

Scientific Committee on Consumer Safety (SCCS) 13th PLENARY

Venue: Luxembourg

Meeting date: 16 March 2016

Minutes

1. WELCOME AND APOLOGIES

The Chair welcomed all the participants. *Prof Ana PROYKOVA* (SCENIHR's Vice Chair) participated as well. There was one apology from SCHER representative. The Chair gave the floor to new Head of Unit SANTE C2, Philippe Roux, to introduce himself and thanked the members for the good work accomplished during this term 2013-2016.

2. ADOPTION OF THE AGENDA

The agenda was adopted as presented and SCENIHR added some points for information.

3. MINUTES OF THE PREVIOUS SCCS PLENARY MEETING – 15 DECEMBER 2015

The minutes were adopted on 15 January 2016 through written procedure and published on the website.

4. DECLARATION OF INTEREST ON MATTERS ON THE AGENDA

The Chair requested participants to declare any conflict of interest regarding matters on the agenda. None of the participants declared any conflict of interest.

5. INFORMATION FROM COMMISSION SERVICES

The SCCS Chair gave the floor to the Secretariat for an update on the state of play of the following issues:

Update on the Call for applications

The members of the new Committees were appointed by the Director General of the DG SANTE from the list of suitable candidates. Candidates not appointed as members stay on the list as a reserve. The publication of this list is planned before Easter. Candidates will be informed by email. The new Committees will enter into service on 28 April 2016. Current Members are encouraged to finalise the ongoing opinions until that date, including via written procedure. Rapporteurs who will not be members but still involved in ongoing files will continue to be invited to future meetings, to finalise the drafting of

the opinion (i.e. intermediate period). Depending on the experts appointed and the needs of the Committee, the Secretariat will decide whether to open the database of experts or not.

Ongoing evaluation of the Scientific Committees - SCs (2009-2015)

The final draft report was received on 11 March and a discussion is foreseen with the Commission steering group members on 18 March in order to finalise the document by the end of April/beginning of May (end of the contract).

Report from the 2013-2015 term of the Scientific Committees

A power point presentation illustrating SCCS achievements was prepared and presented to the group.

Follow-up of work with scientific journals to promote the dissemination of the SCs opinion:

The Opinions on S79 (nano) and Methylisothiazolinone (MI-P94) have been published in the Journal of Regulatory Toxicology and Pharmacology. Next ones are on Carbon Black (nano) and on o-Phenylphenol, Sodium o-phenylphenate and Potassium o-phenylphenate (OPP).

Science Factsheets:

A science factsheet on the safety of hair dyes was published on 26/02. This science factsheet is written in an easy-to-read language, explaining in layman language the SCCS' scientific opinions on this topic. This factsheet is available in English, French, German and Spanish. You can read the factsheet here: http://ec.europa.eu/health/scientific_committees/docs/citizens_hairdyes_en.pdf

Secretariat news:

The Secretariat informed the group about its visit to ECHA on 3-4/03/2016. Details on an ECHA workshop in April 2016 were provided to the group in order to discuss participation of SCCS member(s) – see point below.

Future events:

- SCENIHR representative informed the group about ongoing work.
- BenchMarkDose (BMD) meeting in EFSA (30-31/03/2016) SCCS will not be represented.
- Organisation for Economic Co-operation and Development (OECD): A meeting on Grouping and Read Across for the Hazard Assessment of Manufactured Nanomaterials will take place on 13-14 April in Elsene, Belgium. The published work of SCCS will be discussed there. Vice-Chair, Qasim Chaudhry, has been invited by OECD and will participate on his personal capacity.
- ECHA topical scientific workshop on new approach methodologies in regulatory science (including SEURAT case study), Helsinki 19-20/04/2016: potential interested members are listed for SCs' participation.

• SCCS Invitation received to participate in the International Dialogue for the Evaluation of Allergens (IDEA) Meeting on the feasibility of a study on the effectiveness of the Dermal Sensitisation Quantitative Risk Assessment (QRA) on 6 April in Belgium. One SCCS member may join the meeting as observer.

6. CHAIR'S / MEMBER'S REPORT

- *Thomas Platzek*, SCCS Chair, reported on his participation in the European Parliament event on Endocrine disruptors on 26 January as well as in the meeting with the Health Commissioner on 10 March.
- *Pieter-Jan Coenraads*, SCCS member, presented his mission report on the International Cooperation on Cosmetics Regulation (ICCR) working group for risk assessment of allergens and sensitisers held on 26 January.
- *Qasim Chaudhry*, SCCS Vice-Chair, reported from SCENIHR last plenary meeting.

7. FOLLOW-UP OF ADOPTED OPINIONS BY DG GROW

DG GROW informed the group about legislative measure taken following SCCS adoption of opinions.

It also informed that a second DG GROW Workshop on cosmetic product preservation is foreseen in October 2016 in Brussels where SCCS will be invited too.

