Scientific Committees
on consumer products
on emerging and newly identified health risks
on health and environmental risks

Newsletter of the European Commission Scientific Committees

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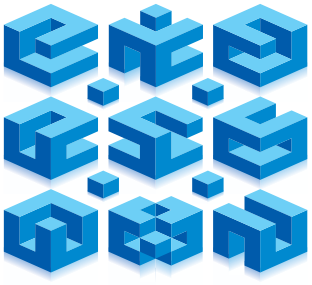
News

ESTABLISHMENT OF THE NEW RISK ASSESSMENT ADVISORY STRUCTURE

Since 2004, three Scientific Committees, i.e. SCCP, SCHER, and SCENIHR, provided the Commission with scientific advice in the non-food area on issues relating to consumer safety, public health and the environment. Their mandate came to an end in early 2009.



As from March 2009 three newly established Scientific Committees (SC) will take up their tasks[1,2].

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

In addition, there is a Pool of Scientific Advisors. Members of the Committees and of the Pool of Scientific Advisors have been appointed by the Commission following a recent open call for expressions of interest[3].

Each Committee is composed of 17 members and may associate, at their own initiative, up to 5 scientific advisors from the Pool to contribute to their work on specific issues. The associated members participate in the activities and deliberations on a given subject and have the same functions, responsibilities and rights as the members of the Committee. The Commission may also ask members of the Pool of Scientific Advisors to replace on a permanent basis members of the Scientific Committees who resign or whose membership is terminated. In addition, members of the Pool may be included in the activities of different working groups, in the provision of rapid advice requested by the Commission, or in thematic workshops/scientific meetings.

Finally, the Commission has established a database of external experts who will support the work of the Scientific Committees on an ad hoc basis, on specific issues, as members of working groups or on the occasion of hearings and workshops. Registration in the database[4] will remain permanently open.

1 Commission Decision (2008/721/EC) please see: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:241:0021:0030:EN:PDF and http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:244:0034:0034:EN:PDF

2 Commission Decision 2009/146/EC of 19/02/09 on the appointment of the members and advisors of the Scientific Committees and the Pool set up by Decision 2008/721/EC http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2009:049:0033:0042:EN:PDF

3 http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:C:2008:245:0023:0025:EN:PDF

4 http://ec.europa.eu/health/ph_risk/committees/call_expression_en.htm

News

REVIEWS OF EVENTS

2ND ANNUAL NANOTECHNOLOGY "SAFETY FOR SUCCESS" DIALOGUE WORKSHOP, BRUSSELS, 2- 3 OCTOBER 2008

This Workshop, organized by the Directorate General for Health and Consumers (DG SANCO) of the European Commission, brought together scientists, risk assessors, public authorities, industry, as well as consumer and environmental Non-Governmental Organizations (NGO). Participants examined and discussed the scientific state-of-the-art, regulation, international developments, risk governance, communication, and identified appropriate means to strengthen guidance in support of the safe, integrated, and responsible development of nanotechnologies.

You may read more on this workshop at the following website: *http://www.nano-safety-for-success.eu*

1ST INTERNATIONAL RISK ASSESSMENT CONFERENCE, BRUSSELS, 13-14 NOVEMBER 2008

About 300 participants (scientists, academics, representatives from member state, industry, NGOs and civil society from the European Union, the United States, Canada, China, Japan, Australia and the Russian Federation) attended the event. The Conference was intended to be the first in a series of regular (bi-annual), international conferences on risk assessment and followed the dialogue that was initiated in a tri-lateral (EU, USA, Canada) meeting of scientists in Washington on 10-11 July 2008.

The aims of the Conference were to facilitate a global dialogue amongst risk assessment bodies and agencies on both methodological and specific risk assessment issues as well as risk assessment policy matters. This included plenary lectures, break out sessions, and discussions focusing on Governmental Structures and Impacts on Risk Analysis, Risk Assessment Terminology and Methodologies: Modelling Dose-Response, Exposure Assessment, Future Challenges, and Challenges between Risk Assessment and Risk Management.

