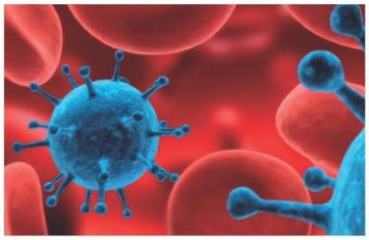
European Commission

REPORT ON THE ACTIVITY OF THE SCIENTIFIC COMMITTEES TERM 2013-2016

Scientific Committees

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





Health and Food Safety

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1. INTRODUCTION

The Scientific Committees, managed by the Directorate General for Health and Food Safety, provide the European Commission with advice on scientifically difficult and politically sensitive issues.
In the period April 2013 - March 2016, three committees provided scientifically sound advice for policy makers to ensure a high level of consumer safety, health and environmental protection that European citizens expect from the European Union institutions.

These committees were the:
- Scientific Committee on Consumer Safety (SCCS)
- Scientific Committee on Health and Environmental Risks (SCHER)
- Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR)

The 2013-2016 mandate was a period of both steady progress and transformation for the Scientific Committees as the Secretariat was transferred to Luxembourg at the beginning of the term. The transfer was successful, resulting in the production of many Opinions and in spite of a reduction of resources, both in terms of Secretariat's staff and budget.
Particular emphasis was given to holding dialogues with stakeholders at workshops and hearings, and to the dissemination of the Opinions to the scientific community and to the general public through a dedicated website, articles in scientific newspapers and material in layman's terms. Cooperation with the Scientific Committee on Occupational Exposure Limits (SCOEL) and other EU risk assessment bodies such as EFSA, ECHA, ECDC and EMA has been strengthened to create synergies and to avoid conflicting Opinions.
The results show the strength of the experts' commitment and the determination of the Secretariat to support delivery of the best scientific advice for the European Commission.

Key figures of the Scientific Committees' activity 2013-2016 are:
- 87 documents adopted (scientific Opinions and scientific advices);
- 334 meetings organised (mainly in Luxembourg) and attended by 41 members and 97 experts of the scientific committees;
- 15 science fact-sheets and 4 web summaries explaining the Opinions in plain language were prepared and published;
- 33 scientific articles published in scientific journals;
- 7 Health-EU newsletter editions were dedicated to the activity of the Scientific Committees;
- The budget spent for all the activities was around 830 000 euros a year: 704 000 euros related to production of Opinions and meetings activities, and 126 000 euros for technical assistance (literature search, editing of Opinions, website mastering and dissemination activities).

SCs	No of adopted documents	No of meetings	Cost in euros	Cost per Opinion
SCCS	66	107	1 006 122	15 244
SCENIHR	15 Including 3 joint Opinions	143	881 244	58 750
SCHER	6	56	225 011	37 502
Total	**87**	**306**	**2 112 337**	

The Scientific Committees may be mandated exclusively by Commission departments. In the term 2013-2016, they received requests from the following departments within the European Commission:

- DG GROW- Consumers, Environmental and Health Technologies Directorates, Industrial Transformation and Advanced Value Chain Directorate
- DG SANTE – Biotechnology Unit, Tobacco Control Unit, Health Threats Unit
- DG ENV
- DG Justice and Consumers, Consumers Directorate
- DG Research
- JRC

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

Fifteen scientists were appointed as members in 2013. One scientist resigned from the Committee during the term of office for personal reasons (September 2013). 75 external experts were involved in producing SCENIHR's Opinions.

Affiliation and expertise of members

Eleven members were associated with universities and four members were employed by national health or research institutes. Areas of expertise included: toxicology, epidemiology, public health, physics, electromagnetic fields, statistics, field measurement and dosimetry, nanomaterials, microbiology, medicine (microbiology and immunology), biomaterials, cell biology, medical engineering, environmental engineering, medical devices and risk assessment.

Opinions

According to its general mandate, the SCENIHR provided Opinions on questions concerning emerging or newly identified risks as well as on broad, complex or multidisciplinary issues requiring a comprehensive assessment of risks to consumer safety or public health and related issues not covered by other Union risk assessment bodies.

During its mandate from April 2013 to March 2016, the SCENIHR adopted 14 Opinions (13 final and 1 preliminary), and one position paper.

