



- on consumer products
- on emerging and newly identified health risks
- on health and environmental risks

Newsletter of the European Commission Scientific Committees

ISSN N° 1830-6993 September 2008 • Catalogue nr: ND-AG-08-001-EN-N

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News

ESTABLISHMENT OF A REVISED RISK ASSESSMENT ADVISORY STRUCTURE

The new structure will be composed of three Scientific Committees

1. the SC on Consumer Safety - SCCS
2. the SC on Health and Environmental Risks - SCHER
3. the SC on Emerging and Newly Identified Health Risk - SCENIHR

In addition, there will be a Pool of Scientific Advisors. Finally, the Commission will establish a permanent data base of experts in relevant areas.

Each Committee is composed of a maximum of 17 members, appointed by the Commission following an open call for expressions of interest.

Each Committee can co-opt up to five additional, "associated" members from the Pool, at its own initiative, to contribute on specific issues or disciplines.

Advisors of the Pool will be appointed by the Commission following an open call for expressions of interest. The Commission will decide the appropriate number of advisors in light of the needs for expertise.

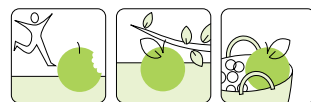
The Scientific Committees will **adopt opinions** on request from the Commission. For the adoption of such opinions, the associated members will have the same rights and responsibilities of the members appointed by the Commission. Mandates for opinions may cover specific risk issues or areas, and/or **needs and priorities for research**. The Commission may request rapid advice on the state of



knowledge concerning specific risks in case of urgent needs. Advisors from the Pool may be invited to contribute to such rapid advice.

At their own initiative, the Committees can adopt and address to the Commission **Memoranda** or **Position Papers** in order to draw the Commission's attention to a specific or emerging problem that they consider may pose an actual or potential risk.

In addition to the current practices, in particular the establishment of working groups, the Committees, at the request of the Commission or at their own initiative in agreement with the Commission, may set up **thematic workshops** which will produce reports, position papers or conclusions.



The Scientific Committees

The participants may include members of the committees, advisors and external experts.

The Commission may invite the Committees to be part of **scientific networks** with other Community bodies or scientific organisations. The Commission may invite the Committees to proceed to **hearing and consultations** as part of the process of preparing an opinion.

An Inter-Committee Co-ordination Group is formally established. In addition to the co-ordination of the work of the committees, it will also be in charge of matters related to **harmonisation of risk** assessment.

The Commission may request the Scientific Committees to adopt **joint opinions**.

The scope of co-ordination and collaboration is extended to national and international bodies in addition to EU bodies. The Scientific Committees are requested to play a pro-active role not just in preventing or resolving divergence, but in establishing and maintaining collaboration with the relevant bodies on the most important issues.

The Commission may take the initiative to request and organise joint work with other bodies. It may also request joint opinions with other EU bodies, upon agreement with such bodies.

Current rules on independence and transparency are confirmed and reinforced. Details will be set out in the new rules of procedure.

THE MAIN OBJECTIVES AND RATIONALE OF THE REVISION ARE:

- To ensure continuity with the current structure and build upon current experience and practice
- To remove direct overlapping with other Agencies, but maintain broad and flexible mandates
- To ensure easy access to a broader range of expertise by establishing a Pool and a data base

- To enhance transparency in the selection process and in the working practices
- To facilitate involvement of scientists with different constraints through a more modular structure
- To increase the scope for initiative of the Committees
- To ensure better recognition of scientists
- To extend the range of practices and ensure more flexibility
- To promote better integration and collaboration with other bodies

Please see also the e-news published at the occasion of the publication of the new Decision at the following address:
http://ec.europa.eu/dgs/health_consumer/dyna/enews/enews.cfm?al_id=770

History: On 5 August 2008, the Commission adopted a Decision (2008/721/EC) establishing a renewed advisory structure in the area of consumer safety, public health and the environment. This structure, which includes three Committees and a Pool of advisors, will replace the current Scientific Committees (on consumer products, on health and environmental risks and on emerging and newly identified health risks).