The overall aim was to improve understanding of the various systems and approaches in order to set the scene for an international sustained dialogue and collaboration between the risk assessors themselves.

Ms. Androulla Vassiliou, Commissioner for Health, and Mr. R. Madelin, Director General of DG SANCO, stressed the importance of a sustained, well structured international dialogue on risk assessment and pledged their continued support for the process. Similar messages were echoed in the remarks of the participants. The Conference lectures and break out sessions provided participants with the opportunity to discuss and identify areas where collaborative projects could be undertaken in the future so that results can be presented at the 2nd International Conference on Risk Assessment scheduled for the fall of 2010.

You may read more on this conference at the following website: *http://www.global-risk-assessment-dialogue.eu*

WORKSHOP ON ELECTROMAGNETIC FIELDS AND HEALTH: SCIENCE AND POLICY TO ADDRESS PUBLIC CONCERNS, BRUSSELS, 11-12 FEBRUARY 2009

This workshop touched upon an issue of great interest to the general public and was attended by more than 180 persons, representing the main stakeholders. Participants came from all over Europe, and also from the USA, Canada, Japan, and Israel.

The aim of this workshop was to generate conclusions that help orient the EU policy process regarding electromagnetic fields (EMF) by means of a broad and constructive dialogue among all stakeholders. It was divided into 4 sessions (The current EU regulatory framework; the latest assessments; comparing assessment approaches; positions from the stakeholders) and a final debate.

The workshop generated a debate between groups which argue that there is enough evidence to call for the application of the Precautionary Principle, and other, more formal scientific assessment bodies such as the SCENIHR, which conclude that there is no scientific basis for revising the current levels of precaution embedded in the EU regulatory framework.

The discussions showed the importance of transparency, trust, and informed policy making. As a result, expert bodies must adhere to strict criteria regarding transparency, conflicts of interest, and expertise in order to maximize the usability of their conclusions for policy making. A consensus was also found to call for more research on the potential health effects of EMF to close the remaining data gaps.

You may read more on this workshop at the following website: *http://ec.europa.eu/health/ph_risk/ev_20090211_en.htm*

The Scientific Committees

THE WORK OF THE CURRENT SCIENTIFIC COMMITTEES

The current three Scientific Committees have completed their work. All opinions are published on the respective websites of the Committees.

Link to the Committees: *http://ec.europa.eu/health/ph_risk/committees/committees_en.htm*

SCCP SCIENTIFIC COMMITTEE ON CONSUMER PRODUCTS

RECENTLY ADOPTED OPINIONS

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

Tetra-Aminopyridine sulfate (A53)
Does not pose a health risk for the consumer at the intended use concentrations
2,2'-Methylenebis-4-aminophenol HCl (A155) Cannot be considered safe at the intended use concentration
2-Methyl-1-naphthol (A156)
Does not pose a health risk for the consumer at the intended use concentrations
Acid Yellow 1 (B1)
Does not pose a health risk for the consumer at the intended use concentrations
Disperse Red 17 (B5)
Data not sufficient to assess safety, additional study requested
2-Nitro-5-glyceryl methylaniline (B60)
Data not sufficient to assess safety, additional study requested
3-amino-2,4-dichlorophenol HCl (A43)
Does not pose a health risk for the consumer at the intended use concentrations also when used in non-oxidative formulations
2-methylresorcinol (A44)
Does not pose a health risk for the consumer at the intended use concentrations also when used in non-oxidative formulations
4-amino-3-nitrophenol (B51)
Does not pose a health risk for the consumer at the intended use concentrations
2-hydroxyethyl picramic acid (B72)
Does not pose a health risk for the consumer at the intended use concentrations
HC Blue n° 12 (B73)
Does not pose a health risk for the consumer at the intended use concentrations

The hair dye opinions are available at:
http://ec.europa.eu/health/ph_risk/committees/04_sccp/sccp_opinions_en.htm#2

Intermediates and reaction products of hair dye ingredients
With regard to the safety assessment of reaction products of oxidative hair dyes, the SCCP reviewed the data presented in a recent dossier. In addition to the results of completed studies a number of planned and ongoing studies to assess exposure have been reported in this dossier. The SCCP will only be able to draw a final conclusion after the results of these studies have become available. If a relevant exposure to reaction products from hair dyeing cannot be excluded, further testing on genotoxicity will be required to exclude the genotoxicity/mutagenicity potential of the reaction products of oxidative hair dye.

