



# Newsletter of the European Commission Scientific Committees

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## News

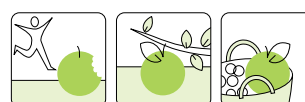
### THE RULES OF PROCEDURE

The Rules of Procedure provide guidance to the Scientific Committees and those who support their work. By defining the appropriate modalities for the operation of the Committees and the Pool of Scientific Advisors, the rules aim at ensuring the effective functioning of the advisory structure according to the principles of excellence, independence, transparency and confidentiality and established scientific principles. They describe and regulate the role and functioning of the Scientific Committees, their Working Groups, the Pool of Scientific Advisors, the role of Members, Scientific Advisors and external experts, as well as the role and responsibilities of the Secretariat of the Scientific Committees and the Interservice Co-ordination Group. They were substantially revised at the start of the new

Scientific Advisory Structure in 2009 and include more detailed provisions on transparency, the stakeholder dialogue and coordination between the Scientific Committees.

The current version of the Rules of Procedure was agreed at a common session of the three Scientific Committees on 20 November 2009 and subsequently approved by the members of these Committees via written procedure. It may be further updated in the future, should it be considered necessary by the Scientific Committees and Commission Services.

You may find information on the Rules of Procedure at:  
[http://ec.europa.eu/health/scientific\\_committees/docs/rules\\_procedure\\_en.pdf](http://ec.europa.eu/health/scientific_committees/docs/rules_procedure_en.pdf)



## REVIEW OF EVENTS

### **3rd Annual Nanotechnology "Safety for Success" Dialogue Workshop, Brussels, 3 and 4 November 2009**

DG SANCO has been successfully conducting the Safety-for-Success Nano Dialogues in three consecutive years (2007, 2008, and 2009). Each year the Dialogue was structured differently with the aim of addressing different aspects of the public perception of and interest in nanotechnology. The latest, 3rd edition of the Dialogue benefited for its preparation from the input of a Steering Committee. Again, it brought together scientists, risk assessors, public authorities, industry, and consumer and environmental NGOs to examine and discuss issues related to the use of nanotechnologies. In contrast with previous editions, this year, the Dialogue focused on the examination of four case studies: TiO<sub>2</sub> in sunscreens/cosmetics, Nanoparticles in paint, Carbon nanotubes, and Nanosilver in textiles. The main objective was to contribute to the gradual increase of the public trust in nanotechnology.



The concrete, product-focused approach to the Dialogue was overwhelmingly accepted and hailed as a major step forward by practically all participants in the event. DG SANCO's Director General, Mr. Robert Madelin closed the Dialogue by proposing to follow-up the event with small-scale and more narrowly focused "conversations" and issuing a call for suggestions regarding the topics to be considered. After an investigative study of the submissions to this call, the Commission services in cooperation with industry, and consumer and environmental NGOs will announce two upcoming conversations planned for June and October 2010. Given the increased public interest in the application of nanotechnology in the food industry, this topic will most likely be the first subject of a nano conversation. Consequently, the next (full-scale) Safety-for-Success Nano Dialogue is expected to take place during the first trimester of 2011.

The program, the presentations, and main conclusions of the Dialogue may be found at:

[http://ec.europa.eu/health/nanotechnology/events/ev\\_20091103\\_en.htm](http://ec.europa.eu/health/nanotechnology/events/ev_20091103_en.htm)

### **MEETING OF CHAIRS/SECRETARIATS OF EU RISK ASSESSMENT BODIES, BRUSSELS, 18 AND 19 NOVEMBER 2009**

The 5th Meeting of Chairs and Secretariats of EU Scientific Committees and Panels involved in Risk Assessment took place in Brussels on 18 and 19 November 2009.

The three objectives of this annual meeting were: a) to introduce and discuss two new subjects, synthetic biology and the next generations of nanotechnologies as well as their implications for risk assessment; b) to review progress with the action points decided at previous meetings, and c) to discuss the future of the Chairs' collaboration and take decisions in that respect. In addition, broader dialogue with the Chairs and Vice-Chairs of some of the EP Committees took place on 18 November.

In the afternoon of 19 November, a special session regarding the progress and perspectives on alternative test methods took place, covering, inter alia, new approaches in the field, such as computational toxicology, toxicogenomics etc.

[http://ec.europa.eu/health/dialogue\\_collaboration/events/ev\\_20091118\\_en.htm](http://ec.europa.eu/health/dialogue_collaboration/events/ev_20091118_en.htm)

### **RISK ASSESSMENT DAY, BRUSSELS, 20 NOVEMBER 2009**

The Directorate General for Health and Consumers of the European Commission organised on 20 November 2009 the third edition of a stakeholder dialogue session with the participation of members of the three Scientific Committees.

