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

Newsletter of the European Commission Scientific Committees

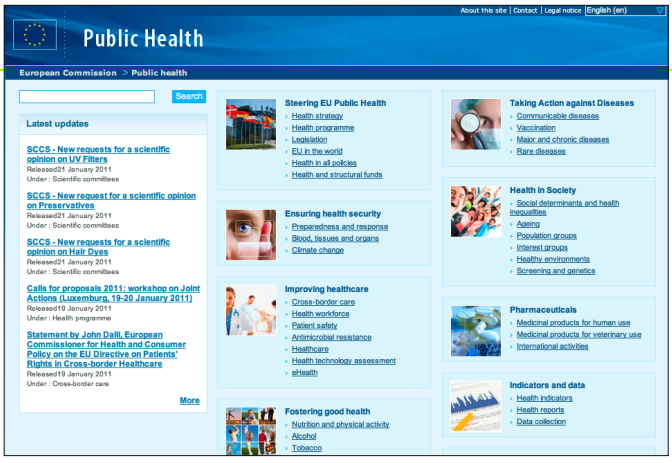
ISSN nr: 1830-6993 February 2011 – Catalogue nr: ND-AG-11-001-EN-N

In this issue:

NEWS

PLANS FOR THE REVAMPING OF THE SCIENTIFIC COMMITTEES WEBSITE

As part of its efforts to ensure the maximum transparency and facilitate public access to the work of the Scientific Committees, initial efforts are underway to revamp the internet site of the Scientific Committees. The idea is to enable potential visitors for a one-click access to the work of the Scientific Committees and the activities related to their functioning (opinions, events, consultations etc).



REPLACEMENT OF MEMBERS OF THE SCIENTIFIC COMMITTEES

Four members of the European Commission Scientific Committees have resigned for personal reasons and two members did not meet the participation criteria as set out in the Rules of Procedures of the Committees and have agreed to be replaced. The European Commission is in the process of initiating procedures to replace those members with experts from the Pool of Advisors with professional profiles similar to those departing.

Directorate-General for Health & Consumers

REVIEW OF EVENTS

WORKSHOP ON THE APPLICABILITY OF QSARS AND COMPUTATIONAL APPROACHES IN CHEMICAL RISK ASSESSMENT, BRUSSELS 30 SEPTEMBER – 1 OCTOBER 2010

The European Commission, in collaboration with the European Commission Joint Research Centre (JRC) and the European Food Safety Authority (EFSA), organised a workshop on the use of QSRARs and computation approaches in chemical risk assessment. A total of 40 participants from the Commission, the EU Scientific Agencies and Bodies, and from the computational developers and users participated. Several modelling and computational models were demonstrated and discussed. Participants felt that computational models are an excellent tool in an integrated, weight of evidence approach in risk assessment and identified a number of areas for further research and refinement to improve their utility.

CHAIRS AND VICE-CHAIRS MEETING, COPENHAGEN, 11 AND 12 NOVEMBER 2010

The 6th meeting of Chairs and secretariats of EU Commission and Agency Scientific Committees and Panels, coordinated by DG SANCO, took place at the EEA in Copenhagen on 11-12 November 2010. It was well attended by Chairs and staff from EFSA, ECHA, EEA, EMEA, ECDC, SCCS, SCHER, SCENIHR and SCOEL.

The meeting was organised by the European Environmental Agency (EEA) and DG SANCO. It was devoted to discussion of a few concrete issues which are currently addressed by one or more Committees/Agencies or are part of collaborative projects launched as follow-up to previous Chairs meetings and international dialogue events. The meeting focused on the assessment of chemical mixtures, the use of "thresholds of toxicological concern" (TTC), and how to ensure transparency and the appropriate terminology in communicating uncertainties.

2ND INTERNATIONAL CONFERENCE ON RISK ASSESSMENT, BRUSSELS, 25 – 28 JANUARY 2011

As a follow-up to the 1st International Conference on Risk Assessment (Brussels, 13–14 November 2008) the European Commission (DG SANCO) organised a 2nd Conference in Brussels on 25–28 January 2011. The Conference aimed at providing a Forum for global dialogue on risk assessment principles, methods, criteria, practices and arrangements in the various jurisdictions around the world, building upon the Transatlantic Risk Assessment Dialogue launched in 2008 between the US, Canada and the EU. It was intended to complement the relevant activities in the area of risk assessment of international bodies and specialised organisations by providing a discussion and collaboration platform to the main actors from the most relevant institutions, agencies, organisations, and professional networks. The focus of the Conference remains on scientific risk assessment as a central element of the risk analysis paradigm.

