEs. For clarity, we also suggest deleting 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.

[3] Cf. essential safety requirements (Annex I of the Directive), Section 2 §b: "Measures of a technical nature should be prescribed in order to ensure that temperatures, arcs or **radiation** which would cause a danger, are not produced";

[4] Cf. essential safety requirements (Annex I of the Directive), Section 1.5.10 "radiation": "Machinery must be so designed and constructed that any emission of **radiation** is limited to the extent necessary for its operation and that the effects on exposed persons are non-existent or reduced to non-dangerous proportions."

[5] Cf. essential safety requirements (Annex I of the Directive), Section 11.1.1. "Protection against radiation": "Devices shall be designed and manufactured in such a way that exposure of patients,users and other persons to **radiation** shall be reduced as far as possible compatible with the intended purpose,whilst not restricting the application of appropriate specified levels for therapeutic and diagnostic purposes."

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 CEEMET/ORGALIME
Article 6, Paragraph 1

Council Common Position	Proposed Amendment
Without prejudice to Articles 10 and 12 of Directive 89/391/EEC, the employer shall ensure that workers who are exposed to risks from electromagnetic fields at work and/or their representatives receive any necessary information and training relating to the outcome of the risk assessment provided for in Article 4(1) of this Directive, concerning in particular: (a) measures taken to implement this Directive; (b) the values and concepts of the exposure limit values and action values and the associated potential risks; (c) the results of the assessment, measurement and/or calculations of the levels of exposure to electromagnetic fields carried out in accordance with Article 4 of this Directive; (d) why and how to detect and report signs of injury; (e) the circumstances in which workers are entitled to health surveillance; (f) safe working practices to minimise risks from exposure.	Without prejudice to Articles 10 and 12 of Directive 89/391/EEC, the employer shall ensure that workers who are exposed to risks from electromagnetic fields at work and/or their representatives receive any necessary information and training relating to the outcome of the risk assessment provided for in Article 4(1) ***and Article 4(2)*** of this Directive, concerning in particular: (a) measures taken to implement this Directive; (b) the values and concepts of the exposure limit values and action values and the associated potential risks; (c) the results of the assessment, measurement and/or calculations of the levels of exposure to electromagnetic fields carried out in accordance with Article 4 of this Directive; (d) why and how to detect and report signs of injury; (e) the circumstances in which workers are entitled to health surveillance; (f) safe working practices to minimise risks from exposure.

Justification

CEEMET and ORGALIME believe that the reference in Article 6 to Article 4(1), on the information of workers on the outcome of the EMF risk assessment, is not relevant, since Article 4(1) closely relates to "action values" as defined in article 2(c).
Such information and training should relate to the prevention of the risk assessed above the “exposure limit values” and we therefore recommend amending Article 4 by adding a reference to Article 4(2), which refers to "exposure limit values".

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

④ Amendment suggested by CEEMET/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; demagnetisers; 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.