The focus of the work of SCENIHR was on medical devices (6 Opinions), physical risks (3 Opinions), other areas of interest (Synthetic Biology - 3 Opinions adopted jointly with SCHER and SCCS), nanotechnologies (2 Opinions) and on public health (1 Opinion – additives used in tobacco products). The SCENIHR also wrote a position paper on emerging issues. They are:

- Opinion on the safety of surgical meshes used in urogynecological surgery
- Opinion on the safety of medical devices containing DEHP plasticized PVC or other plasticizers on neonates and other groups possibly at risk (2015 update)
- Opinion on the safety of dental amalgam and alternative dental restoration materials for patients and users
- Opinion on the safety of the use of bisphenol A in medical devices
- Opinion on the safety of Metal-on-Metal joint replacements with a particular focus on hip implants
- Opinion on the safety of Poly Implant Prothèse (PIP) Silicone Breast Implants (Update of the Opinion of February 2012)
- Guidance on the Determination of Potential Health Effects of Nanomaterials Used in Medical Devices
- Opinion on Nanosilver: safety, health and environmental effects and role in antimicrobial resistance
- Opinion on Potential health effects of exposure to electromagnetic fields (EMF)
- Opinion on Synthetic Biology I: Definition
- Opinion on Synthetic Biology II: Risk assessment methodologies and safety aspects
- Opinion on Synthetic Biology III: Risks to the environment and biodiversity related to synthetic biology and research priorities in the field of synthetic biology
- Opinion on additives used in tobacco products (Opinion I)
- Preliminary Opinion on biological effects of ultraviolet radiation relevant to health with particular reference to sunbeds for cosmetic purposes

- Position Statement on emerging and newly identified health risks to be drawn to the attention of the European Commission

One Opinion was still under development at the end of the mandate: the preliminary Opinion on biological effects of UV-C radiation relevant to health with particular reference to UV-C lamps.

Each Opinion was published for public consultation. There were in total 14 public consultations with more than 2000 contributions received. All of these comments have been studied and answered. Each public consultation was announced by means of press releases and was disseminated to interested parties by e-mails, web and twitter.

Two **public hearings** were organised with the aim of gathering specific, scientifically based comments and contributions on the preliminary Opinions:
- on potential health effects of exposure to electromagnetic fields (EMF)
- on biological effects of ultraviolet radiation relevant to health with particular reference to sunbeds for cosmetic purposes

Members of the SCENIHR were also involved in the Working Groups (WG) of the SCHER and SCCS and in work carried out jointly with other institutions (e.g. EFSA - Increasing Robustness, Transparency and Openness of Scientific Assessments, ERA).

Meetings organised

143 meetings were organised, of which 81 in Luxembourg. During the term, audio meetings increased over physical meetings, thus resulting in time saving for the members and experts while reducing travelling and accommodation costs. Members' participation in other Bodies meetings (e.g. EU bodies involved in risk assessment, or Commission services) increased during time, thus strengthening synergies with them.

Year	Physical meetings	Audio meetings	Total	Attendance of members to meetings of other bodies
2013 (from April)	34	11	45	5
2014	26	14	40	10
2015	15	32	47	13
2016 (until 27 April)	6	5	11	4
	81	**62**	**143**	**32**

Clients in the European Commission

The SCENIHR developed its Opinions on request from the Commission services.
The 6 mandates on medical devices (Dental Amalgam, DEHP, BPA, PIP breast implants, surgical meshes, MoM) were issued by DG SANCO Unit B2 (Cosmetics and Medical Devices) which became Unit D4 of DG GROW in 2015.

Nanotechnology:
- Nanosilver: mandate was issued by DG SANCO, Unit B3
- Nanomaterials: mandate issued by DG SANCO, Unit B2

Physical risks:
- EMF:1 mandate issued by DG SANCO, D3 (Risk Assessment)

- Biological effects of ultraviolet radiation relevant to health with particular reference to sunbeds for cosmetic purposes: the mandate was issued by DG JUST, Unit E3.

- Biological effects of UV-C radiation relevant to health with particular reference to UV-C lamps issued by DG GROW, Unit C3 (Advanced Engineering and Manufacturing Systems).

Public Health:
- Tobacco additives mandate was issued by DG SANTE, Unit D4.

Emerging risks:
- A joint mandate (to SCENIHR, SCHER and SCCS) on Synthetic Biology was issued by DG SANCO E1, DG ENV, DG RTD and DG ENTR and was divided into 3 Opinions: Definition, risk assessment methods and methodologies and research gaps.

The position paper was developed on SCENIHR's own initiative.
The update of the Memorandum on Weight of Evidence together with the SCHER was issued by the Secretariat (DG SANTE, Unit C2) as well as the Guidance on structure and content of SCHEER scientific Opinions. These two last reports will be finalised by the new Scientific Committee on Health, Environmental and Emerging Risks (SCHEER).

Budget

The total cost of SCENIHR activities is about 881 000 euros for the whole term. A decreasing trend should be noticed, due to the increasing number of audio meetings organised and decreasing number of physical meetings.