Relying on independent scientific advice is a long standing practice for the Commission. The organisation of scientific advice on consumer, public health and environmental risks has been gradually developed and has undergone several revisions. Two most important ones have taken place in 1997, in the aftermath of the BSE crisis, and in 2004 with the establishment of EFSA.

Since 2004, three Scientific Committees advise the Commission on consumer, public health and environmental risks in the non-food area.

To consult the Decision (2008/721/EC) please see:
<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:241:0021:0030:EN:PDF>

INVITATION TO APPLY FOR MEMBERSHIP IN THE EU SCIENTIFIC RISK ASSESSMENT ADVISORY STRUCTURE

Would you be interested to become a member of one of our Scientific Committees?

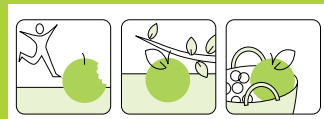
The Commission is now inviting scientists to apply for membership in this advisory structure through the so called 'call for expression of interest'. Scientists who advise the Commission may influence the lives of millions by having their advice taken up in the drafting of new laws and regulations. The Advisory Structure is a place where cutting-edge science meets political and legislative power and serves directly the whole of our society.

Depending on their interests and availability for work, interested scientists may apply for membership in one or more of the following:

1. Scientific Committee on Consumer Safety (SCCS)
2. Scientific Committee on Health and Environmental Risks (SCHER)
3. Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR)
4. Pool of Scientific Advisors
5. Database of Experts



On the 5th of September 2008 the European Commission adopted Decision 2008/721/EC (<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:241:0021:0030:EN:PDF>) establishing the new EU Scientific Risk Assessment Advisory Structure on matters related to consumer safety, public health, and the environment.



The Scientific Committees

More information on the call of expressions of interest and on the application procedure is available at: http://ec.europa.eu/health/ph_risk/committees/call_expression_en.htm

Applications will be accepted starting on the 28th of September 2008, or soon thereafter. The closing date will be 31 October 2008.

LAUNCHING A TRANSATLANTIC RISK ASSESSMENT DIALOGUE

Representatives of the Commission, the Commission Scientific Committees and other EU risk assessment bodies attended a meeting in Washington on 10-11 July 2008, aimed to launch a structured Transatlantic Dialogue on Risk Assessment.

The meeting was convened in Washington by the Executive Office of the US President, Office of Management and Budget (OMB) and the Office of Science and Technology Policy (OSTP) on 10-11 July 2008. It was attended by over 60 participants (list attached) from the US, EU and Canada. Attendance included representatives of the US OMB and OSTP, of the European Commission, of the Canada Treasury Board, as well as experts from various US departments, from EU Scientific Committees and Panels and from Canadians Departments and Bodies.

The overall goal of the meeting was to launch the transatlantic risk assessment dialogue by a first discussion between representatives of relevant departments and bodies and scientific experts on the role and organisation of risk analysis in the US, EU and CA regulatory systems, some methodological risk assessment issues and certain key aspects and challenges for risk assessment. The meeting was also intended to prepare for the First International Risk Assessment Conference planned for 13-14 November 2008 in Brussels, where the subjects discussed at this meeting will be further developed in a broader international context.

It was noted that cooperation aimed at promoting convergence on risk assessment principles and methods is important both in order to reduce the risk of unnecessarily divergent measures and to deal with important risk issues of common interest, particularly emerging risks, in the most effective and efficient way. In that respect, exchanging information and expertise and pooling knowledge and resources for joint or coordinated work, where appropriate and possible, would be beneficial to all parties. Finally, a



structured US-EU-CA dialogue would facilitate a coordinated input into the broader international dialogue to be launched at the November Conference.

It was observed that the dialogue should be established as a lasting process, developing gradually, covering risk assessment principles and methods in general, but also specific case studies and organising collaboration for risk assessment on key/new issues (for example nanotechnology)

Several subjects were discussed including: Governmental Structures and Impacts on Risk Analysis, Risk Assessment Terminology, Risk Assessment Methodologies: Modelling Dose-Response, Exposure Assessment, Future Challenges in Risk Assessment, Challenges between Risk Assessment and Risk Management.

