June 2012

ISSN nr: 1830-6993
Catalogue nr: ND-AG-12-001 EN-N

European Commission

Newsletter

of the European Commission Scientific Committees

REVIEW OF EVENTS

INTERNATIONAL SCIENTIFIC CONFERENCE ON ELECTROMAGNETIC FIELDS AND PUBLIC HEALTH, 16-17 NOVEMBER 2011, BRUSSELS

In order to prepare a request for update of two recent opinions of the SCENIHR on electromagnetic fields (EMF) and Health[1,2], DG SANCO and the SCENIHR held an international scientific conference on electromagnetic fields and public health. Its specific aim was to identify the sub-areas where the scientific consensus on the potential health effects of electromagnetic fields is sufficiently strong to bring closure, to highlight the sub-areas in need of further investigation, and to develop proposals on a strategy to address the remaining knowledge gaps. The conference also helped identify sources of scientific expertise in these domains. About 300 delegates from 34 countries attended the Conference that was structured in 5 Sessions.

Session 1 explored what are EMF, how they physically interact with the body and what are the exposure limits/restrictions and what are the main issues related to EMF exposure assessment.
Session 2 dealt with the main sources of uncertainty in EMF health research and how they are currently addressed.
Session 3 dealt with the current state of knowledge and identification of the main areas of scientific consensus.
In Session 4, the areas of scientific inconsistency and the knowledge gaps were discussed. The main uncertainties related to ELF exposure and in–vitro studies can be found in genotoxicity, apoptosis, epigenetics (gene and protein expression), combined exposure of EMF and other agents, radical pair mechanisms and degenerative processes. Several factors are likely to contribute to the inconsistencies including: i) (too) large number of variables included in the experiments; ii) experimental protocols not adequately described; iii) lack of replication and confirmation studies.

The main uncertainties and gaps regarding biological effects of low level RF EMF relate also to the limited range of signals tested and in the lack of systematic means of exploring various exposures, biological models, or endpoints. Gaps in laboratory studies include the study of effects on young and juvenile animals (brain development, mechanisms, and cancer), ageing and neurodegenerative disease, thresholds for behavioural modifications, use of relevant and responsive in-vitro models for in-vivo findings, methods for identifying localized heating in the brain and the influence on medical implanted devices.

The main uncertainty and knowledge gap in both epidemiological case-control and cohort studies are related to RF exposure assessment (dosimetry aspects). The methods so far used are prone to bias and objective measures of exposure are needed to reduce uncertainty interpretation of the study results, e.g., by prospective cohort studies.

With respect to research needs, the conference highlighted the need to reinforce studies on the effect of ELF exposure on neurodegenerative diseases, to do more replication studies, to address the new technologies, to study the new systems working at frequencies and modulations not yet fully investigated (LTE, WiFi, high frequency RFID, etc), and to study the effects of the increase of the static magnetic field generated by MRI devices.

The final discussion, **Session 5**, dealt mainly with lessons learned and recommendations for the future. In this session, an interesting discussion about the link between the issues and information presented during the two-day conference and their possible influence on research strategies took place. This highlighted the need for more comprehensive and rigorous exposure assessment, studies of long-term effects, studies of neurodegenerative diseases in all frequency bands, the need for an inter-/multidisciplinary approach and the need to resolve the inconsistencies and uncertainties in epidemiological studies of RF effects.

More information is available at
http://ec.europa.eu/health/electromagnetic_fields/events/ev_20111116_en.htm

[1] http://ec.europa.eu/health/archive/ph_risk/committees/04_scenihr/docs/scenihr_o_022.pdf
[2] http://ec.europa.eu/health/archive/ph_risk/committees/04_scenihr/docs/scenihr_o_024.pdf

OPINIONS ADOPTED

SCIENTIFIC COMMITTEE ON CONSUMER SAFETY (SCCS)

Cosmetic ingredients

The Annexes to Council Directive 76/768/EEC on cosmetic products list substances banned or restricted for use in cosmetic products as well as authorised colorants, UV-filters and preservatives. For updates of these annexes, the SCCS has to be consulted to carry out risk assessments based on safety data provided by industry and/or data available in the public domain.