Details can be found at the following site:
http://ec.europa.eu/health/risk_assessment/events/ev_20110126_en.htm#fullwidth

EVENTS COMING UP

INFORMAL WORKSHOP ON SKIN ALLERGY RESEARCH NEEDS, 9 FEBRUARY 2011

In light of the upcoming Health call for research projects under the 7th Framework Programme of research of the EU and the work of the SCCS subgroup on fragrance skin allergies, the European Commission organises a one day informal workshop in order to identify research priorities in the area of skin allergy. About 30 experts from academia, member states, the SCCS and the Commission participate.

4TH NANO SAFETY FOR SUCCESS DIALOGUE: ASSESSING THE SCIENCE AND ISSUES AT THE SCIENCE/REGULATION INTERFACE, 29 AND 30 MARCH 2011, BRUSSELS

Like other materials designed, engineered, and used by humans, nanomaterials promise benefits and raise concerns, in particular for workers, the general public, and the environment. The international community has organised itself to address the potential safety aspects of nanomaterials. Therefore, the European Commission is convening this international conference:

- to take stock of the fast advancing science needed for the accurate characterisation of nanomaterials, the reliable assessment of exposure and hazards associated with them, and appropriate and effective policy measures
- to discuss questions that arise at the science/regulation interface

The conference will deliver a consensus report summarising the state-of-the-art, identifying gaps, and setting priorities.

The registration weblink and conference updates are available at: http://ec.europa.eu/health/nanotechnology/events/ev_20110329_en.htm

OPINIONS ADOPTED

SCIENTIFIC COMMITTEE ON CONSUMER SAFETY (SCCS)

Cosmetic ingredients

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

The following risk assessments have recently been concluded:

Hair Dyes

Opinion on reaction products of oxidative hair dye ingredients formed during hair dying processes

Based on concerns raised by scientific publications that hinted to a possible connection between hair dye use and some types of cancer, the European Commission initiated a strategy to ensure safety of these substances. In addition to a safety assessment of all hair dye substances on the European market, the identification and evaluation of reaction products and intermediates formed during the use of oxidative hair dyes were also included in this comprehensive programme.

Following the submission of a comprehensive dossier on reaction products, the SCCS did not raise major concerns regarding genotoxicity and carcinogenicity of reaction products of hair dyes currently used in the EU. However, the database on genotoxicity on reaction products is at present small and some degree of uncertainty remains. The SCCS recommended further enlarging the database to reduce the degree of uncertainty. With regard to carcinogenicity no clear conclusion can be drawn from the available studies. A causal relationship between personal hair dye use and cancer cannot be established by epidemiology alone and the available studies do not allow the establishment of an excess cancer risk for current users of hair dyes marketed in the EU.

The SCCS recently issued several opinions on individual hair dye substances and concluded the following:

Hair dyes that do not pose a risk to the health of the consumer under intended-use conditions:

- Basic Orange 31
- 2,4-Diaminophenoxyethanol (sulphate salt)
- HC Red n° 3
- HC Yellow n° 2
- HC Yellow n° 7
- HC Yellow n° 13
- 1,5-Naphthalenediol
- 2,7-Naphthalenediol
- 4-Nitrophenyl aminoethylurea
- Picramic acid

Hair dyes that do pose a risk to consumer health under intended-use conditions:

- HC Red n° 16

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

Preservatives

P82, Parabens

This family of cosmetic preservatives comprises esters of 4-Hydroxybenzoic acid with different chain length. While the short chain parabens (methyl-, ethyl paraben) have been considered safe by the SCCS's predecessors, the toxicological properties of propyl-, butyl- and other parabens have been a matter of debate during recent years, in particular in relation to possible endocrine activities of these substances. After review of all available data and based on a worst case assumption, the SCCS concluded, that propyl- and butyl paraben can be considered safe for consumers only when the sum of their individual concentrations does not exceed 0.19 %. No or insufficient data are available on other paraben derivatives, so their safety for use in cosmetic products cannot be assessed.