Overall, it emerged from the discussion that many aspects of the subjects on the agenda of this meeting were of common interest. Further progress is expected at the November Risk Assessment Conference in Brussels on that occasion.

To be continued.....

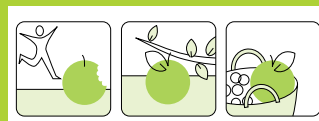
RISK ASSESSMENT DAYS - FOR A CONTINUED DIALOGUE BETWEEN THE THREE SCIENTIFIC COMMITTEES

Given the success of last year's edition, the Directorate-General for Health and Consumers organised two 'Risk Assessment Days' on 24 and 25 June in Brussels to continue the dialogue initiated last year between the three Scientific Committees advising the Commission on risk assessment in the field of consumer products, public health and the environment (SCCP, SCHER and SCENIHR) and institutional, civil society and industry stakeholders. This regular event is a forum to exchange views on the ongoing activities of the Scientific Committees (programme, work) and on the functioning and developments of the EU risk assessment advice structure.

This Year's event included a presentation to the EP-ENVI Committee, a joint meeting of the three Scientific Committees and a meeting with stakeholders.

During this last meeting the experience with the application of the procedure for facilitating dialogue between the Scientific Committees and the interested stakeholders was reviewed. The interest for continuing and further developing this dialogue was confirmed.

More information (presentations from the stakeholders dialogue session, list of participants) is available at: http://ec.europa.eu/health/ph_risk/ev_20080624_en.htm



The Scientific Committees

INTERNATIONAL RISK ASSESSMENT CONFERENCE, BRUSSELS, 13-14 NOVEMBER 2008

The Conference is intended to be the first of regular, international and bi-annual conferences on risk assessment. It is aimed at facilitating a global dialogue amongst risk assessment bodies and agencies in the EU and globally on both methodological and specific risk assessment issues, as well as on risk assessment policy matters. Focus will be put on improved understanding of the various systems and approaches, which would contribute to closer collaboration in view of a more consistent approach, should significant differences emerge. The intention is to set the basis for international sustained dialogue and collaboration between the risk assessors themselves.

Are you interested to participate? You may find the draft programme and organisational aspects for this two-day conference at the following internet site:

<http://www.global-risk-assessment-dialogue.eu>



Recently Adopted Opinions

SCCP SCIENTIFIC COMMITTEE ON CONSUMER PRODUCTS



The Annexes to Council Directive 76/768/EEC on cosmetic products list banned, restricted or allowed substances for use in cosmetic products. For updates of these annexes, the Scientific Committee on Consumer Products (SCCP) has to be consulted to carry out risk assessments based on safety data available in the public domain or provided by industry.

Hair dyes

2-Amino-4-hydroxyethylaminoanisole sulfate
Opinion SCCP/0958/05 of 28 March 2006, requesting a suitable skin penetration study, remains unchanged, since the provided study was considered inadequate.

Acid Red 52

The use of Acid Red 52 as an ingredient in oxidative (max. concentration 1.5% on-head) or non-oxidative hair dye formulations (max. concentration 0.6% on-head), does not pose a risk to the health of the consumer.

Parabens

Parabens are important cosmetic preservatives and they have wide use in multiple product types. Due to contradictory reproductive toxicity studies available the safety assessment of Propyl and Butyl Paraben cannot be finalized yet. The SCCP discussed a proposal made by industry for further skin penetration/metabolism and pharmacokinetics studies, but recommended to include



toxicokinetic studies in human volunteers after dermal application of Propyl and Butyl Paraben to test for significant systemic exposure, in which case a rodent generation toxicity study would be needed.

Diethylene glycol



The SCCP concluded that diethylene glycol (DEG) should not be used as an ingredient in cosmetic products including oral care products, due to its toxicity that has led to human deaths after oral intake and dermal exposure. Reliable data on non-lethal repeated dose toxicity and dermal absorption, which would allow assessment of the safety of use in cosmetic products, is not available.