SCENIHR	**Special indemnities**	**Travel+per diem**	**Total**	**No. of Opinions adopted**
2013 (from March)	158 235	237 762	395 997	--
2014	140 627	143 147	283 774	4 final Opinions 1 statement
2015	77 780	85 535	163 315	8 final Opinions
2016 (until 27 April)	19 315	18 843	38 158	1 final Opinion 1 preliminary Opinion
Total	**395 957**	**235 0762**	**881 244**	

Dissemination activities dedicated to SCENIHR Opinions

9 Science fact-sheets

Factsheets are dissemination tools written in layman's terms to explain the Opinions to the general public in a brief and clear way. They can be found on http://ec.europa.eu/health/scientific_committees/policy/opinions_plain_language/index_en.htm
In the term 2013-2016 9 science factsheets were produced based on SCENIHR Opinions. These were on the topics of:

- Tobacco additives
- Surgical meshes
- DEHP

- Synbio
- Safety of dental amalgam and alternative restorative materials
- EMF
- BPA
- MoM hip implants
- Nano silver

2 Web summaries – easy to read science

Web-summaries are also written in layman's terms and go into a little more depth about the Opinions than factsheets, but they are also intended for the general public and are meant to complement the factsheets. They can be found on http://ec.europa.eu/health/scientific_committees/policy/opinions_plain_language/index_en.htm
In the term 2013-2016 2 web-summaries were produced based on SCENIHR Opinions. They are:

- EMF
- Dental fillings

7 Health-EU newsletter editions were dedicated to the activity of the Scientific Committees, with 3 editorials dedicated to the new SCENIHR term, synthetic biology and surgical meshes.
http://ec.europa.eu/health/scientific_committees/newsletters/index_en.htm

Publications in scientific journals

Publishing articles in scientific journals has become a new dissemination activity, initiated by the Secretariat since beginning 2015, in order to reach peer scientists. Since then, 13 articles based on SCENIHR Opinions have been published in scientific journals:

- 5 articles in Journal of Medical Devices Regulation: on BPA, DEHP, MoM, Nanomaterials in MD, surgical meshes Opinions
- 3 articles in Journal of Regulatory Toxicology and Pharmacology: on Dental Amalgam, BPA, DEHP Opinions
- Bioelectromagnetics: Letter to the Editor – on EMF Opinion
- Electromagnetic biology and medicine on EMF Opinion
- Resource strategies inc. RF Gateway information services – on EMF Opinion
- Materials today: on Nanosilver Opinion
- Science: Editorial – on Synbio I and II Opinions
- Trends in Biotechnology: on Synbio I, II, III Opinions

The articles can be found here:
http://ec.europa.eu/health/scientific_committees/scientific_journals/index_en.htm

Policy follow-up of opinions

What are these Opinions used for? They are used by policy makers and risk managers for shaping EU policy in consumer safety, health and environmental protection and in international fora. The following are examples of ways in which the Opinions and risk assessments produced by the Scientific Committees in the term 2013-2016 have been followed up:

Safety of Poly Implant Prothèse (PIP) Silicone Breast Implants (Update of the Opinion of February 2012) – this Opinion was used as the scientific basis of the 'EU Action Plan for Immediate Actions under Existing Medical Devices Legislation (PIP Action Plan)'.

Guidance on Nanomaterials Used in Medical Devices: this document was cited by RIVM (Dutch National Institute for Public Health and the Environment) in their national Guidance and was used as scientific basis for EU new Regulation on Medical Devices.

Safety of surgical meshes used in urogynecological surgery: this Opinion was taken as a reference in the review of Scotland and England on the same topic. A number of Member States, namely Sweden, Denmark, Spain, Portugal and France have disseminated this Opinion among their professional associations.

Safety of Metal-on-Metal hip implants A second dedicated EU Task Force was established by GROW with the Member States to verify how the recommendations of SCENIHR are implemented.

Additives used in tobacco products (I)
The list of additives formed the scientific basis for the Commission to develop secondary legislation for tobacco products[1].

Synthetic Biology Opinion
The definition of Synthetic Biology proposed by the Scientific Committees was used, with minor changes, by the UN Convention on Biodiversity to deliberate on the operational definition of synthetic biology (September 2015). Moreover, the three Opinions were presented in different workshops and conferences:

- ERASynBio Networking Workshop, 19 November, 2014, Brussels;
- EC Council Working Party International Environmental Issues on Biodiversity, July 9, 2015, Brussels;
- Synthetic Biology Congress, October, 2015, London;
- EC Workshop on Synthetic Biology, December 2015, Luxembourg;
- IRGC-UCL-OECD, Planning Adaptive Risk Regulation Conference, January 2016, London;
- EC Council Working Parties on International Environmental Issues for Biodiversity and Biosafety, Expert Meeting on Synthetic Biology in the CBD context, February 2016, Brussels;
- EFSA Scientific Committee, April 21, 2016, Parma;
- Annual Meeting of the European Biosafety Association, April 22, 2016, Lille;
- Society of Risk Analysis Annual Meeting, June 2016, Bath.

Relations with the Ombudsman's office

In 2015, the Secretariat handled 3 Ombudsman inquiries and 2 inspections related to 3 Opinions (EMF, Dental amalgam and PIP breast implants.
In the case of the Opinion on PIP, the European Ombudsman closed its inquiry into a complaint concerning PIP breast implants 174/2015/FOR against the European Commission, verifying that there was no maladministration.

In the case of the Opinion on Dental Amalgam, the European Ombudsman closed its inquiry into a complaint concerning dental amalgam 2014/1832 against the European Commission, verifying that there was no maladministration.

