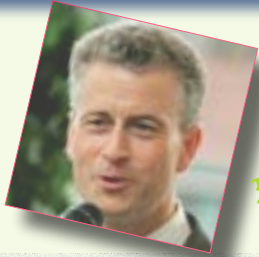




Newsletter of the European Commission Scientific Committees

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*Foreword by Robert Madelin
Director General DG SANCO*

The Health and Consumer Protection Directorate General (DG SANCO) aims at making Europe's citizens healthier, safer and more confident. In our daily work, we are constantly faced with complex scientific issues.

Our initiatives and measures would not be efficient without a sound scientific basis. Science is indeed at the heart of the process which leads to policies and measures for a high level of health, safety and environmental protection.

Three scientific committees SCCP (Scientific Committee on Consumer Products), SCHER (Scientific Committee on Health and Environmental Risks) and SCENIHR (Scientific Committee on Emerging and Newly Identified Health Risks) play a key role in advising DG SANCO and other Commission services on a wide range of health and environmental risks.

Moreover, risk assessment science plays an increasing role beyond the internal work of the Commission, across the EU, national bodies, and international institutions. There is thus a need to work towards a shared approach, to generate better recognition of the added value of scientific risk assessment as a basis for better quality and consistent risk management decisions. In this respect, the first step is to ensure the effective exchange of information within the risk assessment community, with risk managers as well as with stakeholders.

This Newsletter is intended to contribute to dialogue by disseminating news on the activities, results and planned work of SCCP, SCHER and SCENIHR, in a regular, and user friendly manner.

I hope this initiative will contribute to increased co-operation in this essential area.

Robert Madelin

About this Newsletter

This Newsletter is part of a new, more proactive communication policy of DG SANCO in the area of scientific advice. We wish to inform, but also stimulate dialogue and collaboration with scientists and stakeholders on the important themes studied by SCCP, SCHER and SCENIHR.

We intend to publish this Newsletter three times per year; in January, May and September. As you will discover in this Newsletter, the Committees deal with a wide range of scientific issues, of interest to the scientific community, decision makers, stakeholders and the public.

The Scientific Committees work on the basis of the principle of transparency and while much information is already available on our web site, DG SANCO wishes to enhance communication via-a-vis the scientific community, stakeholders and the public.

We are sending this first issue to a large number of organisations and individuals and we are gradually expanding our distribution list. The first two issues will be sent to you automatically. Subsequently, we will ask you to confirm whether you wish to continue to receive it. In case you wish to indicate other organisations or individuals who may have an interest in this Newsletter, please do not hesitate to inform us.

We intend to improve this Newsletter continuously; therefore, any comment and suggestion will be welcome.

We hope you find this Newsletter useful.

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The Scientific Committees

Introduction

Scientific advice plays a key role in the EU decision making process and for many years, EU Institutions have been advised on health, safety and environmental risks by independent scientists. The Commission is committed to base its proposals and its decision on the best available scientific knowledge.

The Committees also draw the Commission's attention to new or emerging problems which may represent an actual or potential threat.

Henceforth, a comprehensive scientific advice structure is in place, with several external agencies and three independent Scientific Committees (SCs), SCCP, SCHER and SCENIHR, advising on health safety and environmental risks in non-food related areas.

The three Scientific Committees are based on three principles:

Excellence, independence and transparency



The area of responsibilities are:

The Scientific Committee on Consumer Products (SCCP.) is systematically consulted on the safety of cosmetics under the Cosmetics Directive and other consumer products such as toys, sun beds etc).

The Scientific Committee on Health and Environmental Risks (SCHER) provides advice on risk assessment of chemicals, health and environment issues like effects of atmospheric pollution, indoor air quality on the health, etc.

The Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) covers broad multidisciplinary issues and examines new issues like potential risks electromagnetic fields, of nano-technology.