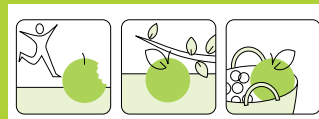
However, a maximum concentration of up to 0.1% DEG from impurities in ingredients like glycerine and polyethylene glycols in the finished cosmetic products can be considered to be safe.

Vitamin K1

The studies provided on the allergenic potential of Vitamin K1 did not supersede the concerns stated in its previous opinion (SCCP/1105/07). The SCCP maintains the view that use of Vitamin K1 in cosmetic products is not safe, since it may cause cutaneous allergy and individuals so affected may be denied an important therapeutic agent.

Quantitative Risk Assessment – Skin sensitisation

The SCCP assessed an industry-developed approach to establish concentration limits of fragrance ingredients according to the risk that these substances induce skin sensitisation.



Recently Adopted Opinions

The SCCP criticised that this approach is based primarily on data from experimental sensitization tests in humans e.g. Human Repeated Insult Patch Tests (HRIPT) and that epidemiological and experimental data, providing information on sensitization/elicitation reactions in consumers by fragrance ingredients are not integrated. Moreover, the application of the dermal sensitization QRA approach would in some cases allow increased exposures to allergens already known to cause allergic contact dermatitis in consumers. The model has not been validated and no strategy of validation has been suggested. Therefore, there is no

confidence that the levels of skin sensitizers identified by the dermal sensitization QRA are safe for the consumer. However, the dermal sensitization QRA approach may, after refinement and validation, in the future be applicable for risk assessment of new substances to suggest a safe level of exposure prior to incorporation into products. In such cases an independent post-marketing surveillance system would be essential.

The adopted opinions are available on the following website:
http://ec.europa.eu/health/ph_risk/committees/04_sccp/sccp_opinions_en.htm

SCHER SCIENTIFIC COMMITTEE ON HEALTH AND ENVIRONMENTAL RISKS

Regulation 793/93 – Existing substances

Propan-1-ol: the SCHER agrees with the risk assessment report (RAR) that there is a need for limiting the risks for consumer and several occupational exposures.

Aluminium fluoride: the SCHER considers that there is not valid justification in the RAR for limiting the RA to the atmospheric compartment. SCHER cannot verify the exposure calculation of the RAR since not all the relevant information was available to the committee. The SCHER agrees that there is no need for further information and/or testing for the atmospheric compartment.

Calcium fluoride: the SCHER is of the opinion that the targeted nature of this risk assessment should be clearly reflected in the title and/or clearly stated in the Introduction and Conclusion section of this report. The SCHER agrees with the RAR that there is no need for further information and/or testing for most scenarios.

p-tert-butylphenol: the SCHER agrees with the RAR that at this stage, there is no need for further information and/or testing for consumers. The SCHER also agrees with the conclusion that is a need for limiting the risks for some occupational scenarios following dermal exposure and for

dermal and inhalation exposure in end users.

Nitrobenzene: the SCHER agrees that there is no need for further information and/or testing regarding reproductive and developmental toxicity due to large margin of safety values. It agrees that there is a need for further information and/or testing on skin sensitisation. SCHER also agrees there is a need for limiting the risk regarding carcinogenicity for dermal and inhalation exposures.

Other opinions recently adopted by SCHER on Regulation 793/93:

Copper, Copper II sulphate pentahydrate, Copper(I) oxide, Copper(II)oxide, Dicopper chloride trihydroxide; hexabromocyclododecane, 6-acetyl-1,1,2,4,4,7-hexamethyltertraline; 1,3,4,6,7,8-hexahydro-4,6,6,7,8,8-Hexamethylcyclopenta-γ-2-benzopyran; 4-tert-Butylbenzoic; styrene; Chlorine; 4-methyl-m-phenylenediamine.

The adopted opinions are available on the following website:
http://ec.europa.eu/health/ph_risk/committees/04_scher/scher_opinions_en.htm

SCENIHR

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

The SCENIHR Committee concluded that dental amalgams are an effective restorative material and may be considered the material of choice for some restorations. While some local adverse effects are seen, the incidence is low and usually readily managed. There is no clinical justification for removing clinically satisfactory amalgam restorations, except in patients allergic to amalgam constituents.