The opinion is available at:
http://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_o_041.pdf

Other cosmetic ingredients

Diethylene glycol monoethyl ether (DEGEE)

DEGEE can be used as a solvent in cosmetic products when used in an on-head concentration of up to 7.0 % in oxidative hair dye formulations, in an on-head concentration of up to 5.0 % in non-oxidative hair dye formulations, and up to 1.5 % in all cosmetic products (with the exception of oral hygiene and eye products), provided that the level of ethylene glycol in DEGEE used is < 0.2 %. Recently, the applicant requested to increase the maximal use concentration in cosmetic products up to 5.5 % in leave-on products and up to 10 % in rinse-off products, based on new studies provided.

After review of the new information submitted, the SCCS concluded that the use of DEGEE as a solvent in cosmetic products in a concentration up to 10% in rinse-off products is safe, however that the increase to a concentration up to 5.5% in leave-on products (in contrast to the previously assessed 1.5%) does pose a risk to the health of the consumer.

The opinion is available at:
http://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_o_039.pdf

Dihydroxyacetone
Dihydroxyacetone is a self tanning agent commonly used in cosmetic products as well as being sprayed onto the customer's entire body in specialised cabins in beauty salons. The tanning effect is due to a chemical reaction with amino acids and amino groups of proteins present in the skin, leading to the production of coloured melanoidins.

The SCCS considered that dihydroxyacetone as a self tanning ingredient is safe when used in body lotions and face creams up to 10% and in spray cabin applications up to 14%.

The opinion is available at:
http://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_o_048.pdf

Trisodium Nitriloacetate
Trisodium nitriloacetate is not used as an ingredient per se in cosmetic products, but as an additive to other ingredients and therefore it can be present in finished cosmetic products. This substance has recently been classified as a carcinogen cat. 2 with a specific concentration limit of 5%. No information on the actual levels in cosmetic products is available; therefore the risk assessment was based on the specific concentration limit of 5%. Based on the available information, the SCCS is of the opinion that the presence of Trisodium nitriloacetate at a maximum concentration of 5% in cosmetic products is not safe for the consumer.

The opinion is available at:
http://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_o_046.pdf

Documents on methodological issues:

Memorandum on Episkin (addendum)
Episkin is an alternative (in vitro) method for the testing of the skin irritation potential of chemicals. This memorandum presents the final assessment of data which were received after the SCCS stated concerns in relation to certain substances e.g. colourants, which might interfere with the test system and not give reliable results. Following analysis of the data, the SCCS maintains its concerns. The official testing guidelines (EC, OECD) developed for this method during the last years have taken account of these limitations by prescribing initial compatibility testing and additional controls.

The memorandum is available at:
http://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_s_003.pdf

The SCCS's Notes of Guidance for the testing of cosmetic ingredients and their safety evaluation, 7th revision
The Notes of Guidance provide instructions for stakeholders in the cosmetic field on how to assess the safety of ingredients and to prepare in-house safety files for inspection by market surveillance authorities and dossiers for submission to SCCS. The revised document takes account of recent developments in testing methodologies as well as incorporating information on changes that will be coming from the new Cosmetics Regulation EC/1223/2009.

SCIENTIFIC COMMITTEE ON HEALTH AND ENVIRONMENTAL RISKS (SCHER)

Opinion on: Chemicals and the Water Framework Directive: Technical Guidance for Deriving Environmental Quality Standards
Adopted by the SCHER via written procedure in October 2010.

Article 16 of the Water Framework Directive (WFD, 2000/60/EC) requires the Commission to identify priority substances among those presenting significant risk to or via the aquatic environment, and to set EU Environmental Quality Standards (EQSs) for those substances in water, sediment and/or biota. The Technical Guidance has been developed to support the derivation of EQSs for priority substances and for river-basin-specific pollutants that need to be regulated by Member States according to the provisions of the WFD. In response to the Commission's request SCHER provided a generally positive opinion on the overall scientific quality of the Technical Guidance for derivation of Environmental Quality Standards (EQSs). SCHER also reflected on the current state of technical and scientific knowledge and elaborated on its reasons for considering any aspect of the guidance inappropriate, suggesting alternative approaches.