Finding Information about the SCs:

By surfing on:

http://ec.europa.eu/health/ph_risk/risk_en.htm



Under the section SCs:

- Consultation mandates (questions)
- Draft agenda of the Plenary meetings
- Minutes of the Plenary meetings
- Opinions adopted
- Rules of procedure
- Members

Under the section "Popularizing Risk Assessment Results"

Versions of selected scientific opinions of particular interest for policy makers, stakeholder and the public presented in a language accessible to non experts (layman language summary versions)

Under the section "News"

The newsletter of the European Commission Scientific Committees, published three times a year in January, May and September. Public consultations on certain opinions before their finalisation, as well as calls for submission of data
News about developments and events related to the work of the Committees as well as relevant risk assessment issues

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By registering to the Scientific Committees Alerts (free). The Alerts will be sent to inform you on new opinions published, new public consultations and mandates

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Recently Adopted Opinions

SCCP



Dr. Ian White, Chair

As you may know, in the Annexes to Council Directive 76/768/EEC on cosmetic products, you find the list of banned, restricted or allowed substances for use in cosmetic products. In order to include substances in the annexes, the SCCP has to be consulted. The Committee then carries out risk assessments based on safety data available in the public domain or provided by industry.

Hair Dyes

In 2001, a scientific report mentioning the possible link between permanent hair dyes and bladder cancer prompted the European Commission to carry out a systematic review of hair dye substances used in Europe in order to establish a positive list of these substances. In the context of the ongoing evaluation of safety dossiers submitted under this 'Hair Dye Strategy', the following opinions have recently been issued:

A18, 1,5-Naphthalenediol

The information submitted is insufficient to allow a final risk assessment. An adequate in vitro percutaneous absorption study should be performed. 1,5-naphthalenediol is a skin sensitiser.

A19, 2,7-Naphthalenediol

The information submitted is insufficient to allow a final risk assessment. An adequate in vitro percutaneous absorption study should be performed. 2,7-naphthalenediol is a moderate sensitizer.

A43, 3-amino-2,4-dichlorophenol hydrochloride

3-amino-2,4-dichlorophenol HCl as an oxidative hair dye at a maximum concentration of 1.5% in the finished cosmetic product does not pose a risk to the health of the consumer, apart from its sensitising potential.

B51, 4-Amino-3-nitrophenol

The information submitted is insufficient to allow a final risk assessment to be carried out. An adequate in vitro percutaneous absorption study and an additional mutagenicity / genotoxicity test to exclude its gene

mutation potential should be performed.

Preservatives & UV Filters

As for preservatives and UV filters to be used in cosmetic products, Annexes VI and VII of Cosmetics Directive 76/768/EC, respectively list substances that are allowed, as well as the concentration limits for a safe use. The following substances were recently evaluated for possible inclusion in these annexes.

P72, Alkyl (C16, C18, C22) trimethylammonium chloride

Since quaternary ammonium compounds are irritating, the following concentration limits should apply for rinse-off cosmetic products: the sum of the cetrimonium and steartrimonium chloride concentrations should not exceed 0.5%, and the total sum of behentrimonium, cetrimonium and/or steartrimonium chloride should not exceed a maximum level of 3%.

S12, Homosalate

The use of homosalate at a maximum concentration of 10% w/w in cosmetic sun screen products and other cosmetic products does not pose a risk to the health of the consumer.

Other Cosmetic ingredients

EGBE

A risk assessment of ethylene glycol monobutyl ether (EGBE) performed by a Member State led to the introduction of certain restrictions on the use of this substance. The SCCP was asked to re-evaluate the safe use of the substance within these concentration limits.

The SCCP came to the conclusion that the use of ethylene glycol monobutyl ether (EGBE) as a solvent at a concentration up to 4.0% in oxidative in hair dye formulations and up to 2.0% in non-oxidative in hair dye formulations does not pose a risk to the health of the consumer.

Phthalates in perfumes

Following a report of Greenpeace raising concern about the presence of phthalates in perfumes, the SCCP was asked to assess if this could present a possible risk for consumer health.

The SCCP concluded that in the view of the data provided that the concentrations of phthalates present in the perfume samples analysed do not pose a risk for the health of the consumer.



