As from March 2009 the following three newly established Scientific Committees took 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 Risks (SCENIHR)

Each Committee is composed of 17 members and includes both members of the preceding Committees and new experts. The rate of the renewal of the Committees was nearly 50%. The following experts have been appointed as chairs and vice-chairs:

SCCS: Dr. Ian White, chair; Prof. Vera Rogiers, vice-chair; Prof. Tore Sanner, vice-chair.

SCHER: Prof. Em. Helmut Greim, chair; Prof. Herman Autrup, vice-chair; Prof. Peter Calow was nominated as the new Vice-chair of the SCHER committee in its plenary meeting on 18 September 2009, following the resignation of Dr José V. Tarazona.

SCENIHR: Prof. James Bridges, chair; Dr Wim De Jong, vice-chair; Prof. Philippe Hartemann, vice-chair.
The core element of the Scientific Committees’ work is the development and drafting of scientific opinions at the request of the Commission. In addition, the Commission may also request the Committees to provide rapid advice on the state of scientific knowledge concerning specific risks in case of urgent need. The Scientific Committees may also be called upon to identify research needs and assess research results in relation to the subject areas covered by its fields of competences.

In order to support the work of the Committees, the European Commission has set up and manages a Database of Experts. This Database is permanently open to scientists who wish to contribute to the work of the Scientific Committees on an ad hoc basis, on specific issues, as members of working groups or on the occasion of scientific hearings and workshops. Members of the working groups actively contribute to scientific discussions, examine documents, make comments during meetings, and may act as “rapporteurs” for the preparation of opinions. Meetings usually take place in Brussels.

Furthermore, the Scientific Committees may decide to set up thematic workshops in order to review data and scientific knowledge on particular risks or on broad risk assessment issues. Finally, on their own initiative, the Committees can draw the Commission’s attention to a specific or emerging problem falling within their remit, which they consider may pose an actual or potential risk to consumer safety, public health or the environment, by adopting and addressing to the Commission memoranda or position statements.

You may find information on the database at:

The European Commission Scientific Committees strive to maintain an open two way dialogue with their stakeholders. The objective of the stakeholder dialogue is to contribute to transparency and to increase the quality of the scientific opinions. At the same time, the efficiency and timeliness of the opinions, the independence of the advice, the legitimate confidentiality of procedure, in compliance with the principles of excellence, independence, transparency and confidentiality as well as with the principles and standards for scientific advice on risk assessment. The Rules of Procedure provide guidance aimed at ensuring the effective functioning of the advisory structure according to the above-mentioned principles by defining the appropriate modalities for the operation of the Committees and the Pool.

In order to achieve these objectives and given the experience with the functioning of the advisory structure in the past, the Rules of Procedure regulate the 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. The common rules of procedure of the new Committees have been substantially revised. They now include more detailed provisions on transparency, the stakeholder dialogue and coordination between the committees.

You may find information on the rules of procedure at:

An alphabetical list of the scientists appointed by the Commission as members of the Scientific Committees can be found on the following website: http://ec.europa.eu/health/ph_risk/committees/committees_en.htm

The core element of the Scientific Committees’ work is the development and drafting of scientific opinions at the request of the Commission. In addition, the Commission may also request the Committees to provide rapid advice on the state of scientific knowledge concerning specific risks in case of urgent need. The Scientific Committees may also be called upon to identify research needs and assess research results in relation to the subject areas covered by its fields of competences.

In addition to the Scientific Committees, 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. It includes nearly 200 scientists covering a wide range of disciplines. The Scientific Committees may associate up to 5 scientific advisors from the Pool to contribute to a committee’s 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 Scientific Committee. Advisors may also replace leaving members of the Scientific Committees.

You may find information on the pool at:

You may find all information about the work of the Scientific Committees on the following webpage: http://ec.europa.eu/health/ph_risk/committees/committees_en.htm

You may find information on the database at:

You may find information on the pool at:

MEETING OF THE EUROPEAN FORUM OF RISK ASSESSORS FOR NANOTECHNOLOGY, BRUSSELS, 17 MARCH 2009

On 17 March 2009, The Risk Assessment unit of DG SANCO organized an exploratory meeting with the EU risk assessors working in the field of nanotechnology. The following three major needs have been identified by the Member States representatives:

1. Concerted contribution to the next Action Plan on nanotechnologies on the scientific aspects of risk assessment (top-down as opposed to bottom-up organization).