8. NEW REQUESTS/MANDATES

• US call for comments on draft guidance entitled: Over-the-Counter Sunscreens -Safety and Effectiveness Data

<u>http://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_q_127.pdf</u>
Hair dye HC Orange No. 6 (B125). Submission I

http://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_q_128.pdf

Both mandates are adopted and the hair dye will be put on the agenda of the next plenary meeting for rapporteur's nomination under the new Committee.

9. DRAFT OPINIONS ON

Cosmetic Ingredients

The Chair of the WG made a report on the ongoing work

- **Phenoxyethanol** draft Opinion was further discussed, finalised, and adopted. <u>http://ec.europa.eu/health/scientific_committees/consumer_safety/opinions/index_en.htm</u>
- **EcoG**+ draft Opinion was finalised and adopted http://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_o_198.pdf

- **Over-the-Counter Sunscreens** Safety and Effectiveness Data: SCCS agreed on comments that will be sent to DG GROW for their use only (internal document).
- Vitamin A draft Opinion was further discussed and is planned to be adopted by written process once the last outstanding issues among members are clarified. <u>http://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_o_199.pdf</u>

Hair Dyes/Fragrances

The Chair of the Working Group made a report on the ongoing work

- Tetrabromophenol Blue, 4,4'-(4,5,6,7-tetrabromo-l,l-dioxido-3H-2,l-benzoxathiol-3-yliden)bis-2,6-dibromophenol (C183) (CAS 4430-25-5). Submission III. The draft Opinion was finalised and adopted. http://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_o_197.pdf
- **N,N''-Bis-(2-hydroxyethyl)-2-nitro-p-phenylenediamine (B34)** Submission I. The draft Opinion was finalised and adopted. <u>http://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_o_196.pdf</u>
- **Basic blue 124** SCCS/1542/14: the revised Opinion (Submission II) was adopted. <u>http://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_o_179.pdf</u>

Nanomaterial in cosmetic ingredients

The Chair of the Working Group made a report on the ongoing work.

Methodologies

The Chair of the Working Group made a report on the ongoing work

10. COMMENTS ON OPINIONS ADOPTED

Cosmetic Ingredients

• UV filter S86 - SCCS/1556/15

Comments on phys.-chem. properties were sent to the applicant prior to the plenary meeting. Toxicity data have been discussed and SCCS responses to applicant's comments have been adopted. They'll be sent to the applicant for further consideration and future submission.

• **Cyclopentasiloxane - D5** - SCCS/1549/15 SCCS still had concerns on some studies and applicant was requested to clarify the outstanding issues. The SCCS responses are planned to be adopted by written process.

Hair Dyes

• HC Yellow 16 (B123) - SCCS/1568/15 Comments have been discussed and SCCS responses to applicant's comments have been adopted. They'll be sent to the applicant. The revised Opinion was adopted. <u>http://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_o_192.pdf</u>

• HC Red 18 (B124) - SCCS/1569/15

Comments have been discussed and SCCS responses to applicant's comments have been adopted. They'll be sent to the applicant. The revised Opinion was adopted. http://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_o_193.pdf

• **Butylphenyl methylpropional (BMHCA)** SCCS/1540/14 Comments have been discussed and SCCS responses to applicant's comments have been adopted. They'll be sent to the applicant. The revised Opinion was adopted. <u>http://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_o_189.pdf</u>

Nanomaterial in cosmetic ingredients

- Hydroxyapatite (nano) SCCS/1566/15
 Both SCCS responses to comments and respective revised Opinion were further
 discussed. They're planned to be adopted by written process once the last outstanding
 issues among members are clarified.
 http://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_o_191.pdf
- Revision of the opinion on 2,2'-Methylene-bis-(6-(2H-benzotriazol-2-yl)-4-(1,1,3,3tetramethylbutyl)phenol)(nano form) Submission III (S79) - MBBT (nano) -SCCS/1546/15 SCCS response to comment has been adopted.

Methodologies

Comments on the Notes of Guidance (NoG) for testing of the cosmetic ingredients and their safety evaluation - NoG (9th revision) were received and a **revision of the document is foreseen**: all comments and SCCS responses were discussed at the methodology meeting on 15 March 2016. The NoG has been revised accordingly. The new version **is planned to be adopted by written procedure**, together with all SCCS responses.

http://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_o_190.pdf

11. ANY OTHER BUSINESS

The working group for hair dyes/fragrances will be merged with the WG for cosmetic ingredients under the new term (2016-2021).

Next plenary meetings 28-29 April 2016

Annex : List of Participants

Members of the SCCS

Ulrike Bernauer, Qasim Chaudhry (Vice-Chair), Pieter-Jan Coenraads, Gisela Degen (Vice-Chair), Maria Dusinska, Werner Lilienblum, Elsa Nielsen, Thomas Platzek (Chair), Christophe Rousselle and Jan van Benthem.

Members of the SCENIHR Ana PROYKOVA

Apologies SCHER representative

SCCS Secretariat (DG SANCO C2) Philippe Roux, Donata Meroni, Natacha Grenier and Diana Herold.

DG GROW D4 Gaetano Castaldo.