The results of the inquiry and the inspection on EMF were still pending at the date of the closure of this Report.

More info on http://www.ombudsman.europa.eu/home.faces

[1] Commission Implementing Decision (EU) 2016/787 laying down a priority list of additives contained in cigarettes and roll-your-own tobacco subject to enhanced reporting obligations.

Workshops, meetings and events involving SCENIHR members

Workshops

A **Workshop on Electromagnetic fields was organised by the SCENIHR and the Greek Atomic Energy Commission** together with the Public Hearing for the Opinion on EMF, Athens, Greece on 27-28 March 2014. The main issues to be addressed were: scientific evidence concerning EMF and health effects and remaining knowledge gaps; management of EMF policy at EU and national level; risk perception and risks communication: effective public information activities.

The **GLORE Conference**, which took place on 19 and 20 of November 2014 in Luxembourg. GLORE (Global Coordination of RF Communications on Research and Health Policy) is a coordination action that involves delegations from Europe, Australia, Japan, Korea and USA, composed by scientists and policy authorities.

A **Workshop on Synthetic Biology** took place on 10 December 2015 in Luxembourg. Some 70 participants from all over the world attended the workshop which provided the opportunity to review the work on synthetic biology at EU level and to discuss challenges that synthetic biology may pose.

In October 2014, a plenary session in the **European Health Forum in Gastein**, Bad Hofgastein, Austria focuses on the Committees' activities Case study Opinions were also analysed with around 100 public health stakeholders who participated in the event.
More info on http://ec.europa.eu/health/scientific_committees/events/index_en.htm

Hearings

Two public hearings were organised.

On 27 March 2014, the Commission and SCENIHR organised a public hearing in Athens on the **preliminary Opinion on potential health effects of exposure to electromagnetic fields (EMF).** Representatives of various stakeholders, including academia, NGOs, industry, and governmental institutions participated in the meeting. Relevant material subsequently submitted via public consultation was considered in the final Opinion. More info on http://ec.europa.eu/health/scientific_committees/emerging/docs/ev_20140328_sumrecord_en.pdf

On 12 April 2016, the Commission and the SCENIHR organised a public hearing in Luxembourg **on the preliminary Opinion on sunbeds**. 25 parties expressed interest after the publication of the announcement and were invited to the meeting. The available scientific data, their shortcomings and additional research that could improve the scientific content of the Opinion were discussed during the meeting. Material subsequently submitted via public consultation was to be considered in the final Opinion. More info on
http://ec.europa.eu/health/scientific_committees/events/ev_20160412_en.htm

Other meetings outside the committee meetings, involving representation of SCENIHR members

2013: Participation of selected members in

- EFSA Working Group BPA TOX, (Rome, Berlin, Brussels)
- EFSA WG on Environmental Risk Assessment (ERA), Parma, Italy
- Preliminary conference of nanoforum, Rome, Italy

2014: Participation of selected members in

- EFSA WG on ERA, Parma, Italy
- EFSA Workshop on BPA, Brussels, Belgium
- European Congress of Radiology Conference 2014, Vienna, Austria
- Emerging Science and Technology Frame Project Workshop, Brussels, Belgium
- AMS Workshop on Pelvic Surgery, Paris, France
- Workshop on EMF, Varna, Bulgaria
- ERA Workshop on Synthetic Biology, Brussels, Belgium

2015: Participation of selected members in

- 2 EMF Meeting with NGOs stakeholders, Luxembourg
- GSMA, EMF Forum 2015, Brussels, Belgium
- GLORE Conference, Seoul, South Korea (audio presentation)
- GMOA Workshop on EMF, Athens, Greece
- Conference Télécom Paris Tech, Paris, France
- WHO 4th InterSun programme, Geneva, Switzerland
- ICNIRP/WHO Workshop on EMF, Istanbul, Turkey
- WHO/Europe meeting on implementation of the Minamata Convention on mercury, Bonn, Germany
- EFSA Workshop on Increasing Robustness, Transparency and Openness of Scientific Assessments, Brussels, Belgium
- EFSA's second scientific conference 'Shaping the future of food safety, together', Milan, Italy
- Council working Party on International Environment Issues Workshop, to present Synthetic Biology Opinions, Brussels, Belgium
- Meeting of the Group Of Experts on Tobacco Policy, Brussels, Belgium
- Synthetic Biology Congress, London, UK

2016: Participation of selected members in

- Society of Toxicology Webinar to present Guidance on Nanomaterials used in Medical Devices – Nanomaterials, USA
- Synthetic Biology Expert Meeting, Brussels, Belgium
- EFSA Scientific Committee, Parma
- Annual Conference of European Biosafety Association (on Synthetic Biology Opinions) Lille, France

3. SCIENTIFIC COMMITTEE ON CONSUMER SAFETY (SCCS)

Fifteen scientists were appointed as members in April 2013. Five scientists resigned from the Committee during the term of office. Seventeen external experts were involved in 4 Working Groups (WG): WG on cosmetic ingredients, WG on Hair Dyes and Fragrances, WG on Nanomaterials in cosmetics and WG on Methodology.