2. Data generation, sharing, and collaboration (market surveillance, reporting of problems, registration of nanomaterials, exposure data measurements, risk assessment research).


The second meeting of the Forum will be conducted during the Third Nanotechnology Safety for Success Dialogue on 3 and 4 November 2009. The aim of that meeting would be for the Member States representatives to provide concrete suggestions on the ways the European Commission could improve and coordinate the nanotechnology risk assessment.

EVENTS COMING UP

3RD ANNUAL NANOTECHNOLOGY “SAFETY FOR SUCCESS” DIALOGUE WORKSHOP, BRUSSELS, 3 AND 4 NOVEMBER 2009

This 3rd Annual Nanotechnology “Safety for Success” Dialogue Workshop will again bring together scientists, risk assessors, public authorities, industry, and consumer and environmental NGOs to examine and discuss issues related to the use of nanotechnologies. This time, the focus will be put on building trust in nanotechnologies and the conference will provide a platform to discuss specific applications that are already on the market.

You may access the draft programme of this workshop at the following website: http://www.nano-safety-for-success09.eu/Default.aspx?doc=50

CHAIRS MEETING, BRUSSELS, 18 AND 19 NOVEMBER 2009

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

RISK ASSESSMENT DAY, BRUSSELS, 20 NOVEMBER 2009

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

The objective of this session is to promote dialogue between scientists advising the Commission on risk assessment and European-level stakeholders. The focus will be on the organisation and functioning of the stakeholder dialogue procedure which was introduced following the first session held in 2007, its results, problems and possible improvements. During the session, the Chairs of the Committees will also provide information on the on-going activities. Moreover, stakeholders will have the opportunity to propose areas and themes for the future activities of the Scientific Committees.

You may read more about this event on the following webpage: http://ec.europa.eu/health/ph_risk/ev_20091120_en.htm
The Scientific Committees

**SCCS**

**Scientific Committee on Consumer Safety**

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 Safety (SCCS) has to be consulted to carry out risk assessments based on safety data available in the public domain or provided by industry.

The SCCS, during its plenary meeting on 8 July 2009, adopted the following opinion:

**Hair dyes:**

2-Hydroxyethylamino-5-nitroanisole (B52)

Does not pose a health risk for the consumer at the intended use concentrations. It should not be used in combination with nitrating substances. The nitrosamine content should be < 50 ppb.

The opinions of the SCCS are available at: http://ec.europa.eu/health/ph_risk/committees/04_sccs/sccs_opinions_en.htm

**SCHER**

**Scientific Committee on Health and Environmental Risks**

The two first scientific opinions of the renewed SCHER will be adopted at its plenary of November 2009. They will be the opinion on "Model implementation and quantification of the eutrophication risk associated to the use of phosphates in detergents - INIA/Green Planet Report" and the opinion on Polycarboxylates in detergents – HERA report.

**SCENIHR**

**Scientific Committee on Emerging and Newly Identified Health Risks**

**Research needs and methodology to address the remaining knowledge gaps on the potential health effects of electromagnetic fields (EMF)**

In line with Council Recommendation 1999/519/EC, the Commission has monitored the state of science to assess whether the proposed exposure limits are adequate for public health protection. This task has been performed successively by independent Scientific Committees, the last two by the SCENIHR. The latest SCENIHR-opinion delivered in January 2009 confirmed the conclusions of the previous assessments, i.e. there is so far no scientific evidence that calls for a revision of current exposure limits. However, the SCENIHR also referred to certain limitations in the database available. More research is needed to resolve the uncertainties leading to scientific debates and unreasonable calls for the application of the precautionary principle. As a result, and in order for the Commission to propose the most relevant topics on this issue for future funding, the Committee was requested to propose a research strategy on this issue.