The adopted opinion is available on the following website:
http://ec.europa.eu/health/ph_risk/committees/04_scenihhr/scenihhr_opinions_en.htm

The opinion is also available in a summary document, which is easy to read and provides the general public with information in order to make informed choices on their health regarding this issue:

http://ec.europa.eu/health/ph_risk/popularizing/popularizing_results_en.htm

<http://ec.europa.eu/health/opinions/en/dental-amalgam/index.htm>

The following two opinions have been adopted at the last SCENIHR Plenary session of 23 September 2008:



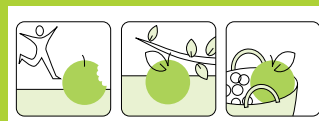
- Light sensitivity



- Potential health risks of exposure to noise from personal music players and mobile phones including a music playing function

Both opinions will be published upon completion of final editing and related press material and will be available on the SCENIHR-website:

http://ec.europa.eu/health/ph_risk/committees/04_scenihhr/scenihhr_opinions_en.htm



Ongoing Work

SCCP

SCIENTIFIC COMMITTEE ON COSMETIC PRODUCTS

Hair dyes

Evaluation of ca 45 remaining substances used in hair dyes in the framework of the European Commission's assessment strategy for hair dye safety

Other cosmetic ingredients:

Tea tree oil, Kojic acid

Preservatives

Chloro-methylisothiazolinone/methylisothiazolinone, Cyclometicone, Triclosan, Climbazole.

UV-filters

Benzophenone-3, Camphor benzalkonium methosulfate.

Joint SCCP/SCHER/SCENIHR Working group on the use of the Threshold of Toxicological Concern (TTC) approach for the health risk assessment of chemicals

SCHER

THE SCIENTIFIC COMMITTEE ON HEALTH AND ENVIRONMENTAL RISKS

Regulation 793/93 – Existing substances

- Voluntary RAR on lead and lead compounds – HH and ENV
- Voluntary RAR on copper and copper compounds - ENV
- RAR on nickel and nickel compounds – ENV
- RAR on vinyl acetate – HH

MANDATE:

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



Phthalates in school supplies

The Commission has asked the SCHER to assess the overall scientific quality of the EPA report on the content of phthalates in school supplies such as school bags, play bags, pencil cases and erasers. It was also asked to assess whether the six phthalates covered by Directive 2005/84/EC may present a risk when used in school supplies and whether there may be a cumulative exposure to these six

phthalates from other sources. The mandate is available at: http://ec.europa.eu/health/ph_risk/committees/04_scher/docs/scher_q_064.pdf

Genotoxicity - RA methodologies approaches

Based on the publicly available information, the SCHER/SCCP/SCENIHR have been asked on the health risk assessment of mutagenic and carcinogenic substances. The request was updated following the results of a public consultation on the working mandate that was closed on 31 January 2008. The preliminary report will be possibly finalized and published for public consultation before the end of October 2008. The mandate is available at: http://ec.europa.eu/health/ph_risk/documents/mandate_Gentox.pdf

Use of non human primates in biomedical research

Directive 86/609/EEG on the protection of animals used for experimental and other scientific purposes provides for controls of the use of laboratory animals and sets minimum standards for housing and care as well as for the training of personnel handling animals and supervising the experiments.

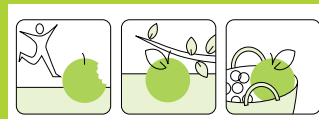
DG Environment is currently revising the Directive addressing, among others, specific problems relating to the use, care and acquisition of non-human primates. In order to participate in the co-decisions procedure and the related discussions at the European Parliament and the Council in a balanced manner, the Commission asked SCHER to give a scientific opinion on the latest status of the possibilities to replace the use of non-human primates. The request was published in the SCHER website as working mandate for comments until 6 June 2008 together with a call for information on the same issue. 140 comments and around 700 scientific articles have been received and forwarded to the committee for consideration. A public hearing will be possibly organized in November. The adoption of the opinion is foreseen by end of November 2008. The mandate is available at:

http://ec.europa.eu/health/ph_risk/committees/04_scher/docs/scher_q_073.pdf

Anaerobic biodegradation of surfactants and biodegradation of non surfactant organic ingredients