Affiliation and expertise of members

Eight Members were employed by national public health and environmental institutes, six members were associated with universities and one member worked as an independent consultant.

Opinions

According to its general mandate, the SCCS addresses questions on all types of health and safety risks of non-food consumer products (such as chemical, biological, mechanical and other physical risks) and services (such as tattooing). In particular, questions related to the safety of cosmetic ingredients, including hair dyes and nanomaterials, were addressed during this term.

During the term 2013-2016, the SCCS adopted 60 Opinions in the following areas:

- Hair dyes (23 Opinions)
- Fragrances (3 Opinions)
- Cosmetic ingredients (26 Opinions)
- Nanomaterial in cosmetics (8 Opinions)

In addition, 3 joint Opinions were adopted with SCENIHR and SCHER (Synthetic Biology I, II and III) as well as 6 memoranda and statements including the SCCS Notes of Guidance for the testing of the cosmetic ingredients and their safety evaluation.

The chart below gives an overview of the number of SCCS Opinions on different categories.

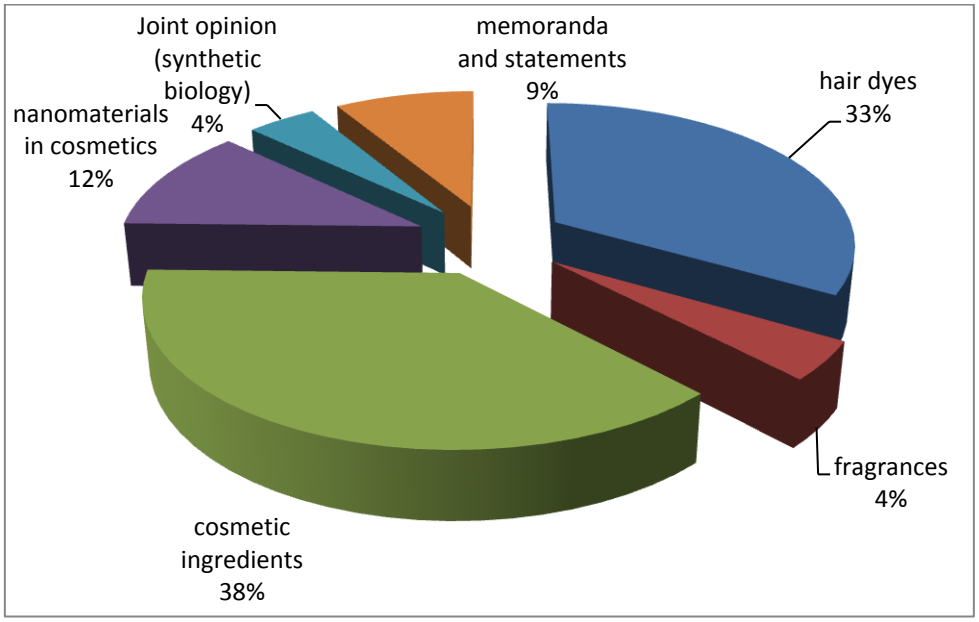

Figure 1: overview of SCCS Opinions

The main focus was on cosmetic ingredients, followed by hair dyes. Cosmetic ingredients included mainly preservatives, but also UV-filters and bleaching agents.

Number of meetings

107 meetings were organised, of which 97 were in Luxembourg and 10 were audio meetings. Audio meetings were organised mainly for the Working Group (WG) on nanomaterials in cosmetics, while the other WGs preferred physical meetings for organisational reasons, due to the fact that several dossiers are usually discussed at the same meeting.
Selected members participated in 34 meetings organised by other bodies (e.g. EU bodies involved in risk assessment) or Commission services, thus strengthening synergies with them.

Year	Physical meetings	Audio meetings	Total
2013 from March	26	1	**27**
2014	35	4	**39**
2015	32	2	**34**
2016 until 27 April	4	3	**7**
total	**97**	**10**	**107**

Year	Plenary	WG cosmetic ingredients	WG hair dyes and fragrances	WG methodology	WG nano in cosmetics	Total
2013 from March	4	7	6	3	7	**27**
2014	4	11	7	8	9	**39**
2015	4	8	8	6	8	**34**
2016 until 27 April	1	3		1	2	**7**
total	**13**	**29**	**21**	**18**	**26**	**107**

Clients in the European Commission

The SCCS develops its Opinions after receiving a mandate from Commission services. In the term 2013-2016, all mandates were issued by DG GROW - Cosmetics and Medical Devices Unit and targeted cosmetic ingredients only.
Six position statements and memoranda as well as guidance documents were adopted on the SCCS or Secretariat's own initiative.