The following risk assessments have recently been concluded:

Polidocanol

Polidocanol is used in cosmetic products as emulsifier, but also frequently present in topical medicaments intended to ease skin itching. Following an earlier opinion on polidocanol, the SCCS was asked to review certain properties (local anaesthetic potential, sensitisation, possible side effects on the cardiovascular system). After consideration of the provided evidence, the SCCS maintained its previous conclusion that polidocanol does not pose a risk to the health of the consumer at the intended use concentration of up to 3% in leave-on and up to 4% in rinse-off cosmetic products.

The opinion is available at:
http://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_o_076.pdf

Furfural

Furfural is a perfumery ingredient and flavouring with widespread use in cosmetic products. It is also present in food. Furfural is classified as a CMR carcinogen cat. 2 and therefore subject to an assessment by SCCS for use in cosmetics. Such an assessment was already issued by SCCNFP in 2004, but due to modified use levels and recent scientific information on the mutagenic potential, the SCCS was asked for a re-assessment.

The Committee concluded that the new evidence on mutagenicity/genotoxicity in relation to the carcinogenicity of furfural indicates that the observed carcinogenicity is likely to be induced by a threshold mechanism. The use of furfural with a maximum concentration limit of 10 ppm in the finished cosmetic product, including oral products, does not pose a risk to the health of the consumer.

The opinion is available at:
http://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_o_083.pdf

Soytrimonium Chloride

This mixture of alkyl trimethylammonium compounds is used in hair colorant products. The applicant submitted only limited data on this compound and proposed a read-across approach from related substances previously evaluated by SCCS.

The SCCS concluded that based on these data a final evaluation of the safety of Soytrimonium Chloride for the intended use is not possible and identified information that will need to be submitted for a final assessment

The opinion is available at:
http://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_o_091.pdf

Nitrosamines and Secondary amines in Cosmetic Products

Nitrosamines are a class of chemical compounds, some of which are known to be carcinogenic. The possible health risks associated with the presence of nitrosamines in cosmetic products are regulated under the Cosmetics Directive (76/768/EEC). The implementation of this Directive in the market place has proven difficult as the chemical terms used in the entries of the Directive are relatively generic and allow for different interpretations among economic operators and public authorities. To address these difficulties, the SCCS has been asked to provide more exact definitions of such terms, taking account of the scientific and toxicological basis, so that it is clear to regulators which products can be considered safe, and which ones hazardous, to health.

The opinion is available at:
http://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_o_090.pdf

Hair Dyes

Under the safety evaluation of hair dyes, the SCCS has recently adopted a number of opinions of which the outcome is as follows:

Hair dye found to be safe under the intended use conditions:

- A16, p-Aminophenol
- A154, 1-Hydroxyethyl-4,5-diamino pyrazole sulphate
- A157, 4-Formyl-1-methylquinolinium-p-toluenesulfonate
- A158, 2-Amino-5-ethylphenol HCl
- B117, Basic Yellow 87
- B118, Basic Orange 31
- C53, Acid Red 92
- C179, Disperse Blue 377

For the following hair dye new data is required before a final conclusion will be reached:

- A136, 2,6-Diaminopyridine
- B7, Basic Brown 17
- C182, HC Blue n° 15

The hair dye opinions are available at: http://ec.europa.eu/health/scientific_committees/consumer_safety/opinions/index_en.htm#2

Preservatives

Quaternium-15 (P63)

Quaternium-15 is a preservative used in cosmetic products. As it has been classified CMR (toxic to reproduction), the SSCS was asked to evaluate whether the continued use in cosmetics could be considered safe.

The SCCS concluded that it cannot perform a quantitative risk assessment due to insufficient quality of available toxicity and dermal absorption data. Considering the CMR classification and the absence of relevant toxicological data, the SCCS questioned the safety for consumers of continued use in cosmetic products.

The opinion is available at: http://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_o_077.pdf

Fragrances

Updated scientific opinion on the labelling of 26 fragrance substances

Allergy to fragrance ingredients is estimated to affect 1-3% of the European population and can significantly impair quality of life. In 1999, the SCCNFP, a predecessor of the current SCCS, identified 26 well-recognised fragrance allergens. Consequently, measures were introduced that required these sub stances to be listed individually on the label of cosmetic products. This allows doctors to diagnose more easily fragrance ingredient allergies, and patients who know the cause of their allergy to avoid cosmetics that will cause reactions.

Since 1999, much more information on fragrance allergens has become available and the European Commission requested the SCCS to provide an up-to-date review of the current knowledge to see whether the list of fragrance allergens relevant for consumers needs to be modified and whether safe limits could be established for the most frequent allergens.