The adopted opinion is available at:
http://ec.europa.eu/health/ph_risk/committees/04_sccp/docs/sccp_o_162.pdf

UV filters

S38, Benzophenone-3
The SCCP concluded that the use of benzophenone-3 as a UV-filter up to 6% in cosmetic sunscreen products and up to 0.5% in all types of cosmetic products does not pose a risk to the health of the consumer, apart from its contact allergenic and photoallergenic potential.

The adopted opinion is available at:
http://ec.europa.eu/health/ph_risk/committees/04_sccp/docs/sccp_o_159.pdf

S57, Camphor benzalkonium methosulfate
In response to opinion SCCP/1015/06 of 19 December 2006, a reduction of maximum authorised concentration from 6.0 to 3.0% as a UV filter in cosmetic products was proposed. On the basis of the available data, a reduced maximum concentration of 3% as a UV filter in cosmetic products is considered safe.

The adopted opinion is available at:
http://ec.europa.eu/health/ph_risk/committees/04_sccp/docs/sccp_o_168.pdf

The Scientific Committees

Preservatives

Citric acid and silver citrate
The SCCP assessed the safety of this novel preservative in cosmetic products in a concentration up to 0.2%. On the basis of the data submitted, a final decision on the safety of citric acid (and) silver citrate cannot be made. An in vitro mammalian gene mutation assay to exclude gene mutation potential is required. With regard to the risk of silver deposition in the skin (argyria), which is the critical endpoint for silver toxicity, the SCCP acknowledged that exposure to silver from citric acid and silver citrate when used in cosmetics is low, but expressed the need for more up-to-date studies, since all current regulatory limits for silver are based on old data.

Moreover, the SCCP stated concern with regard to increased consumer exposure to silver following its widespread use in a variety of products. The Committee recommended considering an aggregate exposure and risk assessment.

The adopted opinion is available at:
http://ec.europa.eu/health/ph_risk/committees/04_sccp/docs/sccp_o_165.pdf

Triclosan (P32)
Triclosan is presently authorised as a preservative in cosmetics in concentrations up to 0.3%. In this updated evaluation, the SCCP concluded that the continued use of triclosan as a preservative in cosmetic products at the current concentration limit of 0.3% in all products is not safe for the consumer because of the magnitude of the aggregate exposure. However, its use at a maximum concentration of 0.3% in toothpastes, hand soaps, body/shower gels and deodorant sticks ("common-use products" as defined by the applicant) is considered safe. The additional use of triclosan in face powders and blemish concealers at this concentration is also considered safe but the use of triclosan in other leave-on products (e.g. body lotions) and in mouthwashes is not considered safe for the consumer due to the resulting high exposures. Before a final conclusion on the safety of triclosan in cosmetic products can be reached, the potential development of resistance to triclosan and cross-resistance by certain micro-organisms must be assessed. This aspect will be discussed in a separate opinion.

The adopted opinion is available at:
http://ec.europa.eu/health/ph_risk/committees/04_sccp/docs/sccp_o_166.pdf

Climbazole (P64)
Climbazole is currently authorised as a preservative in cosmetics in concentrations up to 0.5%. In this updated evaluation, the SCCP considers the continued use of Climbazole as a preservative at 0.5% in all cosmetic products not safe. However, it is considered safe when used as a preservative or non-preservative in hair cosmetics and face cosmetics at 0.5%. It is further considered safe when used in rinse-off hair cosmetics up to a maximum concentration of 2.0%.