Recently Adopted Opinions

SCHER

Prof. Helmut Greim, Chair



The Committee has a very broad mandate. It deals with questions concerning the toxicity of chemicals, biochemical and biological compounds that may have harmful consequences for human health and the environment. In the context of the ongoing evaluation of the risk assessment (RA) reports submitted to the SCHER for peer review, the following opinions have recently been adopted:

Peer review of RA Reports on existing substances carried out under Regulation 793/93/EEC

Council Regulation 793/93 provides the framework for the evaluation and control of the risk of existing substances. Member States prepare Risk Assessment Reports on priority substances. The reports are then examined by the Technical Committee under the Regulation and, when appropriate, the Commission invites the SCHER to give its opinion.

RA report on Methenamine (Human health and environment; CAS 100-97-0)

The SCHER agrees with most of the conclusions proposed in the human health part of the report with some editorial changes recommended for consistency and language.

The SCHER agrees with the report conclusion that there is at present no need for further information and/or testing and for risk reduction measures beyond those which are being applied already and proposed for all environmental compartments. This despite some assumptions that are biased by a substantial lack of information on exposure data and cannot be endorsed by the SCHER.

RA report on Chlorodifluoromethane (Human health and environment; CAS 75-45-6)

For the human part, the SCHER agrees with the report conclusion that there is at present no need for further information and/or testing and for risk reduction measures beyond those which are being applied already for both occupational and consumer exposures.

For the environmental part, the SCHER would have preferred to see a conclusion for a need for further information and/or testing to improve the basis for the risk

characterization regarding the atmosphere and information on possible effects on plants.

RA report on Hexachlorocyclopentadiene (HCCP; Human health; CAS 77-47-0)

The SCHER agrees with the conclusion that there is a need for limiting the risks for some of the occupational exposure scenarios regarding repeated inhalation and dermal exposures and the same conclusion is supported regarding skin sensitization. Due to low MOS the SCHER is of the opinion that a potential for respiratory sensitization by HCCP should be considered in the report. Regarding consumer, due to absence of exposure, the SCHER accepts the conclusion that there is at present no need for further information and/or testing and for risk reduction measures beyond those which are being applied already.

Other opinions

Risk arising from the use of copper-based antifouling paints used in leisure boating

The SCHER has revisited the previous CSTEE opinion and the comments submitted by the Dutch Authorities, and concluded that the risk assessment performed by the Dutch government does not provide sufficient sound scientific evidence to show that the use of copper-based antifouling paints in leisure boats presents significant environmental risks.

RA on indoor air quality

On 30 January, the SCHER adopted a preliminary report on the risk assessment on indoor air to provide the Commission with a sound scientific basis for developing and implementing policies on indoor air. The report was published on the web for public consultation and contributions received will be discussed and possibly integrated into the final opinion that will be proposed for possible adoption on July.

In its preliminary report the committee identified a number of factors in the indoor environment that can affect well-being and health. These include chemicals in products intended for indoor use or unintentional emissions from different sources, particles, microbes, humidity, pets and pests. The SCHER also identified data requirements and gaps in knowledge on human exposure to pollutants, health effects and the impact of indoor air quality on vulnerable groups of the population.

The opinions of the SCHER are available at:
http://ec.europa.eu/health/ph_risk/committees/04_scher/scher_opinions_en.htm



Recently Adopted Opinions

SCENIHR

Prof. James Bridges, Chair



This Committee deals with questions related to emerging or newly identified risks related to e.g. interaction of risk factors, synergic effects, cumulative effects, antimicrobial resistance, new technologies such as nanotechnologies; medical devices including those incorporating substances of animal and/or human origin, tissue engineering, blood products, fertility reduction, cancer of endocrine organs; physical hazards such as noise and electromagnetic fields (from mobile phones,

transmitters and electronically controlled home environments), and methodologies for assessing new risks (including interaction of risk factors, synergic and cumulative effects).

In particular, the SCENIHR issues opinions on scientific and technical questions relating to Community legislation on medical materials and equipment, which were previously dealt with by the former Scientific Committee on Medicinal Products and Medical Devices (SCMPMD).