The opinion makes specific research recommendations covering several frequency bands (radio frequency (RF) fields, intermediate frequency (IF) fields, extremely low frequency (ELF) fields, static fields) and environmental aspects. All studies suggested are considered very important by the SCENIHR and are given high priority based on their relevance for fundamental understanding of the issue and/or their relevance for public health. SCENIHR suggests that three work packages (WP) are given particular consideration. These are multidisciplinary and restricted to a specific frequency band:

- **WP1: RF fields**
  a. Health effects of RF fields from wireless communication in adults
  b. RF field mechanisms and verification of preliminary but important findings

- **WP2: IF fields**
  Possible health effects (pregnancy outcome) of IF

- **WP3: ELF fields**
  Association between ELF and neurodegenerative diseases

The opinion also identifies separate studies within the three work packages that may provide relevant results within a time-frame of 2-3 years.

The opinion, adopted on 6 July 2009 can be found at: http://ec.europa.eu/health/ph_risk/committees/04_scenihr/docs/scenihr_o_024.pdf
Mercury Sphygmomanometers in Healthcare and the Feasibility of Alternatives

In accordance with Directive 2007/51/EC (point 3 of entry 19a on mercury), the Commission was asked to review the availability of reliable safer alternatives for mercury containing sphygmomanometers and other measuring devices. Following a request by the European Parliament and the Council, the Commission will review the issue in autumn 2009. To support this review the SCENIHR was asked to prepare an opinion on this matter, which was adopted on 23 September 2009.

This opinion addresses the issue of whether the replacement of mercury-containing, blood-pressure measuring devices (sphygmomanometers) would (i) endanger proper health care including specific groups of patients, and/or (ii) compromise long-term translational epidemiological studies for public health. In addition, the availability and quality of alternative devices for blood pressure measurements have been considered. Based on long-term experience, blood pressure measurement using the mercury sphygmomanometer is currently regarded as the gold standard for indirect measurement of blood pressure. Alternative devices are gradually replacing the mercury sphygmomanometer. Mercury-free sphygmomanometers which use auscultation for the determination of blood pressure have the same limitations as mercury sphygmomanometers. Accurate blood pressure measurements with oscillometric sphygmomanometers are possible, although they have limitations in certain patient groups. For those patient groups, blood pressure measurement by a trained observer, using mercury sphygmomanometers or a validated auscultatory alternative, remains the most accurate and reliable form of indirect blood pressure measurement. It is recommended that mercury sphygmomanometers remain available as a reference standard for clinical validation of existing and future mercury-free blood-pressure measurement devices until an alternative device is developed and recognised as such.

The opinion, adopted on 23 September 2009 can be found at: http://ec.europa.eu/health/ph_risk/committees/04_scenihr/docs/scenihr_o_025.pdf
You may find all information about the work of the Committees, on the opinions and the mandates (requests) on the homepage: http://ec.europa.eu/health/ph_risk/committees/committees_en.htm

**ONGOING WORK**

Since the beginning of the new term for the Scientific Committees, several working groups have been established and started work on their respective tasks. These are the Working Groups on Hair dyes, on Cosmetic ingredients, on Nanomaterials in Cosmetics, on Sensitisation and Fragrances, on Methodologies, and on Triclosan (AMR aspect). The WG on TTC continued its work which started during the last term of office. An additional WG on Potential risks of food-imitating products will begin its work soon (see also section "New mandates"). The majority of these working groups will exist as “standing” working groups, meaning that they will take on a variety of tasks falling into their remit, while others have been created for one specific, more extensive mandate.

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 40 hair dye remain to be performed. In addition, supplementary data on 25 substances that have been initially evaluated have been received and awaits assessment.

**Preservatives, UV Filters and other cosmetic ingredients**

- **P56 - Mixture of 5-chloro-2-methyl-4-isothiazolin-3-one and 2-methyl-4-isothiazolin-3-one in a ratio of 3:1**
- **Zinc pyrithione**
- **Polysilicone-15 (Evaluation of inhalation toxicity)**
- **ETH-50 (nano-form)**
- **Titanium dioxide (nano-form)**
- **FAT 75’808 (HAA299 in its non-micronized form, C-1332 in its micronized form)**
- **Erythrosine**
- **Cyclomethicone (D4)**
- **Melatonin**