The opinion is available at:
http://ec.europa.eu/health/scientific_committees/environmental_risks/docs/scher_o_127.pdf

All opinions delivered by the Scientific Committees are free from experts' prejudice and personal ethical considerations.

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

The following risk assessments have recently been concluded:

Addictiveness and Attractiveness of Tobacco Additives

Today, tobacco additives, hardly used before 1970, represent up to 10% of a cigarette's weight. In response to a request from the European Parliament, the Commission had asked the SCENIHR to assess the role of additives and characteristics of tobacco products in tobacco take up and addiction.

The SCENIHR has adopted the final opinion by written procedure on 12 November 2010 following a public consultation (from 9 July to 5 September 2010).

In this opinion, the SCENIHR concluded that tobacco has high potential for addiction according to the criteria for dependence established in humans, but it remains difficult to assess the addictiveness of individual additives. No tobacco additives have so far been identified which are addictive by themselves. However, it is thought that certain additives may enhance the addictiveness of nicotine indirectly by different pathways. For example, menthol flavoured cigarettes may promote deeper inhalation.

The attractiveness of tobacco products may be increased in different ways by a number of additives and by other factors (e.g. marketing, price).

The final opinion is available at:
http://ec.europa.eu/health/scientific_committees/emerging/docs/scenihr_o_031.pdf

Link to the result of the public consultation:
http://ec.europa.eu/health/scientific_committees/consultations/public_consultations/scenihr_cons_12_en.htm

Link to the bibliography of the sources examined for the opinion:
http://ec.europa.eu/health/scientific_committees/emerging/docs/scenihr_o_031_biblio.pdf

Scientific Basis for the Definition of the Term "Nanomaterial"

With the increasing use of nanotechnology, there is a need for a common basis to define the term "nanomaterial" in different EU legislative areas. In order to prepare a science-based definition of nanomaterials, the services of the European Commission needed clarification on the size ranges and other relevant characteristics and corresponding metrics reported in the scientific literature, the types of physical and chemical properties particular to nanomaterials, the relevant thresholds, as well as the most appropriate metrics to express such thresholds.

The opinion, approved by the SCENIHR on 8 December 2010, provides guidance on the interpretation and the use of a definition for nanomaterials in a regulatory setting. The SCENIHR proposes to set an upper limit for nanomaterial size and to add to the proposed limit additional guidance (requirements) specific for the intended regulation. Crucial in this guidance is the extended description of the nanoscale, as single upper and lower limits are not sufficient as cut-off points in view of the size distributions of the manufactured nanomaterials. Although many nanomaterials are produced for specific properties at the nanoscale, it is at the moment not possible to identify a specific size or a specific generic property that is suddenly introduced or changed with size. As a result, a tiered approach may be required depending on the amount of information available for any specifically engineered nanomaterial and its proposed use.

A key issue addressed in the opinion is the arbitrary nature of the nanoscale which is currently commonly assumed to range from 1 to 100 nanometres. SCENIHR points to the absence of a scientific basis for the scale's upper limit of 100 nanometres.

The opinion is available at the following link:
http://ec.europa.eu/health/scientific_committees/emerging/docs/scenihr_o_032.pdf

All opinions delivered by the Scientific Committees are free from prejudice and personal ethical considerations.

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

ONGOING WORK

SCIENTIFIC COMMITTEE ON CONSUMER SAFETY – SCCS

The following mandates are currently under evaluation:

Hair dyes
To ensure the safety of hair dye products, a complete review of all hair dye substances on the European market has been initiated by the European Commission. Under this framework, full safety evaluations of 25 hair dyes are yet to be performed. In addition, supplementary data on 11 substances that have been initially evaluated have been received and await assessment.