Possible effects of Electromagnetic Fields (EMF) on Human Health

The opinion of the SCENIHR updates a previous scientific opinion of the Scientific Committee on Toxicity, Ecotoxicity and the Environment (CSTEE) from 2001. The opinion concludes that no health effects have been consistently demonstrated for radio frequency fields (e.g. for mobile phones) below the limits set in Community legislation, although the data available is limited. For intermediate frequency fields (e.g. for video display units), the data is sparse and proper evaluation of possible long term effects is important. For extremely low frequency (ELF) fields (e.g. household appliances or nearby power lines), the opinion confirms the earlier conclusion of CSTEE that ELF magnetic fields are possibly carcinogenic, mostly based on occurrence of childhood leukaemia. The existing data for static fields (e.g. in hospital applications) is inadequate. In view of the knowledge gaps identified in the opinion for all frequency fields, the SCENIHR proposes further and appropriate research to be conducted.

Details: http://ec.europa.eu/health/ph_risk/committees/04_scenihhr/docs/scenihhr_o_007.pdf

Potential risks of nanomaterials

Nanomaterials in the EU Technical Guidance Documents (TGD) of chemicals legislation (The appropriateness of the risk assessment methodology in accordance with the Technical Guidance Documents for new and existing substances for assessing the risks of nanomaterials)

The SCENIHR opinion, approved for public consultation on 29 March 2007, concludes - in a manner reminiscent of the earlier SCENIHR opinion of March 2006 - that the current methodologies are generally likely to be able to identify the hazards associated with the use of nanoparticles. However, modifications for the existing guidance would be necessary and the risk assessment of nanoparticles should be carried out on a case by case basis. The SCENIHR identifies issues requiring improvements in the technical guidance and methodologies and proposes a staged strategy for the risk assessment of nanomaterials. More info: http://ec.europa.eu/health/ph_risk/committees/04_scenihhr/docs/scenihhr_o_004.pdf



Ongoing Work

SCCP

has been asked to assess the health risks of the following substances when used in cosmetic products:

Hair Dyes

74 substances used as hair dyes. This work is in the framework of the Commission's Assessment Strategy for hair dye safety.

Preservatives

P56 (CMI/MI)

P95 ethyl lauroyl arginate

Other substances

beta-Arbutin

Choline chloride

Cyclomethicone

Melatonin

Kojic acid

Vitamin k1

The SCCP has been asked to express its views on:

- Consumer self test of sensitivity to hair dyes*
- Update of the inventory of perfume and aromatic raw materials*
- Nitrosamines in children balloons*

SCHER

has been asked to evaluate the impact of the following:

RA reports on existing substances under Regulation 793/93

2-nitrotoluene (CAS 88-77-2; Human health)

2,3-epoxypropyltrimethylammonium chloride (EPTAC ;CAS 3033-77-0; Human health & environment)

3-chloro-2-hydroxypropyl)trimethylammonium chloride (CHPTAC; CAS 3327-22-8; Human health and environment)

4-tert-butyl phenol (CAS 98-54-4; Environment)

Zinc and its compounds (Environment)

The environmental risks and indirect health effects of mercury in dental amalgam

The opinion should take into consideration all possible mercury emissions resulting from the use of dental amalgam during the products whole life cycle (e.g. dental clinics, sewage disposal systems, crematoria). The committee is also asked to compare the use of mercury in dental amalgam with other available alternatives. To ensure that the SCHER elaborates its opinion on the basis of the most up to date scientific information, the Commission has published a call for scientific information. Details: http://ec.europa.eu/health/ph_risk/committees/04_scher/scher_call_info_01_en.htm

Model implementation and quantification of the Eutrophication Risk associated to the use of phosphates in detergents.

Following a CSTE opinion of 2003 on the environmental impact resulting from banning sodium tri-polyphosphates (STPP) in household detergents, the SCHER was asked for an opinion on a European quantitative eutrophication risk assessment of polyphosphates in detergents.

Non surfactant Organic Ingredients and Zeolite-based Detergents

Following the same above-mentioned opinion and the general concerns over the potential impact on the environment associated with organic compounds added to detergents, the SCHER was asked for an opinion on a project concerning health and environmental risks of various types of zeolites.