The objective of this session was to promote dialogue between the scientists advising the Commission on risk assessment and European stakeholders. The discussion focused on the organisation and functioning of the stakeholders' dialogue procedure, which was introduced following the first session held in 2007. Furthermore, the Chairs of the Committees provided information on on-going activities. Participating stakeholders had the opportunity to clarify issues of concern regarding the work of the Scientific Committees, and to propose areas and themes for possible future activities.

You may read more about this event on the following webpage:

[http://ec.europa.eu/health/risk\\_assessment/events/ev\\_20091120\\_en.htm](http://ec.europa.eu/health/risk_assessment/events/ev_20091120_en.htm)

# News

## **SYNTHETIC BIOLOGY WORKSHOP, BRUSSELS, 18 AND 19 MARCH 2010**

The European Commission organised a workshop on "Synthetic Biology: From Science to Governance" in March 2010. This workshop brought together leading scientists, as well as experts on ethical, social and legal issues, in order to discuss about this emerging field of research.



The first day of the workshop -with a keynote speech from Prof. Kitney, Imperial College- focussed on the major technological developments in a wide range of activities and applications arising from synthetic biology. Presentations included updates on recent developments in health, environment and energy. The day finished with a debate on the definition and scope of the term "synthetic biology", the current state of the science, as well as expected future developments and applications from research in this field.

The second day -with a keynote speech from Prof. Hermerén, Lund University- evolved around the main challenges for governance that might arise from synthetic biology applications. A special session focussed on the possible governance needs, as well as on setting the basis for concrete governance approaches. Presentations touched upon related issues, including intellectual property rights, ethics, and public perception. The workshop finished with a roundtable debate on the main governance approaches and challenges for/from synthetic biology.

You may read more about this event on the following webpage: [http://ec.europa.eu/health/dialogue\\_collaboration/events/ev\\_20100318\\_en.htm](http://ec.europa.eu/health/dialogue_collaboration/events/ev_20100318_en.htm)

## **EVENTS COMING UP**

### **WORKSHOP ON EXPRESSION OF UNCERTAINTY AND RISK OTTAWA, 2 – 4 JUNE 2010**

As a follow-up to the 5th Meeting of Chairs and Secretariats held in Brussels (18-19 November 2009) and as a prelude to the 2nd International Conference on Risk Assessment to be organised by the European Commission (DG SANCO) in Brussels in January 2011, an International Working Group on Evidence, Uncertainty and Expression of Risk was inaugurated in a trans-Atlantic teleconference

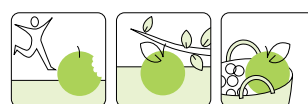
on 19 January 2010. Participants include experts from the EU, the US and Canada. The overall goals of this effort are to promote a better common understanding on the approaches related to the transparent characterization of uncertainty through the exchange of information, expert discussion, the use of a case-study approach, and the establishment of common recommendations. The first face-to-face meeting of the group is tentatively planned to occur during a workshop on 2 – 4 June 2010 in Ottawa, Canada.

## **PRE-ANNOUNCEMENT**

### **2ND INTERNATIONAL CONFERENCE ON RISK ASSESSMENT BRUSSELS, 26 – 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) plans to organise a 2nd Conference in Brussels on 26-28 January 2011. The Conference will aim 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 is 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 will be on scientific risk assessment as a central element of the risk analysis paradigm. The programme and a dedicated internet site for further information and registration details will become available in the first part of 2010 when the practical arrangements will be fully in place.



# The Scientific Committees

## OPINIONS

### SCCS SCIENTIFIC COMMITTEE ON CONSUMER SAFETY

The Annexes to Council Directive 76/768/EEC on cosmetic products list banned or restricted substances 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

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

2-Amino-4-hydroxyethylaminoaniline sulfate (A84)

HC Red n° 7 (B36)

HC Yellow n° 4 (B38)

Hydroxyethyl-3,4-methylenedioxyaniline HCl (A98)

Hydroxypropyl bis(N-hydroxyethyl-p-phenylenediamine) HCl (A121)

Hair dyes that **do pose a risk** to the health of the consumer under the intended use conditions

5-Amino-6-chloro-o-cresol (A94)



The hair dye opinions are available at:

[http://ec.europa.eu/health/scientific\\_committees/consumer\\_safety/opinions/index\\_en.htm#2](http://ec.europa.eu/health/scientific_committees/consumer_safety/opinions/index_en.htm#2)

#### Preservatives

##### Citric acid and silver citrate

The SCCS re-assessed the safety of this novel preservative in cosmetic products after new data, requested in the previous opinion of January 2009, had been submitted. The critical endpoint for silver toxicity is the risk of silver deposition in the skin (argyria). Although available toxicity data in relation to silver, on which various regulatory limits are based, are very limited and old, the SCCS acknowledged that exposure to silver from this cosmetic preservative would be low and concluded that the use of citric acid (and) silver citrate as a preservative in cosmetic products and an ingredient in deodorants at a concentration up to 0.2% does not pose a risk to the health of the consumer. However, the SCCS maintained its concern with regard to increased consumer exposure to silver following its widespread use in a variety of products and the recommendation for an aggregate exposure and risk assessment.