The adopted opinion is available at:
http://ec.europa.eu/health/ph_risk/committees/04_sccp/docs/sccp_o_164.pdf

Other substances

DEGEE, Diethylene glycol monoethylether:
The SCCP has previously concluded that, based on the information provided, the use of diethylene glycol monoethyl ether (DEGEE) in all cosmetic products, excluding oral hygiene and eye products at a concentrations up to 1.5% does not pose a risk to the health of the consumer, provided that the level of ethylene glycol in DEGEE used is <0.2%. Based on an updated dossier, the SCCP concluded in this opinion that the use of diethylene glycol monoethyl ether (DEGEE) as a solvent in an on-head concentration of up to 7.0% in oxidative hair dye formulations and in an on-head concentration of up to 5.0% in non-oxidative hair dye formulations in addition to the use of DEGEE at concentrations up to 1.5% in all cosmetic products except products for oral hygiene and eye products does not pose a risk to the health of the consumer.

The adopted opinion is available at:
http://ec.europa.eu/health/ph_risk/committees/04_sccp/docs/sccp_o_161.pdf

Tea tree oil:
The SCCP was asked to asses the safety of Tea tree oil (TTO) when used undiluted or at different concentrations in cosmetic products. With regard to the problem of the increased skin sensitising potential of oxidised TTO, the SCCP concluded that the Code of Practice and the Guidance document introduced by the Australian Tea Tree Oil Association indicate that safe processing and storage may be achieved and that stability can be controlled by the p-cymene content. The content of methyleugenol, which has been reported as a minor constituent of Tea Tree Oil should be indicated. According to a previous evaluation, its content should not exceed 2 ppm in leave-on products and 10 ppm in rinse-off products.

The SCCP confirmed that Tea Tree Oil is a skin sensitiser. Skin sensitisation may also be enhanced by irritancy. Neat Tea Tree Oil and certain formulations at concentrations of 5% or more can induce skin and eye irritation. Based on clinical data, the current use levels of TTO are shown to induce contact allergy.

A final conclusion on the safety of TTO when used in cosmetic products could not be reached, since the dermal absorption studies available were considered inadequate and the systemic exposure to Tea Tree Oil from cosmetic products is uncertain. Moreover, only rough worst case estimations for No Adverse Effect Levels (NOAEL) for general systemic and reproductive toxicity can be made.

The SCCP envisaged a reassessment of the safety of Tea tree oil in the case that reliable data on percutaneous absorption covering relevant concentrations and cosmetic formulations becomes available. It also demanded the indication of the cosmetic function of Tea Tree Oil as this was not given and several non-cosmetic applications are known.

The adopted opinion is available at:
http://ec.europa.eu/health/ph_risk/committees/04_sccp/docs/sccp_o_160.pdf

SCHER SCIENTIFIC COMMITTEE ON HEALTH AND ENVIRONMENTAL RISKS

REGULATION 793/93 ON THE EVALUATION AND CONTROL OF THE RISKS OF EXISTING SUBSTANCES

Council Regulation 793/93 provides the framework for the evaluation and control of the risk of existing substances. Member States prepare Risk Assessment Reports (RAR) 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.

Lead and its compounds (environmental part)

According to the Voluntary RAR (VRAR), risk characterisations for local characterisations for shooting and hunting areas, marine waters and sediment, secondary poisoning and the indirect ingestion of shot by waterfowl and terrestrial predators stated that there is a need for further information and/or testing. For some local sites for water and sediment in some sectors the VRAR proposes the need for limiting risks (conclusion iii). The other risk characterisations are considered to require no risk reduction measures (conclusion ii).

SCHER does not accept that either conclusions ii) or iii) can be applied due to the uncertainties associated with both exposure and effects for all compartments and at all levels. Hence, SCHER is of the view that the need for further information and/or testing (conclusion i) should be applied to the VRAR as a whole at this stage.