**Update of the scientific opinion on the labelling of 26 fragrance substances**

**Triclosan (antimicrobial resistance)**

The Scientific Committees

NEW MANDATES FOR SCCS

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

Food-imitating and child-appealing chemical consumer products, such as shower gels, shampoos, body lotions, soaps, liquid soaps and dish-washing liquids are common on the European market. These products resemble food-stuffs or are child-appealing due to their shape, colour, appearance, odour, consistence, packaging or other characteristics. In particular, food-imitating or child-appealing chemical consumer products may lead consumers and especially vulnerable people, such as children or elderly people, to ingest them. Be it because of their inherent toxicity properties, be it for other characteristics (viscosity, foaming potential, vomiting induction potential) ingestion of these products may pose a risk to the health of consumers. SCCS has been asked to assess the potential risk of such consumer products.

Review of the scientific opinions on the cosmetic ingredient Phytonadione

Mandates for SCCS are available at: http://ec.europa.eu/health/ph_risk/committees/04_sccs/sccs_questions_en.htm

SCHER SCIENTIFIC COMMITTEE ON HEALTH AND ENVIRONMENTAL RISKS

Since the beginning of the new term for the Scientific Committees, some working groups have been established and started their work. The following mandates are currently under evaluation:

Human health and environmental risks associated with the use of hydrofluorosilicid acid in drinking water fluoridation.

There is a continuous controversy over the benefit of fluoride and, in particular, the practice of intentional water fluoridation in tooth decays prevention. The debate over water fluoridation has prompted several questions from the European Parliament from Ireland and the United Kingdom where intentional water fluoridation is still practiced. In order to obtain an updated advice on the issue, the Commission has requested the advice of SCHER through a mandate on "Critical review of any new evidence on the hazard profile, health effects, and human exposure to fluoride, and assessment of the risks that may be associated with the use of most common drinking water fluoridating agents including silicofluorides (e.g. (hydro)fluorosilicic acid, sodium silicofluoride, disodium hexafluorosilicate or hexafluorosilicic acid)."

Moreover, since this is an issue of wider public interest, the Commission, in line with EU procedures on stakeholder dialogue, launched a public consultation on the working mandate between 17 March 2009 and 8 April 2009. A call for information was also conducted in parallel until 26 April 2009.

The Commission received in total 97 contributions to the working mandate which has been modified to take into account all pertinent comments that were submitted and were within the competences of the Scientific Committee. Concerning the "call for info" SCHER received more than 500 documents.

The preliminary opinion will be published for public consultation by end of March 2010.

The mandate is available at the following webpage: http://ec.europa.eu/health/ph_risk/committees/04_scher/docs/scher_q_084.pdf

Depleted Uranium

Depleted uranium (DU) is a by-product of uranium enrichment. There is public concern about the toxic effects of DU due to exposure of humans and the environment to DU following military use of DU. In 2008 the European Parliament passed a resolution on DU weapons which called on the Commission to promote scientific studies into the use of DU to establish whether a possible negative effect on human health and the environment may be confirmed.

In May 2009 the Commission asked the scientific advice of SCHER on "the environmental and health risks posed by depleted uranium".

The mandate is available at the following webpage:

Model implementation and quantification of the eutrophication risk associated to the use of phosphates in detergents - INIA/Green Planet Report

In November 2007, SCHER adopted an opinion on the INIA study entitled: "Development of a European Quantitative Eutrophication Risk Assessment of Polyphosphates in Detergents". Although in its opinion SCHER recognized that the developed model represented a novel and useful tool to assess the risks of eutrophication due to phosphorus release, it also concluded that the scientific quality of the report was diminished due to a number of key points which were not adequately addressed. Therefore in line with SCHER’s recommendation the rapporteur updated the report that was then resubmitted to the Scientific Committee in May 2009. The deadline for the adoption of the opinion is November 2009.

The mandate is available at the following webpage:

Polycarboxylates in detergents – HERA report

In November 2008, SCHER adopted a scientific opinion which raised certain concerns and concluded that additional information is required before it can be concluded that these chemicals are of low environmental concern. The HERA report on polycarboxylates was then updated in line with SCHER’s recommendation and by inserting new data on the terrestrial toxicity of polycarboxylates. The Commission submitted the revised HERA report to SCHER in April 2009 for further evaluation. The deadline for the adoption of the opinion is end of November 2009.