The adopted opinion is available at:

[http://ec.europa.eu/health/scientific\\_committees/consumer\\_safety/docs/sccs\\_o\\_004.pdf](http://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_o_004.pdf)

##### Methylchloroisothiazolinone and methylisothiazolinone (3:1)

The SCCS re-assessed the safety of this preservative following a request of national authorities. The mixture of methylchloroisothiazolinone and methylisothiazolinone (MCI/MI) is well recognised as a skin sensitiser. While it is currently permitted up to a concentration of 0.0015% in all cosmetic products, the new application only covers the use in rinse-off products (i.e. products that do not stay in contact with the skin for an extended time period, such as shower gels and shampoos). The SCCS concluded that MCI/MI does not pose a risk to the health of the consumer at the maximal use concentration of 0.0015 % in rinse-off cosmetic products. The induction and elicitation of skin allergy would be less likely in a rinse-off product than when the same concentration is present in a leave-on product.

The adopted opinion is available at:

[http://ec.europa.eu/health/scientific\\_committees/consumer\\_safety/docs/sccs\\_o\\_009.pdf](http://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_o_009.pdf)

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

The SCCS, in a previous opinion of March 2007, had expressed concerns with regard to the irritative potential of this preservative. Additional information has been submitted by the applicant with the aim to prove the safety of the ingredient at the intended use conditions. In its revised assessment, the SCCS concluded that, although a irritative potential of the substances exist, the use of cetrimonium chloride, stearyltrimonium chloride and behentrimonium chloride does not pose a risk to the health of the consumer under the following concentration limits: Cetrimonium chloride (C16), stearyltrimonium chloride (C18): in rinse-off hair care products up to 2.5%, in leave-on hair care products up to 1.0%, in leave-on facial cream products: up to 0.5% of both substances; Behentrimonium chloride (C22): In rinse-off hair care products up to 5.0%, in leave-on hair care and facial cream products up to 3.0%.

The adopted opinion is available at:

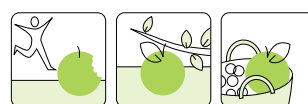
[http://ec.europa.eu/health/scientific\\_committees/consumer\\_safety/docs/sccs\\_o\\_012.pdf](http://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_o_012.pdf)

#### Other cosmetic ingredients

##### Choline salts and esters

The SCCS was asked to provide clarification on the scope of entry II/168 of the Cosmetics Directive 76/768/EEC "choline salts and their esters, e.g. choline chloride", since there were inconsistencies in the interpretation of this entry as well as inaccuracies in the different language versions of this entry.

The SCCS concluded that based on their structural and chemical properties, the following substances listed in the Terms of Reference should fall under the scope of entry II/168: Choline fenofibrate, choline salicylate, choline gluconate, choline theophylline, choline esters of stearic acid and other long alkyl chain carboxylic acids, methylcholine and its salts and esters.





# The Scientific Committees



In contrast, the following substances should not be considered to fall under the scope of entry II/168: Glycerophosphocholine, phosphatidylcholine, lecithin, hydrogenated lysophosphatidylcholine, hydrogenated phosphatidylcholine, and polyphosphorylcholine glycol acrylate.

The adopted opinion is available at:

[http://ec.europa.eu/health/archive/ph\\_risk/committees/04\\_sccs/docs/sccs\\_o\\_002.pdf](http://ec.europa.eu/health/archive/ph_risk/committees/04_sccs/docs/sccs_o_002.pdf)

## Memoranda

### Memorandum on alternative test methods in human health safety assessment of cosmetic ingredients in the European Union

With this memorandum, the SCCS draws the attention of the European Commission to the situation with regard to the availability of alternative methods for safety testing. The performance of animal tests to prove the safety of cosmetic ingredients has been banned in the European Union from March 2009. Presently, for some toxicological endpoints data generated outside of the EU can still be included in safety dossiers, but this possibility will end in 2013. The memorandum lists the alternative methods currently available and the perspective for obtaining new methods in the near future. The SCCS concludes that for five relevant endpoints validated replacement alternative methods exist, but that for other endpoints, which are critical for safety assessment of cosmetic ingredients, such methods are not available. A full human health risk assessment based on replacement methods can therefore not be performed at the present time.