Preservatives
2-Chloroacetamide
Climbazole
Methenamine 3-chloroallylochloride2-chloroacetamide (Quaternium 15)
Triclosan (review of general toxicology)
Zinc pyrithione (P81; CAS 13463-41-7, EU 236-671-3)

UV-filters
Bis(butylbenzoate) diaminotriazine
aminopropyltrisiloxane
ETH-50
HAA299 / C-1332
Titanium dioxide (nano-form)

Fragrances
3 and 4-(4-Hydroxy-4- methylpentyl)-3-cyclohexene-1-carboxaldehyde (HMPCC)
Methyl-N-methylanthranilate
Review of fragrance substances that need to be labelled when present in cosmetic products

Other cosmetic ingredients
Arbutin / desoxyarbutin
Dichloromethane
Hydrolysed wheat proteins
N-methyl-2-pyrrolidone
Peanut oil
Zinc pyrithione

Methodologies
The use of the Threshold of Toxicological Concern (TTC) approach for the safety assessment of chemicals

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

SCIENTIFIC COMMITTEE ON HEALTH AND ENVIRONMENTAL RISKS – SCHER

Critical review of any new evidence on the hazard profile, health effects, and human exposure to fluoride and the fluoridating agents of drinking water
In its opinion adopted for public consultation on 18 May 2010, the SCHER concluded that there are no obvious advantages in favour of water fluoridation as compared with topical application of fluoride. An advantage in favour of water fluoridation is that caries prevention will reach disadvantaged children from lower socioeconomic groups. In several environmental scenarios it was found that fluoridation of drinking water did not add any risk to the organisms in the environment, and thus that the added risk of drinking water fluoridation to the environment has to be considered negligible.

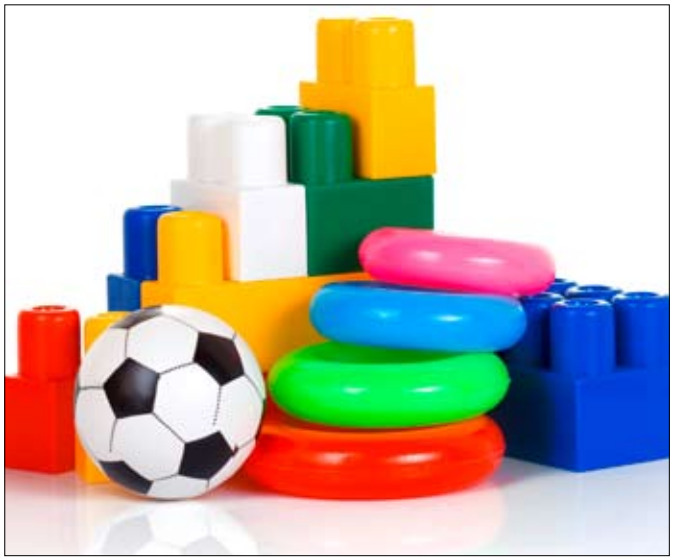
A public consultation on the preliminary opinion was launched on 14 June 2010, which generated a voluminous amount of comments and papers from more than 30 different individuals and organisations. The deadline for submissions was 22 September 2010. In addition, on 17 September 2010, the European Commission held a Hearing on the Fluoridation of Drinking Water (based on the preliminary opinion). A total of 20 representatives of NGOs, individuals, academic institutions, and public authorities took part in this event (mostly from Ireland and the UK).

Risk-benefit analysis and the optimisation of risk assessment in relation to the need of risk managers
The work consists of (i) reviewing the current risk assessment practices, (ii) exploring the needs of risk managers and other stakeholders and (iii) identifying approaches that can provide results which are based on the best available science, and which are informative, consistent, transparent and easy to interpret and communicate. Since the issue is of general interest, experts from other EU bodies dealing with risk assessment and socio-economic issues are also involved.

Interviews with high-level risk managers were conducted in November and December 2010. The objective of this exercise is to collect feedback from actors in the EU decision-making chain on their experience and their expectations from risk assessment.

A public workshop/hearing will be held on 15 June 2011 before the final adoption of the opinion (preliminary deadline: June 2011).

Risks when Tris(2-chloroethyl) phosphate (TCEP) is used in toys
Recently SCHER gave its opinion on the risks from organic CMR substances in toys, stating in particular that the presence of CMR category 2, when characterised by a threshold mechanism, can be accepted, pending a case-by-case evaluation. With the present mandate, the Enterprise Directorate General of the Commission seeks the advice of the Scientific Committee on the expected risks when TCEP is used in toys, parts of toys intended for use by children, or in other toys intended to be placed in the mouth, in the concentrations limit below those set up under the classification and label-



ling legislation and if lower concentration limits should be set for TCEP. The preliminary investigation shows that, in fact, TCEP is no longer used in toys. A possible alternative is tris(2-chloro-1-methyethyl) phosphate (TCPP) for which there is a risk assessment available. The Committee is expected to deliver its opinion by March 2011.