The mandate is available at the following webpage:

Heavy metals in jewellery

The Danish Environmental Protection Agency (EPA) analysed a number of jewellery samples for their release of chemicals. Four metals migrated into artificial sweat in concentrations above the detection limit: Cd, Cu, Ni and Pb. They were selected for exposure and risk assessments for consumers. No health risk was related to skin and oral exposure to jewellery containing Cu. Migration limits exist at European level for Ni and Cd but, at present, no specific limits apply for Pb in jewellery. SCHER is asked to give an opinion on whether there may be reasons for concern arising from the exposure of consumers from jewellery containing Pb and to assess whether a limit of Pb in jewellery can be established.

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.

In order to obtain a comprehensive picture on the status and validity of alternative methods in risk assessment, the Commission asked SCHER, in collaboration with SCCS and SCENIHR to elaborate an opinion on the status of development, validation of alternative methods used in the hazard characterisation of chemicals as replacements to experimental animal studies and assess their applicability in risk assessment of chemical substances.

In addition to the issues mentioned above, DG SANCO is planning to submit to SCHER before the end of 2009 mandates on:

• Possible improvements in risk assessment approaches in view of risk management needs and effective risk communication.
• Methodologies and approaches for risk assessment on chemical mixtures
• Guidance for biomonitoring studies

Mandates for SCHER are available at:
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, 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 addictive 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.

The mandate is available at the following webpage: http://ec.europa.eu/health/ph_risk/committees/04_scenihr/docs/scenihr_q_020.pdf

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 health-care 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, EFSA, EMEA, ECDC and SCENIHR are requested to provide a common scientific report on a set of related questions. These should consider also the scientific reports that were recently published by European and international scientific bodies.

The mandate is available at the following webpage: http://ec.europa.eu/health/ph_risk/committees/04_scenihr/docs/scenihr_q_019.pdf

NEW MANDATES FOR SCENIHR

The safety of reprocessed single-use medical devices

The development and use of single-use 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 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.

The mandate is available at the following webpage: 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, 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, 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. Antimicrobial 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.

The mandate is available at the following webpage: http://ec.europa.eu/health/ph_risk/committees/04_scenihr/docs/scenihr_q_022.pdf

All SCENIHR mandates are available at: http://ec.europa.eu/health/ph_risk/committees/04_scenihr/scenihr_questions_en.htm

The European Commission considers the issue of safety for the success of nanotechnologies of the utmost importance and is continuously monitoring all relevant developments. As part of a range of initiatives in this issue, the Health and Consumers Directorate General of the European Commission (DG SANCO) held on 10 September 2009 a scientific hearing on the risk assessment of nanotechnologies.

The aim of the hearing was to discuss the scientific comments and questions of stakeholders and, through this dialogue, to support the future work of the independent Scientific Committees of the European Commission in the area of risk assessment of nanotechnologies. Specifically, the main objectives were (i) to identify scientific topics that had not yet been addressed, (ii) to determine the main potential risks that could emerge from the use of nanomaterials in the future, and (iii) to acquire relevant background information on those issues.

A wide range of stakeholders -including members of the European Commission’s scientific committees, NGOs, industry representatives and concerned citizens- attended the hearing. The large attendance (more than 170 participants in addition to web streaming), indicated the importance and necessity of such dialogues, focusing on scientific aspects in the decision-making process. The event took place in a constructive ambiance and confirmed the input received during the previous public consultation organised in preparation for the hearing.

You can find all related documents regarding this scientific hearing at the following webpage: [http://ec.europa.eu/health/dyna/nanohearing/](http://ec.europa.eu/health/dyna/nanohearing/)

A targeted hearing with the stakeholders who have contributed to the public consultation (22.11.08-12.09.09) of the SCHER, SCCP and SCENIHR preliminary report on the use of the TTC approach for the safety assessment of chemical substances took place on 24 September 2009. Following the public consultation, the opinion has been revised and comments received were addressed. The targeted consultation aimed to allow for an exchange of views between the members of the Working Group and the stakeholders who have contributed in the public consultation in order to improve the quality of the opinion before it is brought for adoption in its final form to the plenaries of the three Scientific Committees.