The memorandum is available at:

[http://ec.europa.eu/health/scientific\\_committees/consumer\\_safety/docs/sccs\\_s\\_001.pdf](http://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_s_001.pdf)

## SCHER

SCIENTIFIC COMMITTEE ON HEALTH AND ENVIRONMENTAL RISKS

### Model implementation and quantification of the eutrophication risk associated to the use of phosphates in detergents (INIA/Green Planet – report April 2009)

In November 2007, SCHER adopted an opinion on the INIA study entitled: "Development of a European Quantitative Eutrophication Risk Assessment of Polyphosphates in Detergents". In that opinion SCHER concluded that although the model represented a useful tool to assess the risks of eutrophication due to phosphorus release, the scientific quality of the report needs to be improved. Therefore and in line with SCHER's recommendation, the rapporteur updated the report for resubmission to the Scientific Committee in May 2009.

In the opinion adopted in November 2009, SCHER recognizes the improvements of the report in terms of assumptions and data used for the development and validation of the INIA/Green Planet model. However, SCHER emphasizes that the applicability of the model, provided that certain issues related to data quality are resolved, is limited to its intended use, i.e. a pan-European generic assessment of the risk of eutrophication due to detergents.



The opinion is available at:

[http://ec.europa.eu/health/scientific\\_committees/environmental\\_risks/opinions/scher\\_o\\_116.pdf](http://ec.europa.eu/health/scientific_committees/environmental_risks/opinions/scher_o_116.pdf)

### Updated HERA Report on Polycarboxylates in Detergents (HERA report April 2009, version 2)

The updated HERA report on polycarboxylates in detergents addressed some of the drawbacks highlighted in the previous SCHER opinion. However, some major concerns still remain on data gaps and the inadequate interpretation of the available information. SCHER recognises the complexity associated with the environmental risk assessment of these polymers, but considers that the available evidence, in particular related to exposure and solubility behaviour of these polymers, has not been adequately considered in the report.

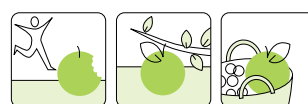
SCHER considers that, based on the available information, a potential environmental risk may be identified. It disagrees with the conclusions of the HERA report. Moreover, SCHER considers that additional information and a proper risk assessment, fully considering the specific characteristics of the polycarboxylate polymers, should be required before concluding that these chemicals are of low environmental concern.

The opinion is available at:

[http://ec.europa.eu/health/scientific\\_committees/environmental\\_risks/docs/scher\\_o\\_117.pdf](http://ec.europa.eu/health/scientific_committees/environmental_risks/docs/scher_o_117.pdf)

You may find all information about the work of the Committees, on the opinions and the mandates (requests) via the following webpage:

[http://ec.europa.eu/health/scientific\\_committees/policy/index\\_en.htm](http://ec.europa.eu/health/scientific_committees/policy/index_en.htm)



# The Scientific Committees

## SCENIHR SCIENTIFIC COMMITTEE ON EMERGING AND NEWLY IDENTIFIED HEALTH RISKS

### **Antimicrobial resistance (AMR) focussed on zoonotic infections based on the information currently available**

Conclusions of the Council, adopted in June 2008, call upon the Commission and Member States to act in the area of healthcare associated infections, monitoring and control of AMR in humans and animals/food. To get an overview about the scientific state of play in the area of AMR, the European Centre for Disease Prevention and Control (ECDC), the European Food Safety Authority (EFSA), the European Medicines Agency (EMA) and the SCENIHR were requested to provide a common scientific report on a set of related questions. The report considered the scientific opinions that were recently published by European and international scientific bodies. It focused on infections transmitted to humans from animals and food. The joint opinion calls for strengthening surveillance activities, for developing new antimicrobials and for encouraging new strategies to combat the

spread of resistance and foster a prudent use of these products. It also notes that research is needed on other strategies to control infectious diseases in animals, such as vaccination programmes. There is some evidence that bacterial resistance to antibiotics may emerge not only from the use of antibiotics but also from the use of biocides. As a result, the latest scientific advice recommends an approach built around the understanding of resistance mechanisms that considers simultaneously the genetic and biochemical aspects, antibiotics and biocides, as well as environmental, veterinary and medical aspects.

The opinion was adopted by all participating bodies at the end of October 2009 by written procedure. It is available at the following webpage:

[http://ec.europa.eu/health/scientific\\_committees/emerging/opinions/scenih\\_r\\_o\\_026.pdf](http://ec.europa.eu/health/scientific_committees/emerging/opinions/scenih_r_o_026.pdf)

## ONGOING WORK

## SCCS SCIENTIFIC COMMITTEE ON CONSUMER SAFETY

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 33 hair dye remain to be performed. In addition, supplementary data on 9 substances that have been initially evaluated have been received and await assessment.