The adopted opinion is available at:
http://ec.europa.eu/health/ph_risk/committees/04_scher/docs/scher_o_111.pdf

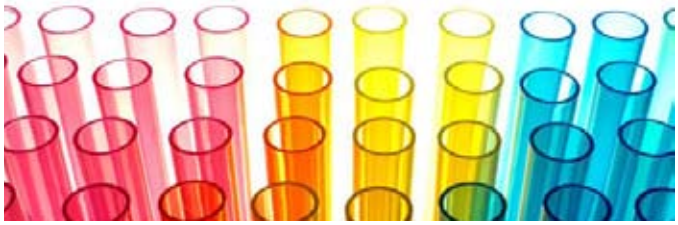
Lead and its compounds (human health part)

The health part of the document is of good quality and the assessment follows the Technical Guidance Document (TGD). The VRAR bases most of its conclusions on human data and only uses animal data when necessary.

The VRAR uses only a Margin of Safety (MOS) of 1 and justifies this due to the large database on effects of lead in humans and the well defined exposure conditions. SCHER agrees with this approach.

SCHER agrees that there is a need for limiting the risks, and risk reduction measures which are already being applied shall be taken into account (conclusion iii) for some of the occupational scenarios.

Regarding consumer exposure SCHER also agrees that there is at present no need for further information and/or testing (conclusion ii).



Finally, SCHER supports the VRAR conclusion that there is a need for limiting the risks (conclusion iii) for children living at some highly contaminated sites near lead production or processing plants and for some specific exposure scenarios.

The adopted opinion is available at:
http://ec.europa.eu/health/ph_risk/committees/04_scher/docs/scher_o_114.pdf

Nickel (Ni) and its compounds (environmental part)

The RAR on Ni and Ni-compounds is of a very high quality. It has followed the guidance provided in the TGD to a large extent and has included additional higher tier methods where required or possible. Nevertheless, some refinements, particularly in the risk assessment for soil organisms, are required.

SCHER agrees with RAR that there is no need for risk reduction measures (conclusion ii) for most of the scenarios in the aquatic (including the marine environment), and terrestrial compartments, and for secondary poisoning.

The adopted opinion is available at:
http://ec.europa.eu/health/ph_risk/committees/04_scher/docs/scher_o_112.pdf

Copper and its compounds (environmental part)

The VRAR on copper is a very complex document, based on a huge amount of scientific data and information useful for both exposure and effects assessment. The general quality is very good and some procedures proposed are quite innovative and scientifically sound. The theoretical approaches used are appropriate and, in general, properly applied. It is the opinion of the SCHER that the information available allows to perform a sound risk assessment, even if some additional information could be helpful.
Proposed conclusions on risk characterisation can be accepted. However, taking into account that the document may represent a reference point for future assessment of copper risk in the European environment, the SCHER supports the need to better explore some data and to carefully account for some controversial issues. According to the SCHER most of the amendments proposed do not require the production of additional information, except for a few issues mentioned in the opinion.

The adopted opinion is available at:
http://ec.europa.eu/health/ph_risk/committees/04_scher/docs/scher_o_115.pdf

OTHER OPINIONS

Use of non-human primates (NHP) in biochemical research, production and testing products and devices

Directorate General Environment (ENV) is currently revising Directive 86/609/EEC[5] on the approximation of laws, regulations and administrative provisions of the Member States regarding the protection of animals used for experimental and other scientific purposes. The revision addresses issues such as compulsory authorisation of all experiments, inspections, severity classification, harm-benefit analysis and compulsory ethical review. In addition, specific problems relating to the use, care and acquisition of non-human primates are addressed.

In May 2008, DG ENV requested DG SANCO to initiate a new scientific consultation in order to participate in the debate in the European Parliament and Council, with independent scientific information on the latest status of the possibilities to replace the use of non-human primates.

The scope of the SCHER opinion is confined to the scientific aspects and does not consider the ethical, economic, cultural and social aspects of NHP use. SCHER recognises that there are promising developments towards the replacement of NHP in biomedical research. A number of alternative methods (either in vitro or using other animal species) have been developed and implemented over the last decade. However, based on the available scientific evidence, SCHER concludes that at present, for many areas of biomedical research, there are no valid alternatives which would allow for a discontinuation in the use of NHP. Moreover, a specific timetable for the complete replacement of NHP use is difficult to predict. Based on the available science, the total replacement of NHP in many areas of use, either by other animal species or by non-animal methods, is unlikely to be achieved in the foreseeable future.