In its draft opinion, the SCCS identified fragrance ingredients which are established contact allergens in humans based on human clinical and epidemiological evidence. This included the 26 previously listed substances, but also an additional 30 individual chemicals and 26 natural extracts. In addition, evidence from animal studies and analysis of chemical structures were used to identify ingredients which will be expected to cause allergy also in humans. Chemical processes which can transform seemingly innocuous fragrance chemicals into allergens were also considered.

With regard to fragrance allergens which have been reported to cause a high number of allergy cases, the SCCS derived a concentration limit which is expected to protect most patients with allergies to these ingredients from reacting to the cosmetics containing them. The SCCS also considers this concentration limit as appropriate to prevent consumers who are not allergic from developing allergy to these fragrance ingredients.

A pre-consultation opinion was adopted in the SCCS Plenary of December 2011 and a public consultation on this opinion took place from 20 December 2011 – 29 February 2012. In addition, a public hearing was held on 5 March 2012 to allow for an exchange of views between the SCCS Working Group and stakeholders.

The Committee is currently in the process of reviewing the comments received from these two occasions and an updated version will be presented to the SCCS for final adoption.

The opinion is available at:
http://ec.europa.eu/health/scientific_committees/consultations/public_consultations/sccs_consultation_04_en.htm

Hydroxyisohexyl 3-cyclohexene carboxaldehyde (HICC)

Hydroxyisohexyl 3-Cyclohexene Carboxaldehyde is a fragrance substance used in cosmetic products with a known potential to cause allergies. The SSCS evaluated the safety of its use and concluded that HICC has been shown to be a significant cause of disease. Voluntary restrictions of use concentration by the fragrance industry were not reflected in recent information on prevalence of HICC-induced allergy. The SCCS considers that the number of cases of HICC allergy documented over the last decade is exceptionally high and that continued exposure to HICC by the consumer is not considered safe.

The opinion is available at:
http://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_o_074.pdf

Methyl-N-methylanthranilate

Methyl-N-methylanthranilate is a fragrance substance with a known phototoxic potential. Considering recently submitted additional scientific information, the SCCS concluded that 0.1% methyl-N-methylanthranilate may be safe for use in many leave-on cosmetic products, including deodorants and antiperspirants. However, as there is no information on UV irradiation given soon after application of methyl-N-methylanthranilate or the effects of repeated low dose exposures with UV irradiation, the SCCS considers that for the use in sunscreen/sun care products or products (including fragrances) intended for use on areas exposed to light (especially face and neck), a risk cannot be excluded. There is no safety concern on the use of methyl-N-methylanthranilate at up to 0.2% in rinse-off products.

The opinion is available at:
http://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_o_075.pdf

SCIENTIFIC COMMITTEE ON HEALTH AND ENVIRONMENTAL RISKS (SCHER)

Toxicity and Assessment of Chemical Mixtures

This is a joint opinion (SCHER in the lead) which was adopted also by SCENIHR and SCCS.

Its main conclusions are:

1. Under certain conditions, chemicals may act jointly in a way that the overall level of toxicity is being affected. Chemicals with common modes of action may act jointly to produce combination effects that are larger than the effects of each mixture component applied singly. These effects can be described by dose/concentration addition.
2. For chemicals with different modes of action (independently acting), no robust evidence is available that exposure to a mixture of such substances is of health or environmental concern if the individual chemicals are present at or below their zero-effect levels.
3. Interactions (including antagonism, potentiation, synergies) usually occur at medium or high dose levels (relative to the lowest effect levels). At low exposure levels, they are either unlikely to occur or are toxicologically insignificant

The opinion is available at:
http://ec.europa.eu/health/scientific_committees/environmental_risks/docs/scher_o_155.pdf

Cadmium in Fertilisers – Request for a SCHER opinion on the Risk Assessment report from the Kingdom of Sweden

On 17 October 2011, the Kingdom of Sweden has notified the Commission of its intention to reduce its national provision on the cadmium content of mineral phosphate fertilisers from 100 mg Cd/kg P to 46 mg Cd/kg P. This request was based on a report submitted by Sweden. Overall, the SCHER concluded that it does not consider the assumptions made in the Swedish report as appropriate for calculating risk in the Swedish environment.