### **Preservatives**

Ethyl lauroyl arginate  
Triclosan (antimicrobial resistance and toxicity)

### **UV-filters**

Titanium dioxide (nano-form)  
ETH-50  
HAA299 / C-1332  
Polysilicone-15 (Evaluation of inhalation toxicity)

### **Fragrances**

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

### **Other cosmetic ingredients**

Cyclomethicone (D4/D5)  
Erythrosine  
Melatonin  
Phytonadione (vitamin K1)  
Zinc pyrithione

### **Consumer products**

Potential health risks posed by of food imitating and child-appealing chemical consumer products

### **Methodologies**

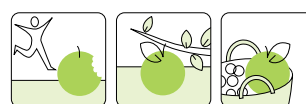
The use of the Threshold of Toxicological Concern (TTC) approach for the safety assessment of chemicals

## NEW MANDATES FOR SCCS

### **Assessment of boron compounds newly classified as mutagenic and/or toxic to reproduction**

A number of boron compounds have recently been classified as mutagenic and/or toxic for reproduction, in the latter case with specific concentration limits. These specific concentration limits set for the boron compounds

indicate that thresholds for the reproductive toxicity could be established. Boric acid, borates and tetraborates are regulated in the Cosmetics Directive 76/768/EEC with maximum use concentrations. The SCCS is asked to review the safety of use of the classified boron compounds as cosmetic ingredients.



# The Scientific Committees

## Assessment of sodium perborate and perboric acid newly classified as toxic to reproduction

Sodium perborate and perboric acid have recently been classified as toxic to reproduction (category 2 and 3) with specific concentration limits. Following an application for the continued use of sodium perborate in specific cosmetic uses, the SCCS is asked to evaluate the safety of these ingredients.

## Diethyleneglycol monoethyl ether (DEGEE)

The Committee has previously evaluated DEGEE and found safe for certain use levels and applications. The SCCS is asked to re-evaluate the safety of DEGEE at increased use concentrations based on new data submitted.

## Dihydroxyacetone (DHA)

Dihydroxyacetone is used as an ingredient in self-tanning

cosmetic products up to a concentration of 5.0%. In addition, dihydroxyacetone is also used in "spray cabins" in aqueous solutions in concentrations between 8 and 14%. The SCCS is asked to evaluate the safety of these applications.

## Methenamine 3-chloroallylochloride

Methenamine 3-chloroallylochloride, or Quaternium-15, is used as a preservative in cosmetic products. It has recently been classified as toxic to reproduction (category 3). For this reason, the SCCS is asked to evaluate the safety of its use in cosmetic products up to a concentration of 0.2%.

All mandates of the SCCS are available on:

[http://ec.europa.eu/health/scientific\\_committees/consumer\\_safety/requests/index\\_en.htm](http://ec.europa.eu/health/scientific_committees/consumer_safety/requests/index_en.htm)

## SCHER SCIENTIFIC COMMITTEE ON HEALTH AND ENVIRONMENTAL RISKS

### Depleted Uranium (DU)

In 2008, the European Parliament passed a resolution on DU weapons which called on the Commission to promote scientific studies to examine the possible negative effects of DU on human health and the environment. Therefore, in May 2009 the Commission asked the SCHER for scientific advice on the environmental and health risks posed by depleted uranium. Depleted uranium is a by-product of uranium enrichment less radioactive than uranium but retaining the chemical properties of natural uranium. As a consequence, it is generally agreed that the chemical toxicity of uranium is the major hazard to be considered when assessing health risks from potential exposures to DU: therefore, the toxicity data on natural uranium can be applied to assess potential human health risks from DU-exposures. SCHER agrees that any synergy between chemical toxicity and radioactivity is also expected to be less pronounced with DU as compared to natural uranium due to the lower radioactivity of DU.

The preliminary opinion is mostly completed and, due to the public concern about the toxic effects of DU on humans and the environment following military use of DU, it will be published for public consultation upon approval by SCHER by the end of February 2010.

The mandate is available at: [http://ec.europa.eu/health/archive/ph\\_risk/committees/04\\_scher/docs/scher\\_q\\_085.pdf](http://ec.europa.eu/health/archive/ph_risk/committees/04_scher/docs/scher_q_085.pdf)

### Human health and environmental risks associated with the drinking water fluoridation.

Following several questions from the European Parliament, from Ireland and from the United Kingdom where intentional water fluoridation is still practiced, the Commission has requested the SCHER in March 2009 to examine the risks associated with intentional drinking water fluoridation. SCHER, with the collaboration of external experts and representatives of community bodies, is addressing inter alia the following points: risk for dental fluorosis in young children vs. caries reduction, the possible link between fluoride in drinking water and osteosarcoma, the development and functions of the brain at high concentrations, as well as carcinogenic and reproductive effects.

The preliminary scientific opinion will be published around the end of March 2010 for public consultation.