A public hearing on the opinion took place on 6 November 2008. Forty-eight representatives of various stakeholders, including academia, NGOs, industry, and governmental institutions participated in the meeting. The outcome of the discussion was considered in the final opinion.

The adopted opinion is available at: *http://ec.europa.eu/health/ph_risk/committees/04_scher/docs/scher_o_110.pdf*

SCENIHR SCIENTIFIC COMMITTEE ON EMERGING AND NEWLY IDENTIFIED HEALTH RISKS

Health Effects of Exposure to EMF

As part of its mandate the SCENIHR is asked to continuously monitor new information in this area and to provide regular updates on the scientific evidence base to the Commission. Recently, there have been numerous alarming media reports alleging that new scientific evidence had shown health effects from exposure to EMF, notably from mobile phone technology. Many of these were based on the conclusions of the BioInitiative Report, published in 2007, claiming that new evidence proves the carcinogenic nature of EMF, even at levels well below current exposure limits. Consequently, the SCENIHR was asked to examine this and other relevant publications that were published after its own scientific opinion in March 2007 and to provide a methodological framework and corresponding guidelines to evaluate available scientific evidence in order to ensure the best possible quality for risk assessment.

The opinion arrives at similar conclusions as the earlier opinion. Based on current evidence the main conclusions remain that radio frequency (RF) fields used e.g. in wireless communication technologies are unlikely to lead to an increase in cancer in the human population at large. However, further studies are needed to clarify if long-term exposure to mobile phones (well beyond 10 years) increases cancer risk for an individual using a mobile phone frequently and to examine the effects on children. Data for health effects of intermediate frequency fields used, for example, in metal detectors or anti theft devices in shops, are still lacking. This area of research is considered important given the increasing exposure to these products. Likewise, SCENIHR notes a lack of adequate data for risk assessment on static fields. The report confirms the 2007 opinion that extremely low frequency (ELF) fields used in high voltage power lines might contribute to childhood leukaemia. Furthermore, the SCENIHR identified 2 new epidemiological studies that indicate a possible link to Alzheimer's disease. Finally, SCENIHR points out that scientific studies still fail to provide support for an effect of RF fields or ELF fields on self-reported symptoms but indicate that the expectation or belief that something is harmful may play a role in symptom formation.

The opinion, adopted on 19 January 2009, can be found at: *http://ec.europa.eu/health/ph_risk/committees/04_scenihr/docs/scenihr_o_022.pdf*

Midday Express: *http://ec.europa.eu/health/ph_risk/committees/04_scenihr/midday_en.htm*

5 http://ec.europa.eu/food/fs/aw/aw_legislation/scientific/86-609-eec_en.pdf

Risk Assessment of Products of Nanotechnologies

In its opinions of 2006 and 2007, the SCENIHR concluded that nanomaterials may have different (eco)toxicological properties than the same substances at larger scales, and that the current methodologies are generally likely to be able to identify the hazards linked to nanomaterials. SCENIHR also concluded that the risk assessment methods and instruments may require further development and that, as a result, the risk assessment of nanomaterials must be performed on a case-by-case basis. In view of the fast growing body of new scientific information, the Commission asked the SCENIHR to update its scientific advice on the risk assessment of nanomaterials.

This new opinion concludes that the procedure for assessing the potential risks of manufactured nanomaterials is still under development but identifies the in-depth characterization of a manufactured nanomaterial as essential for a proper risk assessment. The SCENIHR also warns that structures, aggregates and agglomerates which have dimensions well beyond 100 nm may retain specific properties which are characteristic of nanomaterials. The SCENIHR notes that the lack of high quality exposure data remains a major limitation for risk assessment, and calls for research in this area. It also identifies some specific hazards for human health (e.g. short rigid nanotubes) and a potential for nanoparticles to penetrate into sub-cellular compartments, opening the possibility for genotoxicity. Furthermore, the SCENIHR observes that when contacting biological fluids, a nanomaterial may become coated with proteins which may affect its behaviour including its biological effects. Knowledge on the behaviour of manufactured nanoparticles in the environment is gradually becoming available and for some, toxic effects on environmental organisms have been demonstrated.