Organic chemicals in toys

The SCHER was asked for an opinion on a European Committee for Standardisation (CEN) report on the RA of organic chemicals in toys. The request deals with the previous CSTE opinion as regards the inconsistencies and errors in the report from CEN on risk assessment and the setting of standards on organic chemicals in toys.

More info: http://ec.europa.eu/health/ph_risk/committees/04_scher/scher_questions_en.htm

SCENIHR

Health Effects of Smokeless Tobacco Products

The prohibition on the marketing of tobacco for oral use (moist snuff, oral tobacco) on the basis of tobacco directives 92/41/EEC and 2001/37/EC intends to prevent people from starting to use a new tobacco product. Given recent developments with regard to the composition of some smokeless tobacco products and the claims that the use of smokeless tobacco as substitute for smoking could reduce harm generated by other tobacco products, the SCENIHR is requested to examine the health effects and the addiction potential of smokeless tobacco products by June 2007.

http://ec.europa.eu/health/ph_risk/committees/04_scenihhr/docs/scenihhr_q_004.pdf

The safety of medical devices containing DEHP-plasticized PVC or other plasticizers on neonates and other groups possibly at risk

Plastic materials are widely used in medical devices. Council Directive 93/42/EEC regulates their quality requirements. Di-(2-EthylHexyl) Phthalate (DEHP) is the most frequently used plasticizer in PVC-based medical devices, but due to its reproduction toxicity, neonates and prepubertal males may suffer adverse effects from DEHP exposure in medical devices. The SCENIHR is requested to review and update the opinion adopted in 2002 by the Scientific Committee on Medicinal Products and Medical Devices (SCMPMD), to assess the safety of alternatives to DEHP in PVC-based medical devices and to establish Tolerable Intake Values of DEHP leaching from soft PVC as a basis for risk assessment for high risk patient groups, taking into account the route of exposure.

http://ec.europa.eu/health/ph_risk/committees/04_scenihhr/docs/scenihhr_q_007.pdf



The safety of dental amalgam and alternative dental restoration materials for patients and users

Dental amalgam and its substitutes are regulated under Council Directive 93/42/EEC on medical devices and must comply with the health and safety of patients. The use of alternative materials is increasing but relatively little is known about their safety. Pursuant to Action 6 of the Community Strategy Concerning Mercury aiming at the reduction of mercury in the environment and human exposure, the use of dental amalgam should be evaluated to assess whether additional regulatory measures are appropriate. In view of the above, the SCENIHR is requested to evaluate the health effects and safety of dental amalgam and its alternatives possibly by the end of 2007.

More info: http://ec.europa.eu/health/ph_risk/committees/04_scenihr/docs/scenihr_q_009.pdf

New Mandates

SCCP

In the coming months, the SCCP will be working on the following issues:

- Oakmoss/Treemoss
- Fragrance ingredients pre-evaluated using the QRA approach
- Tea tree oil
- Hydrogen peroxide in oral hygiene products

The specific questions on ongoing and future work of the SCCP can be found on http://europa.eu.int/comm/health/ph_risk/committees/04_sccp/sccp_questions_en.htm

SCHER

The SCHER will soon be starting working on the following risk assessment reports on existing substances (Regulation EC/793/93):

- 2-nitrotoluene- (human health)
- 4-tert-butyl phenol- (environment)
- 2,3-epoxypropyltrimethylammonium chloride (EPTAC - environment & human health)
- 3-chloro-2-hydroxypropyl)trimethylammonium chloride (CHPTAC - (environment & human health)

The specific questions on future work of the SCHER can be found on: http://ec.europa.eu/health/ph_risk/committees/04_scher/04_scher_en.htm

SCENIHR

In the coming months, the SCENIHR will be working on the following issues:

Assessment of the Antibiotic Resistance Effects of Biocides.
Potential health risks of exposure to noise from personal music players and mobile phones including a music playing function.