The mandate is available at: [http://ec.europa.eu/health/archive/ph\\_risk/committees/04\\_scher/docs/scher\\_q\\_084.pdf](http://ec.europa.eu/health/archive/ph_risk/committees/04_scher/docs/scher_q_084.pdf)

### Heavy metals in jewellery

SCHER has been requested to evaluate the Danish Environmental Protection Agency (EPA) report which analysed a number of jewellerys for their release of heavy metals. Since most of those metals are already regulated by EU legislation, SCHER focused its evaluation only on parts related to the release of lead that, for these specific products, is not covered by legislation at European level. The opinion will be adopted by the end of March 2010.

The mandate is available at:

[http://ec.europa.eu/health/archive/ph\\_risk/committees/04\\_scher/docs/scher\\_q\\_086.pdf](http://ec.europa.eu/health/archive/ph_risk/committees/04_scher/docs/scher_q_086.pdf)

### Mercury in energy-saving light bulbs

SCHER is asked to assess the possible health risks to consumers from the mercury released from accidental breakage of compact fluorescent lamps (CFLs) and the risk to the environment from the mercury liberated upon disposal of CFLs.



The main points under discussion are related to the possible reduction of mercury emissions from coal-based power plants due to the lower electricity consumption of CFLs compared to conventional household lamps (Term of Reference point D) and some environmental issues (mostly arising from the lack of information).

The mandate is available at:

[http://ec.europa.eu/health/archive/ph\\_risk/committees/04\\_scher/docs/scher\\_q\\_087.pdf](http://ec.europa.eu/health/archive/ph_risk/committees/04_scher/docs/scher_q_087.pdf)

# The Scientific Committees

## **Risk from organic CMR substances in polymeric toy materials**

The limits for most organic CMRs in toys are set at the individual concentration limits established for the classification of CMR substances in mixtures. The Commission would like to establish a sound scientific basis for setting safe limits for the presence of organic CMR substances in toys.

In case SCHER is of the opinion that the development of additional standardized testing procedures is necessary to obtain reliable migration data, the opinion should also provide sufficient guidance to ensure that a suitable specification can be provided to the European Committee for Standardization (CEN).

The opinion is foreseen for adoption by the end of April and will be used as a basis for other Commission mandates on toys such as the mandate on the Risk from the use of diantimony trioxide in toys.



The mandates for these two opinions are available at:

[http://ec.europa.eu/health/scientific\\_committees/environmental\\_risks/docs/scher\\_q\\_088.pdf](http://ec.europa.eu/health/scientific_committees/environmental_risks/docs/scher_q_088.pdf)

and

[http://ec.europa.eu/health/scientific\\_committees/environmental\\_risks/docs/scher\\_q\\_089.pdf](http://ec.europa.eu/health/scientific_committees/environmental_risks/docs/scher_q_089.pdf)

## **NEW MANDATES FOR SCHER**

### **Risk-benefit assessment and the optimization 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. Moreover, the participation of risk managers and other stakeholders is foreseen at different stages of the process. A public consultation on the preliminary opinion and the organisation of a workshop are foreseen before the final adoption of the opinion (preliminary deadline: June 2011).

The mandate is available at:

[http://ec.europa.eu/health/scientific\\_committees/environmental\\_risks/docs/scher\\_q\\_090.pdf](http://ec.europa.eu/health/scientific_committees/environmental_risks/docs/scher_q_090.pdf)

### **Evaluation of migration limits of elements in toys**

The recent Toys Safety Directive establishes that migration limits for some elements shall not exceed certain listed values, depending on the material used. However, the elements can be used if the toy or components of the toy exclude any hazard to children. The Commission has asked SCHER to evaluate the sound scientific basis for setting safe migration limits for 19 elements. The adoption of the opinion is asked by July 2010.

The mandate is available at:

[http://ec.europa.eu/health/scientific\\_committees/environmental\\_risks/docs/scher\\_q\\_091.pdf](http://ec.europa.eu/health/scientific_committees/environmental_risks/docs/scher_q_091.pdf)

Mandates for SCHER are available at:

[http://ec.europa.eu/health/scientific\\_committees/environmental\\_risks/requests/index\\_en.htm](http://ec.europa.eu/health/scientific_committees/environmental_risks/requests/index_en.htm)

## **SCENIHR**

SCIENTIFIC COMMITTEE ON EMERGING AND NEWLY IDENTIFIED HEALTH RISKS

### **Addictiveness and Attractiveness of Tobacco Additives**

Article 12 of the Tobacco Products Directive (2001/37/EC) invites the Commission to submit a proposal providing a common list of ingredients authorised for tobacco products, taking into account, inter alia, their addictiveness.