The request is available at:
http://ec.europa.eu/health/scientific_committees/environmental_risks/docs/scher_o_156.pdf

Tris(2-chloroethyl) phosphate TCEP in Toys

The substance tris(2-chloroethyl)phosphate (TCEP) is an alkyl phosphate ester used as a flame-retardant plasticiser and viscosity regulator in polyurethanes, polyester resins, polyacrylates and other polymers. Given the daily burden coming from all possible sources of TCEP which is already around the Tolerable Daily Intake (TDI) level, the SCHER concluded that no additional exposure to TCEP from toys can be considered safe. There is no reason to set any limit for TCEP in toys, since no safe limit could be identified for children of all ages. This limit should be set at the detection limit of a sufficiently sensitive analytical test method. Judging by the physico-chemical properties of the halogenated alternatives of TCEP, the SCHER concluded that the considerations given for TCEP could be applied to its halogenated alternatives as well, if used in toy manufacturing.

The opinion is available at:
http://ec.europa.eu/health/scientific_committees/environmental_risks/docs/scher_o_158.pdf

Chemicals and the water framework Directive: draft environmental quality standards – Zinc

This opinion is related to article 16 of the Water Framework Directive (WFD, 2000/60/EC) which requires the Commission to identify priority substances among those presenting significant risk to or via the aquatic environment, and to set EU Environmental Quality Standards (EQS) for those substances in water, sediment and/or biota. The SCHER agreed with the way the EQS for freshwater are derived and that the most critical EQS (surface water) has been correctly identified in EQS dossier on zinc (13-14 µg/l total dissolved zinc). However, SCHER did not agree with the derivation of the marine EQS.

The opinion is available at:
http://ec.europa.eu/health/scientific_committees/environmental_risks/docs/scher_o_157.pdf

SCIENTIFIC COMMITTEE ON EMERGING AND NEWLY IDENTIFIED HEALTH RISKS (SCENIHR)

Risk assessment on PIP implants ruptures

The European Commission Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) adopted a scientific opinion on the safety of silicone breast implants manufactured by the Poly Implant Prothèse (PIP) Company. In its opinion, the SCENIHR considered that in view of the available physical, chemical and irritation findings, it is reasonable to have concerns about the safety of PIP implants. However, the limited clinical data and the absence of epidemiologic data on PIP implants did not allow the SCENIHR to establish whether women with PIP implants have a greater risk to their health than women with breast implants manufactured according to the safety and quality provisions of the Medical Devices Directive. To this end, the SCENIHR identified the data and research needed to establish with greater certainty the health risks that may be associated with PIP implants.

The opinion is available at: http://ec.europa.eu/health/scientific_committees/emerging/docs/scenihr_o_034.pdf

Health effects of artificial light:

The opinion concludes that, in general, the probability is low that artificial lighting for visibility purposes induces acute pathologic conditions, since expected exposure levels are much lower than those at which effects normally occur, and are also much lower than typical daylight exposures.

However, certain lamp types (including incandescent light bulbs) may emit low level UV radiation which could in theory (according to a worst case scenario based on the highest measured UV emissions from lamps used in offices and schools) add to the number of squamous cell carcinomas in the EU population.

Regarding blue light, there is no evidence that artificial lighting belonging to Risk Group 0 ("exempt from risk") would have any impact on the retina graver than that of sunlight. Lamps belonging to other risk groups could, in theory, induce photochemical retinal damage but there is no evidence that this constitutes a risk in practice. Other damages to the eye from chronic artificial light exposure during normal lighting conditions are unlikely.

For pathological conditions, artificial lighting is reported to play a role in some cases.

The current standardization of lighting lamps and luminaires in four risk categories appears sufficient to limit the personal short-term risk. However, Risk Group 0 should not be taken to imply adequate protection of the general population as a whole from long-term UV-exposure effects.

For the benefit of patients (around 250,000 EU citizens) that are exceptionally sensitive to UV/blue light exposure, it may be advisable to make sufficient information on the emitted spectrum for individual lamp models available to allow them to choose their lighting solutions optimally.

The opinion is available at: http://ec.europa.eu/health/scientific_committees/emerging/docs/scenihr_o_035.pdf

SCENIHR opinion on the health effects of security scanners for passenger screening (based on X-ray technology)

The Commission decided to make this request to the SCENIHR when it adopted legislation allowing security scanners which do not use X-rays in order to further assess the impact of X-ray security scanners on human health.