The Commission, in order to decide whether further legislative action would be justified concerning the anaerobic biodegradation of surfactants (as indicated in Article 16(2) of the Detergents Regulation), has asked SCHER an evaluation and a scientific opinion on anaerobic biodegradability. The SCHER was also provided with two reports: the HERA-2007 report on Linear Alkylbenzene Sulphonates-LAS and the HERA-2007 report on polycarboxylates in detergents. As requested by the Commission the opinion will be adopted by end of November 2008. The mandate is available at:

http://ec.europa.eu/health/ph_risk/committees/04_scher/docs/scher_q_072.pdf



Ongoing Work

SCENIHR SCIENTIFIC COMMITTEE ON EMERGING AND NEWLY IDENTIFIED HEALTH RISK

Antibiotic Resistance Effects of Biocides

The SCENIHR is requested to evaluate whether certain active substances in biocidal products used in various settings contribute to the occurrence of antibiotic resistant bacteria, both in humans and in the environment. In light of recent scientific evidence, clarification is sought as to whether cross resistance to antibiotics should be an additional criterion to consider in the common principles for the evaluation of dossiers for biocidal products as laid out in Annex VI of the Directive (98/8/EC) of the European Parliament and of the Council on the placing of biocidal products on the market.

More info:

http://ec.europa.eu/health/ph_risk/committees/04_scenihr/docs/scenihr_q_012.pdf



Risk Assessment of Products of Nanotechnologies

The SCENIHR is requested to identify and assess new information and update its opinions on potential risks of products of nanotechnologies, in particular, with respect to characterisation, eco-toxicology and toxicology as well as exposure assessments.

More info:

http://ec.europa.eu/health/ph_risk/committees/04_scenihr/docs/scenihr_q_015.pdf

Health Effects of Exposure to Electro Magnetic Fields - EMF

The SCENIHR is requested to update its previous opinion of 21 March 2007 in the light of newly available information. In addition, the Committee should provide a methodological framework and corresponding guidelines to evaluate available scientific evidence in order to ensure the best possible quality for risk assessment.

More info:

http://ec.europa.eu/health/ph_risk/committees/04_scenihr/docs/scenihr_q_014.pdf

New Mandate

SCCP SCIENTIFIC COMMITTEE ON COSMETIC PRODUCTS

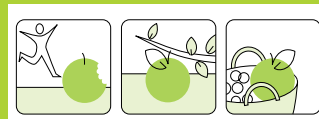
Hair Dyes

Evaluation of the safety of Hair dye reaction products (3rd step of the hair dye strategy)
The Commission agreed in April 2003 with Member States and stakeholders a strategy to regulate hair dye substances within the framework of the Cosmetics Directive. The main element of the strategy is a three step modulated approach requiring industry to submit, by certain deadlines, safety files on hair dye substances for a risk assessment by the Scientific Committee on Consumer Products (SCCP) according to safety requirements.
The overall objective of this assessment process is to establish a positive list of hair dye substances, which are considered safe for human health and allowed for use by the cosmetics industry.

In the previous steps of the strategy, precursors, couplers and developers used in oxidative hair dyes are evaluated separately. But in the reaction process during hair dyeing transient intermediates as well as reaction products are formed on the scalp to which the consumer is exposed. The 3rd step of the modulated hair dye strategy aims to evaluate the reaction products actually formed when dyeing the hair. The current submission provides data on such reaction products for evaluation by the SCCP.

All requests to the SCCP can be found on the following web page:

http://ec.europa.eu/health/ph_risk/committees/04_sccp/sccp_questions_en.htm



Public Consultation

SCHER

Genotoxicity - RA methodologies approaches

In the framework of the stakeholder dialogue procedure, a preliminary report will be published for public consultation possibly by end of October 2008.

Public Hearings

Use of non human primates in biomedical research

A public hearing to present a preliminary report on this issue will be possibly organized in November, before the opinion adoption. Date and agenda will be communicated on the SCHER website. Representative stakeholders will be invited in due time.



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