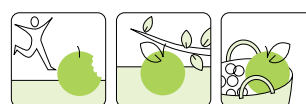
In its comments to a Green Paper<sup>1</sup>, the European Parliament invited the Commission to propose an amendment to the Tobacco Products Directive (2001/37/EC) including an evaluation and authorisation procedure for tobacco additives and an immediate ban on all additives that are addiction-

enhancing. In its 2nd Report on the implementation of the Tobacco Products Directive the Commission stressed the need for further work on addictiveness. DG SANCO would like to obtain a better understanding of the criteria based on which an additive can be considered (classified) as addictive and/or attractive, the role of additives in tobacco products and the role of design features in the attractiveness and addictiveness of a tobacco product. A call for information closed on 11 January 2010. The WG is currently assessing the 18 documents received from 9 contributors.

The mandate is available at the following webpage:

[http://ec.europa.eu/health/archive/ph\\_risk/committees/04\\_scenihhr/docs/scenihhr\\_q\\_020.pdf](http://ec.europa.eu/health/archive/ph_risk/committees/04_scenihhr/docs/scenihhr_q_020.pdf)

<sup>1</sup> "Towards a Europe free from tobacco smoke: policy options at EU level" [http://ec.europa.eu/health/ph\\_overview/health\\_forum/docs/ev\\_20071128\\_rd03\\_en.pdf](http://ec.europa.eu/health/ph_overview/health_forum/docs/ev_20071128_rd03_en.pdf)





# The Scientific Committees

## The safety of reprocessed single-use medical devices

The development and use of single-use<sup>2</sup> medical devices has been supported by the emergence of blood transmitted diseases and nosocomial infections on the one hand and technological developments on the other hand. Triggered by increasing pressure to reduce costs, some single-use medical devices are being reprocessed. The reprocessing practice of single-use medical devices is not regulated at the Community level for the time being and is handled quite differently by the Member States. To address the concerns raised regarding patient safety and to clarify the notion of single-use, Directive 2007/47/EC<sup>3</sup> provided further clarification on the definition of the term 'single use', and introduced new requirements for single-use medical devices. In addition to these requirements and to ensure that the reprocessing does not endanger patients' safety or health, the Commission has asked the SCENIHR to assess the potential risk of reprocessed single-use medical devices for patients' health. A call for information closed on 15 December 2009 and the WG is currently assessing the approximately 80 documents received from 18 contributors.



methods to evaluate the ability of a biocide to induce/select for resistance against biocides and antibiotics and environmental studies focussing on the identification and characterisation of resistance and cross-resistance to antibiotics following use and misuse of biocides. Anti-microbial resistance AMR remains a sensitive political subject and more research is needed to address the issues identified. To allow the Commission to propose the most relevant research topics on this issue for future funding, the SCENIHR is requested to further develop the research recommendations presented in its earlier opinion and to propose a research strategy.

All SCENIHR mandates are available at:

[http://ec.europa.eu/health/scientific\\_committees/emerging/requests/index\\_en.htm](http://ec.europa.eu/health/scientific_committees/emerging/requests/index_en.htm)

## Health Effects of Artificial Light

A working mandate on the Health Effects of Artificial Light has been presented to SCENIHR. According to the provisions of the Rules of Procedure of the Scientific Committees, the working mandate regarding an opinion on the health effects of artificial light has been under a public consultation from 3 December until 4 January 2010. Commission services are currently evaluating the 16 contributions in order to finalise the mandate that will be published on SCENIHR's webpage. The working version of the mandate can be found here:

[http://ec.europa.eu/health/ph\\_risk/committees/04\\_scenihr/docs/scenihr\\_q\\_023.pdf](http://ec.europa.eu/health/ph_risk/committees/04_scenihr/docs/scenihr_q_023.pdf)

## Position Paper

### Methodology / Weight of Evidence Approach

The SCENIHR is currently developing a self-standing paper to describe the methodology and the weighting of evidence approach used in the risk assessments performed. Thereby, SCENIHR would like to respond to increasing demands of stakeholders to improve the transparency of individual risk assessments by explaining how individual papers have been selected and weighed and how the findings have been integrated to reach the final conclusions. It should also consider the issue of expressing uncertainties. Upon finalization, a common approach will be discussed with SCCS and SCHER. The document should also contribute to the global dialogue on risk assessment.