Budget

SCCS	Special indemnities	Travel+per diem	Total	No. of Opinions adopted
2013 from March	154 542	198 655	353 197	**15**
2014	150 667	153 517	304 184	**21**
2015	143 170	192 847	342651	**24**
2016 until 27 April	4 220	1 870	6 090,48	**6**
total	**452 599**	**546 889**	**1 006 122**	**69** (including 3 joint Opinions)

Dissemination activities dedicated to SCCS Opinions

Layman versions were produced for a number of SCCS Opinions:

4 science fact-sheets

- SCCS Notes of Guidance for the testing of cosmetic ingredients and their safety evaluation
- Is it safe to use cosmetics containing silica in nanoform?
- Sunscreens with titanium dioxide as nanoparticles
- The EU is the safest market in the world for hair dyes

2 web summaries

- Nano form zinc-oxide in sunscreens
- Perfume allergies

2 Health-EU newsletter editions

Two health-EU newsletter editions focused on SCCS, with 1 foreword dedicated to the new term of the SCCS and 1 dedicated to nanomaterials in cosmetics.

Publications in scientific journals

Since January 2015 onwards, 15 Opinions were published in 'Regulatory Toxicology and Pharmacology' and 1 summary of adopted Opinions was published in 'Contact Dermatitis Journal'.

More information on http://ec.europa.eu/health/scientific_committees/index_en.htm

Policy follow-up of Opinions

According to Cosmetic Regulations[2], manufacturers are primarily responsible for the safety of their products and are required to ensure that their products have undergone

[2] Commission Regulation (EU) 2015/1190 of 20 July 2015 amending Annex III to Regulation (EC) No 1223/2009 of the European Parliament and of the Council on cosmetic products (hair dyes)

expert scientific safety assessment before they are sold. The process involves preparing dossiers to show that the substance does not pose a health risk for consumers. These dossiers are then submitted to the European Commission for a risk assessment by the SCCS.

Hair dye
Since 2003, the European Commission has been implementing a global strategy for the safety assessment of hair dyes in Europe. As a result of the strategy, hair dyes have been assessed by the SCCS and so far 176 hair dye substances are permitted for use under the Cosmetic Regulation. In addition, more than 180 ingredients were banned either due to negative SCCS Opinions or due to industry's lack of interest in updating safety dossiers.

Cosmetic ingredients
Numerous evaluations of cosmetic ingredients made by SCCS have been implemented as technical adaptations of the Annexes of the Cosmetic Regulations, such as:

KOH: Commission Regulation (EU) 2016/622 amending Annex III to Regulation (EC) No. 1223/2009 of the European Parliament and of the Council on cosmetic products was adopted on 21 April 2016 and published in the OJ L106 of 22.04.2016, p. 7.
http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2016.106.01.0007.01.ENG&toc=OJ:L:2016:106:TOC

ZnO: Commission Regulation (EU) 2016/621 amending Annex VI to Regulation (EC) No. 1223/2009 of the European Parliament and of the Council on cosmetic products was adopted on 21 April 2016 and published in the OJ L106 of 22.04.2016, p. 4.
http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2016.106.01.0004.01.ENG&toc=OJ:L:2016:106:TOC

DEGEE: Commission Regulation (EU) 2016/314 of 4 March 2016 amending Annex III to Regulation (EC) No. 1223/2009 of the European Parliament and of the Council on cosmetic products was adopted on 4 March 2016 and published in the OJ L 60 of 5.3.2016, p. 59–61
http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32016R0314&from=EN

New amendment ingredients UV-filter: benzylidene camphor from annex VI to II (negative Opinion SCCS). Thioglycolic Acid (TGA) and salts (professional use in some case) and use of 9 HDs in same amendment (Annex III). The following updates are available here:
http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32015R1298&from=EN
http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32015R1190&from=EN

Workshops, meetings and events involving SCCS members

Workshops organised in Luxembourg

The Annual Review on the International Dialogue for the Evaluation of Allergens (IDEA) Project was held in Luxembourg in December 2013, 2014 and 2015.

Participation of selected members in meetings:

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http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2015.193.01.0115.01.ENG

Commission Regulation (EU) No 1197/2013 of 25 November 2013 amending Annex Ⅲ to Regulation (EC) No 1223/2009 of the European Parliament and of the Council on cosmetic products (hair and eyelash dyes):

http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32013R1197

2013:
- European Partnership for Alternative Approaches to Animal Testing (EPAA) Annual Conference, Brussels
- WHO/International Program on Chemical Safety (IPCS) Workshop on characterisation and communicating uncertainty analysis in hazard assessment for chemicals, Bilthoven
- IDEA workshops on Quantitative Risk assessment (QRA) method and on Pre and Pro Haptens, Genval

2014:

- Workshop "The read-across case study for safety assessment contributing to the SEURAT-1 Proof on Concept", JRC Ispra
- Joint Meeting of the Preliminary Assessment of Regulatory Relevance Network (PARERE) and the ECVAM Stakeholder Forum (ESTAF), JRC organisation
- EFSA-WHO workshop on "Threshold of Toxicological Concern" (TTC), Brussels
- ECHA Topical Scientific Workshop on Regulatory Challenges in Risk Assessment of Nanomaterials, Helsinki
- The European Partnership for Alternative Approaches to Animal Testing (EPAA) workshop on knowledge sharing to facilitate regulatory decision making, Brussels
- Cosmetics Europe International Conference, Brussels
- IDEA workshops on Quantitative Risk assessment (QRA) method, Genval and Leuven
- International Cosmetic And Device Association (ICADA) Symposium, Frankfurt

2015:

- Workshop on cosmetic preservatives organised by DG GROW, Brussels
- JRC-Read across workshop, ISPRA
- Preliminary Assessment of Regulatory Relevance (PARERE) Network and the ECVAM Stakeholder Forum (ESTAF), JRC Ispra
- Technical Meeting on the JRC Methodology for evidence screening of chemicals, Brussels
- EFSA Workshops on Benchmark Dose (BMD), Amsterdam and Brussels
- Joint Symposium on Nanotechnology, Berlin
- Cosmetics Europe International Conference, Brussels
- IDEA workshops on Pre and Pro Haptens, Genval

2016:

- European Parliament event on endocrine disruptors as well as a Commissioners' meeting on the same topic, Brussels International Cooperation on Cosmetic Regulation (ICCR), Working Group on Allergens (by audio)
- IDEA workshops on the feasibilitystudies to assess the effectiveness of the Quantitative Risk assessment (QRA) method and on inclusion of animal testing alternatives into QRA for skin sensitisation, Genval

4. SCIENTIFIC COMMITTEE ON HEALTH AND ENVIRONMENTAL RISKS (SCHER)

Affiliation and expertise of members

Eleven scientists were appointed as members. Eight members were employed by national or regional health research institutes, two members were associated with universities and one member had retired from research institution.

The expertise covered included: epidemiology, toxicology, public health, ecology, environmental fate, ecotoxicology, chemistry, biochemistry, modelling, and *in vitro* and *in vivo* testing.

Five external experts were involved in SCHER Opinions.

Opinions

According to its general mandate, the SCHER provided Opinions on questions concerning the health and environmental risks related to pollutants in the environmental media and other biological and physical factors which may have a negative impact on health and the environment, for example in relation to air quality, waste and soils.
During its mandate from April 2013 to March 2016, SCHER adopted 5 Opinions and 1 Guidance document in addition to 3 joint Opinions.

The Opinions adopted were:

- Opinion on environmental risks and indirect health effects of mercury from dental amalgam (update 2014)
- Opinion on Chromium VI in toys
- Opinion on new conclusions regarding future trends of cadmium accumulation in EU arable soils
- Opinion on potential risks to human health and the environment from the use of calcium cyanamide as fertiliser
- Opinion on estimates of the amount of toy materials ingested by children
- Three Opinions on Synthetic Biology I, II, III (jointly with SCENIHR and SCCS)

Other activities connected to the production of the Opinions consisted in:

- Public consultations: 3 (Dental amalgam, chromium VI in toys, toy materials ingested by children)
- Commenting periods: 2 (cadmium in arable soils, calcium cyanamide as fertiliser)
- Public hearing: 1 (Dental amalgam)

The SCHER was also tasked to carry out a risk assessment in case of cross-border chemical health threats (according to the Commission Decision 1082/2013/EU on serious cross border threats to health). This activity resulted in the production of the **Guidance on procedure for *ad hoc* rapid risk assessment.**

At the request of the Secretariat, the Memorandum on Weight of Evidence was developed together with the SCENIHR as well as the Guidance on structure and content of SCHEER scientific Opinions.

Number of meetings

56 meetings were organised, 44 of which were in Luxembourg and 12 were audio meetings. Selected members participated in 11 meetings organised by other Bodies (e.g. EU bodies involved in risk assessment), or by Commission services, thus strengthening synergies with them.

Year	Physical meetings	Audio meetings	Total
2013 from March	10	1	**11**
2014	15	3	**18**
2015	14	4	**18**
2016 until 27 April	5	4	**9**
Total	**44**	**12**	**56**

Clients in the European Commission: DG SANTE, DG GROW, DG ENV, DG RTD

SCHER developed its Opinions at the request of the following Commission services:

- DG GROW (toys, fertilisers, synbio)
- DG ENV (dental amalgam, synbio)
- DG SANTE (RRA, synbio)
- DG RTD (synbio)

Budget

	Special indemnities	Travel+per diem	Total	No. of Opinions adopted
2013 from March	27 735	29 030	**56 765**	
2014	49 940	35 795	**85 735**	1 Opinion
2015	41 030	36 646	**77 676**	2 Opinions
2016 until 27 April	4 835	/	**4 835**	2 Opinions 1 Guidance RRA
Total	**123 540**	**101 471**	**225 011**	**6 Opinions** (in addition to 3 joint Opinions)

Dissemination activities dedicated to SCCS Opinions

2 Science fact-sheets were prepared and published:

- Environmental risks and indirect health effects of mercury from dental amalgam
- Chromium VI in toys

1 Health-EU newsletter edition was dedicated to the new term of the SCHER.

More information on http://ec.europa.eu/health/scientific_committees/index_en.htm

Publication in Scientific Journals

Since January 2015 onwards

2 articles were published in the Journal of Regulatory Toxicology and Pharmacology

- ✓ Indirect effects of dental amalgam
- ✓ Chromium VI in toys

Policy follow-up of Opinions (examples)

Dental amalgam Opinion served as a scientific basis for Commission's ratification of Minamata Convention.