Lead in Drinking Water
Following the reduction of the use of lead in car fuels and in the food processing industry, the Committee was asked to evaluate the rationale for the current 10µg/L limit for lead levels in drinking water and whether a change of the lead standard for drinking water, i.e. relaxing the standard from 10 µg/L to 15 or 20 µg/L, will not cause a potential risk for human health. The reason behind this request is that the strong reduction of the sources of lead other than water makes possible an increase of lead in the drinking water while keeping the same total intake. In its opinion adopted on 11 January 2011, the SCHER states that relaxing the standard from 10 µg/L to 15 or 20 µg/L will cause a risk to human health, especially to the mental and neurological development of children aged 0-14. Therefore, not only should the proposed WHO water concentration limit not be alleviated but a further lowering would be beneficial for European children.

Environmental Quality Standards under the Water Framework Directive
Article 16 of the Water Framework Directive (WFD, 2000/60/EC) requires the Commission to identify priority substances among those presenting significant risks to or via the aquatic environment, to review periodically the list of priority substances, and to set EU Environmental Quality Standards (EQSs) for those substances in water, sediment and/or biota. Article 8 of the EQSD required the Commission to finalise its next review by January 2011, accompanying its conclusion, where appropriate, with proposals to identify new priority substances and to set EQSs for them in water, sediment and/or biota. A shortlist of 19 possible new priority substances was identified in June 2010 and submitted to SCHER by DG Environment for review.

Combination Effects of Chemical Mixtures (SCHER in the lead/SCENIHR/SCCS)
EU Chemicals legislation, in common with the situation in other parts of the world, is based predominantly on assessments carried out on individual substances. However, in reality humans are exposed to a wide variety of chemicals throughout their lives as indeed are animals and plants. While current assessment methods incorporate safety factors to take account of a range of uncertainties, the Commission is concerned to ensure that EU chemicals' legislation takes proper account of the latest scientific information on mixture toxicity. Therefore, SCHER/SCCP/SCENIHR are asked to advise the Commission if different chemical substances to which man/environment are exposed can be expected to act jointly in a way which affects their impact/toxicity on/for man and the environment, and if the current assessment methods take proper account of these joint actions.

A call for information related to this work was launched on 7 July 2010, which resulted in 14 contributions plus 93 attachments by the deadline of 8 September 2010.

Expressing the Uncertainties for Risk Assessment and Risk Management:

An International Perspective
In discussions among EU scientific bodies and their overseas counterparts involved in risk assessment, the approaches to evaluating and expressing uncertainties have been identified for further collaborative work with a particular focus on transparency. As a result, the SCHER, in cooperation with SCENIHR and SCCS members and our Trans-Atlantic partners, is working to provide guidance for the Commission aiming to establish and validate a common global reference framework for the characterisation and expression of uncertainty.

Assessing Human Exposures for Risk Assessment and Risk Management:

An International Perspective
Practical experience has shown that differences in human exposure assessment, due to different approaches, models, data sets, and assumptions, are a key source of uncertainty and divergence in the assessment of risks of chemicals. Thus, there is a clear need to collect and critically examine the different methodologies, tools, and uncertainty analysis techniques for exposure assessment used. The issue of exposure assessment is one of the themes identified as a priority in the context of the Trans Atlantic Dialogue in Risk Assessment and a working Group has been working with the aim to establish and validate a common global reference framework for the exposure assessment of chemicals. As a result, the SCHER, in cooperation with SCENIHR and SCCS members and our Trans-Atlantic partners is working to provide guidance for the Commission aiming to establish and validate a common global reference framework for the characterization and expression of uncertainty.

The work of the Scientific Committees on both the uncertainty and the exposure assessment was presented for public scrutiny at the 2nd International Risk Assessment Conference on 25–28 January 2011.