In spite of the health and environmental hazards that have been demonstrated for a variety of manufactured nanomaterials, the SCENIHR notes that not all nanomaterials induce toxic effects and maintains its recommendation for a case-by-case approach to risk assessment as there is no generally applicable paradigm for nanomaterial hazard identification.

The opinion, adopted on 19 January 2009, can be found at:
http://ec.europa.eu/health/ph_risk/committees/04_scenihr/docs/scenihr_o_023.pdf

Midday Express:
http://ec.europa.eu/health/ph_risk/committees/04_scenihr/midday2_en.htm

Assessment of the Antibiotic Resistance Effects of Biocides

In light of recent scientific evidence, the SCENIHR was asked to clarify 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 Directive (98/8/EC)[6] of the European Parliament and of the Council on the placing of biocidal products on the market.

In this opinion the SCENIHR concludes that bacteria can survive exposure to antimicrobials by using a battery of resistance mechanisms. Furthermore, the SCENIHR states that some resistance mechanisms are common to both biocides and antibiotics and that scientific evidence from bacteriological, biochemical and genetic data does indicate that the use of active molecules in biocidal products may contribute to the increased occurrence of antibiotic resistant bacteria. The selective stress exerted by biocides may favour bacteria expressing resistance mechanisms and their dissemination. Some biocides have the capacity to maintain the presence of mobile genetic elements that carry genes involved in cross-resistance between biocides and antibiotics. The dissemination of these mobile elements, their genetic organisation and the formation of biofilms, provide conditions that could create a potential risk of developing cross-resistance between antibiotics and biocides.

In view of the large use of biocides and the increase of bacterial resistance to antibiotics, the SCENIHR emphasizes that the following is needed: quantitative data on exposure to biocides; methods to evaluate the ability of a biocide to induce or select for resistance against biocides and antibiotics; surveillance programmes and environmental studies focussing on the characterisation of resistance and cross-resistance to antibiotics.

The opinion, adopted on 19 January 2009 following public consultation, can be found at:
http://ec.europa.eu/health/ph_risk/committees/04_scenihr/docs/scenihr_o_021.pdf

eNews:
http://ec.europa.eu/dgs/health_consumer/dyna/enews/enews.cfm?al_id=830

Position Paper on Emerging Issues and the Role of SCENIHR

The purpose of this position paper is to draw the attention of the Commission services to emerging issues in the non-food area, that have been identified by SCENIHR members as having the potential for a significant impact on human health and/or on the environment in the future. It is intended to supplement the information that is already accessible to the Commission services through other sources. SCENIHR recognises the need to establish a very flexible framework to aid the correct identification of emerging issues and their potential impacts. The purpose of the framework is to help in the recognition and characterisation of trends pertinent to human health and environmental change (e.g. signals) but in a way that does not exclude the identification of issues for which there is no precedent.

The position paper, adopted on 19 January 2009, can be found at:
http://ec.europa.eu/health/ph_risk/committees/04_scenihr/docs/scenihr_s_01.pdf

6 http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:1998:123:0001:0063:EN:PDF

The Scientific Committees

JOINT OPINIONS SCCP, SCHER, SCENIHR

Risk assessment methodologies and approaches for genotoxic and carcinogenic substances

The issue of risk assessment of genotoxic and carcinogenic substances is relevant for chemicals used in all applications. The three Committees (with SCHER in the lead) were asked on the basis of the available evidence to critically review the available methodologies and approaches used for the risk assessment of genotoxic and carcinogenic substances.