Opinion on toys provided risk assessment under Toy Safety Directive 2009/48/EC

Opinion on Calcium cyanamide and Cadmium accumulation in soil served as the scientific basis for the activity of Working Group on fertilisers

Rapid risk assessment was carried out in the framework of Decision 1082/2013/EU on serious cross-border threats to health

Workshops, meetings and events involving SCHER members

Hearings

The Commission and SCHER organised a hearing on the preliminary Opinion on dental amalgam in 2013. 11 representatives of various stakeholders, including academia, NGOs, industry and governmental institutions participated in the meeting. The outcome of the discussion and material submitted subsequently were considered in the final Opinion. http://ec.europa.eu/health/scientific_committees/events/ev_20131014_en.htm

Selected SCHER members participated in the following meetings/workshops:

2013:

- WHO/IPCS Workshop on Characterizing and Communicating Uncertainty Analysis in Hazard Assessment for Chemicals, Bilthoven
- EFSA Colloquium and WG on ERA, Parma

2014:

- Workshop on a systematic approach to risk in environment policies, Brussels
- EFSA Scientific Colloquium XIX on Biodiversity as Protection Goal in Environmental Risk Assessment for EU agro-ecosystem , Parma
- Meeting of the EFSA WG on Environmental Risk Assessment, Parma
- Meeting of the Fertiliser Working Group, Brussels
- ASHT/ECHEMNET Workshop, Brussels
- Quicksilver Exercise, organised by the European Commission, Public Health Directorate

2015:

- ECHEMNET EU Project workshop, Utrecht
- Quicksilver Exercise Plus organised by the European Commission, Public Health Directorate

- EFSA Workshop on Emerging Risks, Brussels
- ECHA Workshop on Soil Risk Assessment, Helsinki.

5. INTER-COMMITTEE COORDINATION GROUP (ICCG)

The Coordination Group (ICCG) is composed of the chairs and vice-chairs of the three Scientific Committees (SCCS, SCENIHR and SCHER) and supports the coordination of the committees, addressing issues such as:

- matters relating to harmonization of risk assessment
- questions common to the committees
- diverging scientific Opinions
- exchange of information on the activities of the committees.

The total budget allocated for the ICCG activity and the number of meetings organised from April 2013 until April 2016 are illustrated in the table below:

Budget

	Special indemnities	**Travel + per-diem**	**TOTAL**	**No of meetings**
2013	23 870	33 640	57 510	2 (Joint Plenary of the SCs and 1 audio meeting of ICCG)
2014	6 165	6 466	12 631	2 meetings
2015	5 585	6 047	11 874	4 (2 physical, 2 audio)
Total	**35,620**	**46,153**	**81,733**	**8**

6. DISSEMINATION ACTIVITIES COMMON TO THE 3 COMMITTEES

Website

All activities of the Scientific Committees and all communication material were made available on the Scientific Committees' website, as required by the Committees' transparency principle, including Opinions, agenda and minutes of the meetings, members and experts appointed, communication material, and the newsletters.

Beside the web activities, other actions were performed by the Secretariat to promote the work of the Scientific Committees.

Press releases

When high-impact Opinions were published, an e-news (EC press release) was always sent out and disseminated through various channels. Press material for events was prepared.

EU Bookshop

International identifiers (ISBN, DOI, ISSN and ND) have been attributed to every final Opinion adopted in the 2013-2016 term. All concerned Opinions have been published on the online EU Bookshop. In this way, the widest possible access to the Opinions is guaranteed.

Promotional material

This leaflet was prepared to explain the work of the 3 Scientific Committees SCCS, SCHER and SCENIHR:
http://ec.europa.eu/health/scientific_committees/docs/leaflet_sc_2013_en.pdf

Corporate business cards, with a link and QR code to the Scientific Committees' website, were prepared together with pens, with the logo of the Scientific Committees and the link to the Committees' web, to be used during meetings and events.

Compilation CD's with opinions

Yearly compilation CD were made available on the EU Bookshop and distributed during meetings, workshops and other events.
http://ec.europa.eu/health/scientific_committees/publications/index_en.htm

More information on our activities:

Non-Food Scientific Committees of the European Commission:
http://ec.europa.eu/health/scientific_committees/

Public Health website:
http://ec.europa.eu/health

Health-EU e-newsletter:
http://ec.europa.eu/health/newsletter/newsletter_en.htm