Overall, the SCENIHR concluded that the security scanners based on backscatter X-ray deliver doses much lower than any known threshold so that their use would not result in short-term health effects due to tissue damage. Also, the potential magnitude of cancer risk from doses received from security scanners cannot be estimated but is likely to remain so low that it cannot be distinguished from the background risk.

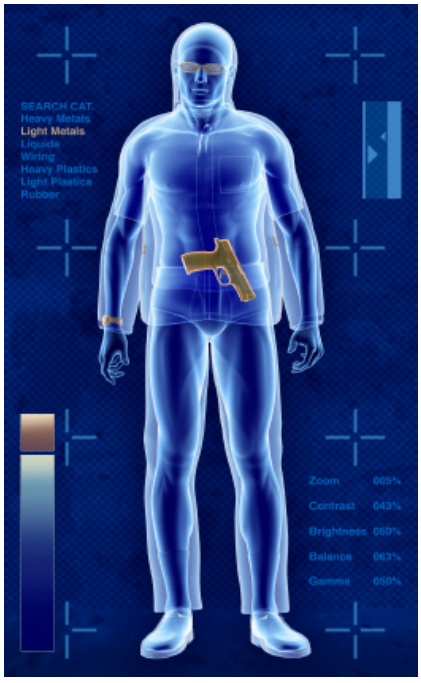
Security scanners based on transmission X-rays deliver much higher doses than those based on X-ray backscatter. This could result in significantly higher cumulative doses which may exceed the annual dose limit for members of the public if transmission scanners are used as routine screening devices for frequently exposed individuals.

However, for all cases the SCENIHR adds that while the expected health detriment will probably be very close to zero for any single scanned person, the assessment of acceptability of the introduction of the security scanners using X-rays for passenger screening cannot ignore the possible effect at the population level, as required by EURATOM radiation protection legislation.

Finally, the SCENIHR could not compare health risks from use of ionising against non-ionising radiation scanners as the necessary scientific evidence is not available.

The opinion is available at: http://ec.europa.eu/health/scientific_committees/emerging/docs/scenihr_o_036.pdf

All opinions delivered by the Scientific Committees are without prejudice to personal ethical considerations of the experts.



ONGOING WORK

SCIENTIFIC COMMITTEE ON CONSUMER SAFETY – SCCS

The following mandates are currently under evaluation:

Hair dyes

To ensure the safety of hair dye products, a complete review of all hair dye substances on the European market has been initiated by the European Commission. Under this framework, full safety evaluations of 15 hair dyes remain to be performed. In addition, supplementary data on 14 substances that have been initially evaluated have been received and await assessment.

Preservatives

- Climbazole
- Zinc pyrithione
- Benzoisothiazolinone

UV-filters

- HAA299 / C-1332
- Titanium dioxide (nano-sized)
- Zinc oxide (nano-sized)

Fragrances

- Review of fragrance substances that need to be labelled when present in cosmetic products

Other cosmetic ingredients

- Acetaldehyde
- Arbutin / desoxyarbutin
- Kojic acid
- Dichloromethane
- Hydrolysed wheat proteins
- Peanut oil
- Oxidised Vitamin K1

Others

- NDELA in cosmetic products and nitrosamines in balloons

NEW MANDATES FOR SCCS

Methylene glycol in hair straighteners

Methylene glycol or hydrated formaldehyde is formed upon dissolution of formaldehyde in water and exists in equilibrium with formaldehyde in aqueous solutions. While restrictions for the use of formaldehyde in cosmetic products exist (concerning formaldehyde in nail hardeners and formaldehyde and paraformaldehyde used as preservatives), methylene glycol is not explicitly included.

Methylene glycol has been found in hair straightening products and was considered as unsafe by some member states due to the release of formaldehyde during normal and foreseeable use conditions of such products. The SCCS is asked whether, based on the current knowledge on its chemistry, biology and toxicology, methylene glycol should be considered equivalent to formaldehyde. If this is the case, the SCCS should assess whether the currently established safe level of 0.2% formaldehyde/paraformaldehyde for use as preservatives also ensure the safety of methylene glycol when used as an ingredient in hair straightening products, taking into account the specific conditions of use of such product. If methylene glycol is considered different from formaldehyde, the SCCS is asked to establish a safe level for the use of methylene glycol in hair straightening product.

