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Scientific Committee on Toxicity, Ecotoxicity and the Environment

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SCIENTIFIC COMMITTEE ON TOXICITY, ECOTOXICITY AND THE ENVIRONMENT (CSTEE)

OPINION OF THE CSTEE ON "EFFECTS OF ELECTROMAGNETIC FIELDS ON HEALTH" Reply to question B Opinion expressed at the 33rd CSTEE plenary meeting

Brussels, 24 September 2002

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The Plenary focussed on question B posed in the original mandate to CSTEE; which remained unanswered in the CSTEE opinion of October 30, 2001. The question was reiterated in Dr. Sauer's letter of January 23rd [SANCO/C/2/JCD/pcd D(2002) – CSTEE/2000/26 Add 50].

The terms of question B are:

"Whether for thermal and non thermal effects, the technical annex for the Council Recommendation (OJ No. L 199/59 dated 30 July 1999) setting up basic restrictions and reference levels limiting the exposure to non-ionising radiation and based on the guidelines published by the International Commission on Non-Ionising Radiation Protection (ICNIRP) is still the appropriate scientific basis for a system of health protection against the risks from non-ionising radiation."

Background

• ICNIRP's restrictions have been established on the basis of nerve and muscle tissue stimulation by electric currents which are induced in the cells. This is an effect that can be assumed to be thresholded.

Summary of Data base available

- ICNIRP's scientific procedure for setting limit values on nerve and muscle tissue stimulation (identification of dose-response patterns, consideration of the most sensitive endpoints, etc) is robust. However, relevance of induced electric currents in cells to *unproven but suspected* health effects in humans for low frequency EMF (such as childhood leukaemia) is doubtful.
- The long-term experiments on transgenic mice of the Emu-Pim1 strain intended to test the reproducibility of previous "positive" findings with high frequency EMF (Repacholi et al. Radiat Res 1997;147:631-640) has been finalised and published (Utteridge TD et al Radiat Res 2002 158:357-364). The new study does not provide any suggestion of carcinogenicity.
- Two long-term experiments with ELF on the same transgenic mice failed to provide any evidence of carcinogenicity

Data base used for risk assessment

- The unproven but suspected health effects in humans (in particular childhood leukaemia in relation to the highest level of exposure to ELF in the meta-analysis) which are suggested by epidemiological investigations and for which for the time being there is no mechanistic explanation, are not taken into consideration by the procedure set by ICNIRP. On the other hand, risk estimates and/or dose-response analysis provided by such investigations only allow for hazard identification. Therefore, these data cannot be used for setting limit values.
- In order to set limit values for workers occupationally exposed, ICNIRP has identified, in the frequency range between a few Hz and 1 kHz (a range which includes ELF), that at levels of induced current densities above 100 mAm⁻² central nervous system excitability and other acute effects in humans such as reversal of visually evoked potential are exceeded. They have used an uncertainty factor of 10 to set a workplace standard. A further uncertainty factor of 5 has been introduced by ICNIRP in order to set limit values for the general population. The rationale for these uncertainty factors is not provided.

Use of uncertainty factors

- If a consistent approach to risk characterisation were adopted between EMF and • chemicals (see Position paper on Margins of Safety (MOS) in human health risk assessment expressed at the 22nd CSTEE plenary meeting, Brussels, 6-7 March <2001 <u>http://europa.eu.int/comm/food/fs/sc/sct/out110_en.html</u>), the approach would have been different: a) a decision would have to be reached whether the effect was thresholded or not; b) if the effect was judged to be thresholded, the inclusion of uncertainty factors would be undertaken; c) if the effect was judged to be nonthresholded -as in the case of ionising radiation- a mathematical low-dose extrapolation would be considered; d) the use of the uncertainty factor approach would take into account uncertainties and variability in the data base, including results from short-term exposures for predicting long-term effects and interindividual variability in sensitivity: a default uncertainty factor of 10-100 would be used to extrapolate from acute to chronic effects and an additional default factor of 10 would be applied to allow for inter-individual differences in toxicokinetics and toxicodynamics (e.g. a default factor of 3.2 for increased sensitivity in children). [Assessing human health risks of chemicals: Derivation of guidance values for health-based exposure limits. Environmental Health Criteria No. 170, Geneva, 1994. World Health Organisation].
- The CSTEE acknowledges that with regard to scientifically-based risk assessment approaches and the use of uncertainty factors, harmonisation between chemical and physical agents has not been sufficiently addressed and requires attention at

international level. The issue is being addressed by a task force of the Scientific Steering Committee on harmonisation of risk assessment procedures.

Conclusion

• The CSTEE appreciates the high scientific standard of the evaluation of the published literature made by ICNIRP and accepts that the value of 100 mAm⁻² provides a reasonable basis to derive a standard at the present time. However, the CSTEE considers that, particularly for ELF additional concerns may arise at the level of risk management because of the uncertainties stemming from the gaps in the scientific literature.