The SCs concluded that risk assessment of compounds that are both genotoxic and carcinogenic should be done on a case-by-case basis. Whenever sufficient information is available, the linear extrapolation or the Margin of Exposure (MOE) approach should be applied. Both have advantages and disadvantages. The SCs have identified several conditions where one or the other approach may be preferable:

- For risk communication the MOE is considered preferable.
- For prioritisation of measures to reduce risk, both the MOE approach and the linear extrapolation from a dose descriptor are applicable.
- Linear extrapolation is a method that provides a quantitative expression of risk that is commensurate with cost benefit analysis.
- When appropriate the SCs also recommend application of the Threshold of Toxicological Concern (TTC).
- The ALARA (As Low As Reasonably Achievable) principle is a valuable measure to minimize exposure to genotoxic and carcinogenic substances but it is a qualitative procedure and not applicable for risk assessment.

The adopted opinion is available at:
http://ec.europa.eu/health/ph_risk/committees/04_scher/docs/scher_o_113.pdf

NEW AND UPCOMING MANDATES

SCCS SCIENTIFIC COMMITTEE ON COSMETIC SERVICES

Erythrosine (CI 45430)

CI 45430 is regulated as a cosmetic colorant in Annex IV of the Cosmetics Directive and permitted together with its lakes and salts to be used in all cosmetic products without any restrictions. In September 2006, in order to reduce the intake of iodine from cosmetic products, the Commission proposed to delete CI 45430 from Annex IV if no safety dossier was submitted. A dossier subsequently provided applies for a restricted use in toothpaste products with a maximum concentration of 0.0025%. The SCCS is asked to evaluate the safety of this application.

Polysilicone-15 (Dimethicodiethylbenzalmalonate)

The use of Polysilicone-15 as an UV-filter in cosmetic products is currently authorised up to 10%.

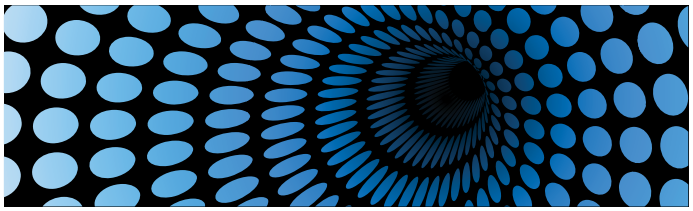
Polysilicone-15 was tested via inhalation route in an acute exposure scenario. The outcome of the study will classify polysilicone-15 as toxic by inhalation. In order to evaluate whether this classification will have any influence on the current authorisation, the SCCS is asked if the continued use in cosmetic products in a concentration up to 10% can be considered safe taken into account the new scientific data on inhalation.

SCHER SCIENTIFIC COMMITTEE ON HEALTH AND ENVIRONMENTAL RISKS

- Methodologies and approaches for risk assessment on chemical mixtures.
- Guidance for biomonitoring studies.
- Human health and environmental risks associated with the use of hydrofluorosilicid acid in drinking water fluoridation.

The Scientific Committees

SCENIHR SCIENTIFIC COMMITTEE ON EMERGING AND NEWLY IDENTIFIED HEALTH RISKS



- Mercury sphygmomanometers in healthcare and the feasibility of alternatives.
- Addictiveness of ingredients in tobacco products.

PUBLIC CONSULTATIONS AND PUBLIC HEARING

Use of the Threshold of Toxicological Concern (TTC) Approach for the Safety Assessment of Chemical Substances

SCHER, SCCP and SCENIHR approved the preliminary report by written procedure on 19 November. The opinion concludes that the principle of the TTC approach in itself is scientifically acceptable. However, the applicability of this principle for risk assessment in specific areas is dependent on the quality, quantity and relevance of the underlying toxicity database and a reliable estimation of the exposure to the chemical.

The public consultation on the preliminary report closed on 2 January.

Twenty-one contributions were received from Academia, Industry and NGOs. The comments received are under discussion by the TTC WG and, where relevant, will be taken into account for the final report. The work on the finalisation of the opinion on TTC will continue with the renewed Scientific Committees.

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