All mandates for the SCCS are available on: http://ec.europa.eu/health/scientific_committees/consumer_safety/requests/index_en.htm

SCIENTIFIC COMMITTEE ON HEALTH AND ENVIRONMENTAL RISKS – SCHER

The following mandates are currently under evaluation:

Assessment of the Tolerable Daily Intake of Barium in Toys

The new Toys Safety Directive (TSD) establishes migration limits of 19 elements from toys or components of toys. The migration limits shall not exceed the listed limits, depending on the toy material used. However, the elements can be used if the toy or components of the toy exclude any hazard due to sucking, licking, swallowing or prolonged contact with the skin when used as intended or in a foreseeable way, bearing in mind the behavior of children.

The migration limits are based on a study by the Dutch National Institute for Public Health and the Environment (RIVM) and opinions of the Scientific Committee. In the SCHER opinion on the evaluation of migration limits for chemical elements in toys, it was noted that SCHER supports the RIVM approach as a starting point for risk assessment of chemical elements in toys, namely the basis for all approaches is a health-based limit value, e.g. tolerable daily intake (TDI). The SCHER also recommended the amount allocated to the toy to be limited to 10% (CSTEE 2004).

In view of the RIVM report and other documents on barium, SCHER has been asked to deliver an additional opinion on the evaluation of the migration limits for barium. The final text of the opinion is now undergoing targeted public consultation with the Member States.

Chemicals and the Water Framework Directive: Draft Environmental Quality Standards

Article 16 of the Water Framework Directive (WFD, 2000/60/EC) requires the Commission to identify priority substances among those presenting significant risk to or via the aquatic environment, and to set EU Environmental Quality Standards (EQSs) for those substances in water, sediment and/or biota. In 2001 a first list of 33 priority substances was adopted (Decision 2455/2001) and in 2008 the EQSs for those substances were established (Directive 2008/105/EC or EQS Directive, EQSD). The WFD Article 16 requires the Commission to review periodically the list of priority substances. Article 8 of the EQSD requires the Commission to finalise its next review by January 2011, accompanying its conclusion, where appropriate, with proposals to identify new priority substances and to set EQSs for them in water, sediment and/or biota.

A shortlist of 19 possible new priority substances was identified in June 2010. A group of experts from Member States, EFTA countries, candidate countries and more than 25 European umbrella organisations representing a wide range of interests (industry, agriculture, water, environment, etc.) was established. This group has been deriving EQS for these substances and have produced draft EQS for most of them. In some cases, a consensus has been reached, but in some others there is disagreement about one or other component of the draft dossier. Directorate-General Environment seeks the opinion of the SCHER on these draft EQS for the proposed priority substances and the revised EQS for a number of existing priority substances. The SCHER has already published its opinions on aclonifen, anthracene, beta-estradiol, bifenox, cybutryne, cypermethrin, dichlorvos, diclofenac, dicofol, dioxins, ethinylestradiol, fluoranthene, HBCDD, heptachlor, ibuprofen, lead, naphthalene, nickel, PBDE, polyaromatichydrocarbons, quinoxyfen, and terbutryne. The work on cyanides and zinc continues and is expected to be completed by the end of the year.

Mercury in Energy-saving Light Bulbs

The issue of mercury emissions from certain energy-saving light bulbs (compact fluorescent lamps, CFLs) upon breakage is still causing concern, including in the European Parliament and in the media. In particular the potential risk for children has been raised.

The SCHER provided an opinion on mercury released from breaking CFLs (in May 2010), but could not conclude on the potential risk of children due to lack of data. Now SCHER is asked for an opinion on the potential mercury exposure to children, and thus the risk. The opinion will be adopted by the end of May 2012.

Mandates for SCHER are available at: http://ec.europa.eu/health/scientific_committees/environmental_risks/requests/index_en.htm

SCIENTIFIC COMMITTEE ON EMERGING AND NEWLY IDENTIFIED HEALTH RISKS (SCENIHR)

The following mandates are currently under evaluation:

Nanosilver: safety, health and environmental effects and role in antimicrobial resistance

Silver (Ag) nanomaterials ("nanosilver") are widely used today for their antibacterial activity. It can be expected that, with prices of medical applications of nanosilver decreasing, their use will increase. Nanosilver has also been used in consumer products such as sports textiles, other textiles, washing powder and deodorants.

Recent review papers suggest that nanosilver may not be hazardous to humans. However, data are insufficient to carry out a full risk assessment. In addition, indirect adverse effects on human health may occur via an increasing resistance of micro-organisms against silver. This may limit the usefulness of nanosilver in medical devices and other medical applications.