Appropriateness of the existing risk assessment methods for key nanomaterials and/or products of nanotechnologies

The scientific aspects of the existing and proposed definitions relating to products of nanoscience and nanotechnologies. The communication between different disciplines of nanotechnologies and between various actors and citizens call for clear and scientifically coherent terminologies, reflecting also the risk assessment needs. In order to assure this, the SCENIHR is requested to provide a scientific review on definitions and base concepts in the area of nanotechnologies. More info: http://ec.europa.eu/health/ph_risk/committees/04_scenihr/docs/scenihr_q_010.pdf



SCCP

Call for information on Tooth whitening products

To ensure a conclusive assessment of the possible health risks associated with the use of hydrogen peroxide in oral hygiene products, a call for the submission of safety information available since 15 March 2005, when the SCCP had issued its last opinion on hydrogen peroxide in oral hygiene products, has been recently issued. The call has been open for four weeks until the 25 May 2007.

More details: http://ec.europa.eu/health/ph_risk/call_en.htm

SCHER

Call for Information on environmental risks and indirect health effects of mercury in dental amalgam

Interested parties are invited to submit: scientific peer reviewed research papers and reviews (later than 1990), scientific data on safety evaluation of dental amalgams and alternatives, other publicly available credible scientific information that may not be easily available and which is directly relevant to this issue and information on trends in the clinical usage of dental amalgam and alternatives.

More details: http://ec.europa.eu/health/ph_risk/committees/04_scher/scher_call_info_01_en.htm

SCENIHR

Public Consultation on nanomaterials in the EU Technical Guidance Documents (TGD) of chemicals legislation (The appropriateness of the risk assessment methodology in accordance with the Technical Guidance Documents for new and existing substances for assessing the risks of nanomaterials)

The SCENIHR opinion, approved for public consultation on 29 March 2007, concludes - in a manner reminiscent of the earlier SCENIHR opinion of March 2006 - that the current methodologies are generally likely to be able to identify the hazards associated with the use of nanoparticles. However, modifications for the existing guidance would be necessary and the risk assessment of nanoparticles should be carried out on a case by case basis. The SCENIHR identifies issues requiring improvements in the technical guidance and methodologies and proposes a staged strategy for the risk assessment of nanomaterials. (Deadline 23 May 2007)

More details: http://ec.europa.eu/health/ph_risk/committees/04_scenihr/scenihr_cons_04_en.htm

Call for information : Health Risks has received a request for a scientific opinion on the safety of dental amalgam and alternative dental restoration materials for patients and users.

The safety of dental amalgam and available alternatives will be considered. Interested parties are invited to submit the following information: 1) scientific peer reviewed research papers and reviews on this issue (published in or after 1998), 2) scientific data on safety evaluation of dental amalgams and alternatives (including ancillary equipment), 3) other publicly available scientific information that may not be easily accessible and which is directly relevant to this issue, 4) information on trends in the clinical usage of dental amalgam and alternatives.

More details: http://ec.europa.eu/health/ph_risk/committees/04_scenihr/scenihr_call_info_03_en.htm



News - News - News

Risk Assessment Days Conference, Brussels, 21-22 March 2007

The Directorate General Health and Consumer protection has organised in Brussels for the first time two Risk Assessment Days on 21 and 22 March 2007. The objective was to present the Scientific Committees SCCP, SCHER and SCENIHR, their activities and their results to the major stakeholders, and to launch a more sustained and structured dialogue with them.

The Programme for the Risk Assessment Days included, in particular, an information session for Members and Staff of the European Parliament, a joint meeting of the three Committees and a Stakeholder Dialogue Session.

The programmes for the three sessions are available on http://ec.europa.eu/health/ph_risk/risk_days_en.htm, together with the slides presented at each session and the list of participants of the stakeholder dialogue session. A report on the event including the planned follow-up initiatives planned will be soon available and published on the site.

Nanotechnology Conference, Brussels, Autumn 2007 - Pre-announcement

DG SANCO is planning a Dialogue Workshop on "Nanotechnologies for Food, Consumer Products, and Medical Applications: Safety for Success", in Brussels, in October 2007. The expected outcomes of the meeting include establishing a stakeholder dialogue and monitoring forum, mapping stakeholders' interests and concerns, and drawing a road map to address these interests and concerns.



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