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

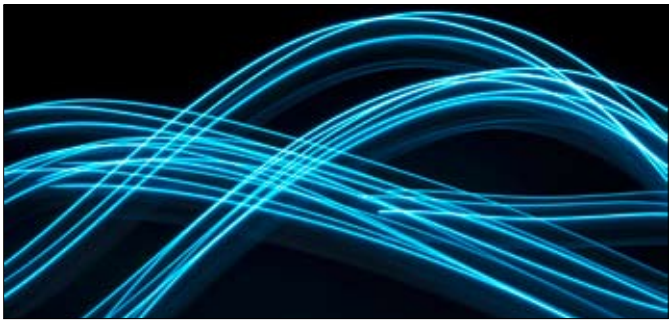
SCIENTIFIC COMMITTEE ON EMERGING AND NEWLY IDENTIFIED HEALTH RISKS (SCENIHR)

The following mandate is currently under evaluation.

Health Effects of Artificial Light

The European Commission has requested a scientific opinion from the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) on health effects of artificial light. This includes a wide range of commonly used lamps, for example halogen lamps, or normal incandescent lamps. The request is made within the context of promoting the wide-spread use of energy saving lamps and phasing-out incandescent lamps. It follows the SCENIHR opinion on Light sensitivity of 23 September 2008.

A consultation on the mandate, resulting in minor changes in wording, and a call for information have been carried out.



The final mandate is available at the following link:
http://ec.europa.eu/health/scientific_committees/emerging/docs/scenihr_q_025.pdf

NEW MANDATES FOR SCCS

Two new mandates have been submitted to SCCS in the framework of its advisory role for adaptation to technical progress of the annexes of the Cosmetics Directive 76/768/EEC.

Ethyl Lauroyl Arginate HCl

This preservative has been evaluated in an earlier opinion to be safe when used in a maximum concentration of 0.4 % in all cosmetic products (excluding products for the lips, oral hygiene products and spray products) and up to 0.8 % in soap, anti-dandruff shampoos, and non-spray deodorants. New information has been submitted recently to support the use of ethyl lauroyl arginate HCL in oral hygiene products and to provide reliable information on dermal absorption to allow revision of the worst case assumption-based exposure assessment in the previous opinion.

Benzoisothiazolinone

In a previous opinion, the information provided on this substance was considered insufficient to allow authorisation as a cosmetic preservative. New data have been made available and the SCCS is requested to assess the safety of Benzoisothiazolinone when used at a concentration of 0.005 % in cosmetic products excluding oral products.

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

NEW AND ONGOING JOINT MANDATES FOR SCENIHR, SCCS AND SCHER

Addressing the new challenges for Risk Assessment

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

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

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

PUBLIC CONSULTATION

Preliminary report open for public consultation.

The SCCS approved on 14 December 2010 a preliminary report on **the potential health risks posed by chemical consumer products resembling food and/or having child-appealing properties.**

Chemical consumer products resembling food and/or having child-appealing properties, such as shower gels, shampoos, body lotions, and soaps are common on the European market. Such products may lead consumers, especially vulnerable groups such as young children or the elderly, to put them in their mouths and/or swallow them. In practice, the determination of the potential health risks of these products has proven to be difficult, due to the large number of elements that need to be taken into account, e.g. the inherent toxicological properties of the ingredients, the probability of the product being confused with food and the amount ingested. In its preliminary report approved for public consultation, the SCCS concluded that the weight of evidence from accidental ingestion of cosmetics suggests that there is a low risk of acute poisoning in either children or the elderly. For household products, there is a slight increase of a more serious outcome. There is a lack of specific data on accidental ingestion from consumer products resembling food and/or having child-appealing properties.

This preliminary report is open for public consultation until 11 February 2011. More information on the public consultation is available on the following web page:
http://ec.europa.eu/health/scientific_committees/consultations/public_consultations/sccs_cons_02_en.htm

Pre-consultation opinion:
http://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_o_047.pdf

E-news:
http://ec.europa.eu/dgs/health_consumer/dyna/enews/enews.cfm?al_id=1098

To subscribe/unsubscribe to the Newsletter please go to the following web link:

http://ec.europa.eu/coreservices/mailing/index.cfm?form=register&serviceid=1

Website:

http://ec.europa.eu/health/index_en.htm

Contact details:

SANCO-C7-newsletter@ec.europa.eu