Therefore, the SCENIHR is asked to assess whether the use of nanosilver, in particular in medical care and in consumer products could result in additional risks compared to more traditional uses of silver. Furthermore, the SCENIHR is asked to assess whether the use of nanosilver to control bacterial growth could result in resistance of micro-organisms.

Potential health effects of exposure to electromagnetic fields (EMF)

Council Recommendation of 12 July 1999 on the limitation of exposure of the general public to electromagnetic fields (0 Hz to 300 GHz) fixes basic restrictions and reference levels for the exposure of the general public to electromagnetic fields (EMFs). These restrictions and reference levels are based on the guidelines published by the International Commission on Non Ionising Radiation Protection in 1998 (ICNIRP). In response to the Council Recommendation, all member states have implemented measures to limit the exposure of the public to EMF, either by implementing the provisions proposed by the Council Recommendation, or by implementing more stringent provisions.

The Council Recommendation also invites the Commission to "keep the matters covered by this recommendation under review, with a view to its revision and updating, taking into account possible effects, which are currently the object of research, including relevant aspects of precaution". The ICNIRP guidelines were endorsed by the Scientific Steering Committee (SSC) in 1998. Their scientific validity was further assessed by the Scientific Committee on Toxicity, Ecotoxicity and the Environment (CSTEE) in 2001, and by the SCENIHR in 2007 and 2009. These assessments confirmed the earlier conclusion of the CSTEE and highlighted the need for additional data and research.

Since September 2008, the cut-off date for the previous review by the SCENIHR, enough new scientific publications have appeared to warrant a new analysis of the scientific evidence on possible effects on human health of exposure to EMF. In addition, the development of new technologies using EMF in the THz range, especially imaging techniques such as security scanners for passenger screening, calls for new assessments.

Consequently, the SCENIHR is being asked to examine this new scientific evidence and to develop a set of prioritized research recommendations. The SCENIHR is asked to address in particular the potential adverse effects of EMF on the nervous system, the understanding of biophysical mechanisms that could explain observed biological effects and epidemiological associations, and the potential role of co-exposures with other environmental stressors in biological effects attributed to EMF. It is also asked to review the scientific evidence available to understand the potential adverse health effects of EMF in the THz range.

Health effects of nanomaterials used in Medical Devices

Today, a more widespread application of nanotechnologies and nanomaterials is imminent or already occurring in many areas, including health care. For nanomedicine, the three largest areas of application are diagnostics, drug delivery and regenerative medicine. In addition there are applications in surgery and thermotherapy.

In the field of medical devices, the quite a few cases of alleged use of nanomaterials have been identified, such as carbon nanotubes in bone cements, nanopaste hydroyapatite powder for bone void filling, polymer setting material with nanoparticles in dental cements, polycrystalline nanoceramics in dental restorative materials, nanosilver or other nanomaterials used as coatings on implants and catheters, etc.

Although the general risk assessment requirements applicable for materials used in medical devices and previous scientific opinions on risk assessment of nanomaterials (see e.g SCENIHR 2006, 2007 and 2009) are useful when assessing nanomaterials for medical applications, there is a need for further clarification in the risk assessment of such products.

The European Commission is currently preparing a proposal for a revision of the medical devices directives. This proposal might include provisions on the risk classification, the labelling and the instructions for use of medical devices containing nanomaterials. The risk classification influences the stringency of the applicable conformity assessment procedure.

Therefore, the SCENIHR is requested to provide a risk assessment of both invasive and non-invasive medical devices containing nanomaterials. In this assessment, where relevant, the SCENIHR is invited to differentiate between free, fixed, and encapsulated nanomaterials.

The safety of PIP silicone breast implants (follow-up)

Following the rapid scientific opinion adopted by SCENIHR on 1 February 2012 covering "The Safety of PIP Silicone Breast Implants", the Commission recognised that an update of this opinion would be necessary, mainly because the data available on PIP silicone breast implants at the time of the opinion was limited.

The update of the rapid opinion should be based on additional data to be produced by and collected from the Member States and other international fora, such as the International Laboratory Testing Panel for PIP breast implants. Efforts to produce this data are already ongoing.

In order to accomplish the collection of data on an as complete and broader possible scale, two types of activities are envisaged:

1. The development of an EU questionnaire on implanted patients, to be distributed at national level. The EU questionnaire will be developed based on available models from the Member States and will be used to collect data on implanted patients.