The mandate is available at the following webpage:

[http://ec.europa.eu/health/ph\\_risk/committees/04\\_scenihr/docs/scenihr\\_q\\_021.pdf](http://ec.europa.eu/health/ph_risk/committees/04_scenihr/docs/scenihr_q_021.pdf)

## Research strategy to address the knowledge gaps on the antimicrobial resistance effects of biocides

Recent scientific evidence suggests that during the last decade, antibiotic resistance has increased worldwide leading to treatment failures in humans and animals. In its earlier opinion delivered in January 2009<sup>4</sup>, the SCENIHR confirmed that at least some resistance mechanisms are common to both biocides and antibiotics. Scientific evidence does indicate that the use of active molecules in biocidal products may contribute to the increased occurrence of antibiotic resistant bacteria. The SCENIHR had also identified a number of data and knowledge gaps to be filled, in particular regarding quantitative exposure data,

<sup>2</sup> Directive 2007/47/EC defines a 'single-use' medical device as 'a device intended to be used once only for a single patient'

<sup>3</sup> <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2007:247:0021:0055:EN:PDF>

<sup>4</sup> [http://ec.europa.eu/health/archive/ph\\_risk/committees/04\\_scenihr/docs/scenihr\\_q\\_021.pdf](http://ec.europa.eu/health/archive/ph_risk/committees/04_scenihr/docs/scenihr_q_021.pdf)

# The Scientific Committees

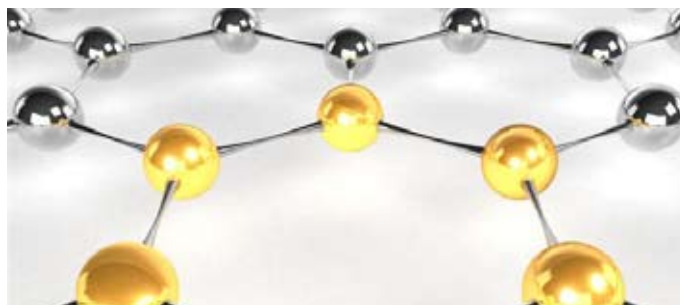
## NEW MANDATES FOR SCENIHR

### Nanodefinitions

The services of the European Commission are asking SCENIHR for advice on the types of novel physical and chemical properties that may appear at the nanoscale, the relevant thresholds, and the most appropriate metrics to express such thresholds, in support of the preparation of a science-based definition of nanomaterials.

The mandate will be available at the following webpage:

[http://ec.europa.eu/health/scientific\\_committees/emerging/docs/scenih\\_r\\_q\\_024.pdf](http://ec.europa.eu/health/scientific_committees/emerging/docs/scenih_r_q_024.pdf)



## PUBLIC CONSULTATIONS

### **PUBLIC CONSULTATION ON THE WORKING MANDATE ON HEALTH EFFECTS OF ARTIFICIAL LIGHT**

According to the provisions of the Rules of Procedure of the Scientific Committees, the working mandate for an opinion on the health effects of artificial light has been in public consultation from 3 December until 4 January 2010. Commission services are currently evaluating the 16 contributions in order to finalise the mandate, which will be published on SCENIHR's webpage.

The working version of the mandate can be found here:

[http://ec.europa.eu/health/ph\\_risk/committees/04\\_scenih\\_r/docs/scenih\\_r\\_q\\_023.pdf](http://ec.europa.eu/health/ph_risk/committees/04_scenih_r/docs/scenih_r_q_023.pdf)

### **PUBLIC CONSULTATION ON A PRELIMINARY OPINION ON ENVIRONMENTAL AND HEALTH EFFECTS POSED BY DEPLETED URANIUM**

In line with its procedures for stakeholder dialogue the European Commission has launched a public consultation on the preliminary opinion. All interested parties are invited to submit their comments and proposals on the preliminary opinion via the following website:

<http://ec.europa.eu/yourvoice/ipm/forms/dispatch?form=depleted-uranium>

The deadline for submission of comments is **12 April 2010**. Please note that only comments submitted in accordance with the Rules of Procedure of the Scientific Committees (Annex IV) will be taken into account.

### **CALL FOR EXPRESSION OF INTEREST FOR EXPERTS IN BEHAVIOURAL PSYCHOLOGY.**

In line with the Rules of procedure of the Scientific Committees, a call for expression of interest for experts in this topic is launched on basis of a mandate on possible health risks from food-imitating and child-appealing chemical consumer products. Experts with relevant professional experience in the area are invited to register to the database of experts. Please find more information and the application form here:

[http://ec.europa.eu/health/scientific\\_committees/consultations/calls\\_experts/sccs\\_exp\\_01\\_en.htm](http://ec.europa.eu/health/scientific_committees/consultations/calls_experts/sccs_exp_01_en.htm)

Deadline for submission of applications: **9 April 2010**.

**To subscribe/unsubscribe to the Newsletter please go to the following web link:**  
<http://ec.europa.eu/coreservices/mailling/index.cfm?form=register&serviceid=1>

**Website:**  
[http://ec.europa.eu/health/index\\_en.htm](http://ec.europa.eu/health/index_en.htm)

**Contact details:**  
[SANCO-C7-newsletter@ec.europa.eu](mailto:SANCO-C7-newsletter@ec.europa.eu)