2. The collection of available and forthcoming scientific information on PIP silicone breast implants. If available, besides the data produced by the testing, additional literature data published in the meantime will be taken into account.

Therefore, the SCENIHR is asked to contribute to the creation of an EU questionnaire to collect data on implanted patients, to provide guidance on the testing undertaken by the member states, and to update its scientific opinion on the safety of the PIP silicone breast implants on the basis of the new data collected.

The safety of the use of Bisphenol A in medical devices

Bisphenol A (BPA) is an intermediate that is mainly used in combination with other chemicals to manufacture plastics and resins, especially in high performance transparent, rigid plastics used to make food containers. Residues of BPA are also present in epoxy resins used to make protective coatings and linings for food and beverage cans and vats. BPA can migrate in small amounts into food and beverages stored in materials containing the substance.

BPA is a weak oestrogen, as demonstrated by in vitro studies. Many in vivo studies have been performed to examine its potential effects on reproduction and development. The safety of BPA in food contact materials has already been evaluated by the US Food and Drug Administration and by the European Food Safety Authority. Although these evaluations did not identify outright reasons for concern, a number of uncertainties in the current scientific knowledge concerning the safe use of BPA remain.

Recently, safety concerns have been expressed for vulnerable groups such as infants, pregnant and breast-feeding women exposed to BPA through other products. Medical devices are a particular product category in which BPA is often found. Examples include implants, catheters, and most dental devices. Some BPA-containing medical devices may have direct and/or indirect contact with the patients (e.g. auto-transfusion apparatus, filters, bypasses, tubing, pumps, instruments, etc). These products are used on all types of patients.

Due to these uses, low level human exposure to BPA occurs, but the health significance of the exposure levels has been controversial.

Therefore, the SCENIHR is asked to assess exposure of patients to BPA from medical devices, to determine whether these levels of exposure could give reasons for concern from the health point of view and, if possible, to provide indications on limit values for BPA release from medical devices.

The SCENIHR is also asked to identify whether any particular medical devices containing BPA could result in human exposures which will give reasons for concern under their normal use and to identify whether any patient group may be particularly at risk in light of the answer to the above questions. Finally, in case reasons for concern are found, the SCENIHR is asked to propose possible alternative approaches that could reduce potential risks.

Mandates for SCENIHR are available at:
http://ec.europa.eu/health/scientific_committees/emerging/requests/index_en.htm

NEW AND ONGOING JOINT MANDATES FOR SCCS, SCHER AND SCENIHR

Working on Improvement of Risk Assessment

The ICCG established a joint Working Group including members designated by SCCS, SCHER and SCENIHR for 1) reviewing the current risk assessment (RA) practices, 2) exploring what risk managers and policy makers need from risk assessment 3) identifying approaches to risk assessment that can provide results which are based on the best available science and which are informative, consistent, transparent and easy to interpret and communicate. The motivation for this review has been the perception, from all parties, that risk assessments as currently carried out do not inform the risk management process as well as they should. The preliminary opinion has undergone public consultation and the final version will be adopted by all three committees by September 2012.

The mandate is available on the following webpage:
http://ec.europa.eu/health/scientific_committees/environmental_risks/docs/scher_q_090.pdf

Addressing the New Challenges for Risk Assessment

Risk assessment must be based on the best available scientific evidence. While the data base that supports risk assessments continues to expand and despite several challenges encountered, the general procedures have not changed significantly in the last two decades. Some challenges highlighted in earlier opinions by the Scientific Steering Committee (SSC) in 2000 and 2003 include access to data, exposure assessment and the explanation/ expression of findings. Furthermore, there are a number of anticipated changes concerning both the nature and the interpretation of data available for risk assessment in the near future.

Following discussions at the last Meeting of Chairs and Secretariats of EU bodies involved in Risk Assessment, the SCENIHR, SCCS and SCHER are requested to carry out a comprehensive review of risk assessment procedures and new challenges for Risk Assessment taking into account both fundamental and practical considerations (sampling, instrumentation, cost, analysis, etc.), and to provide a scientific opinion on the issue.

More information can be found at the following webpage:
http://ec.europa.eu/health/scientific_committees/docs/challenges_mandate_en.pdf

You may find all information about the work of the Committees, on the opinions and the mandates (requests) via the following webpage:
http://ec.europa.eu/health/scientific_committees/policy/index_en.htm

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