

Scientific Committee on Consumer Safety (SCCS)

3rd PLENARY meeting - term 2016-2021

Venue: Luxembourg

Meeting date: 07 March 2017

Minutes

• WELCOME AND APOLOGIES (CHAIR: QASIM CHAUDHRY)

The Chair, Qasim Chaudhry, welcomed the members including one representative from SCHEER, Renate Krätke. There was one apology.

• ADOPTION OF THE AGENDA

The agenda was adopted as presented.

• DECLARATION OF INTEREST ON MATTERS ON THE AGENDA

The Chair invited participants to declare any interest regarding matters on the agenda. None of the participants declared any interest conflicting with the matters on the agenda.

• FOLLOW-UP OF ADOPTED OPINIONS BY DG GROW

DG GROW D4 reported on recent legislative measures taken following SCCS adoption of opinions:

• Commission Regulation (EU) 2017/237 of 10 February 2017 amending Annex III to Regulation (EC) No 1223/2009 of the European Parliament and of the Council on cosmetic products (hair and eyelash dyes) was published in the OJ L36on 11.2.2017, p. 12:

http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1486978094623&uri=CELEX:32017R0237

• Commission Regulation (EU) 2017/238 of 10 February 2017amending Annex VI to Regulation (EC) No 1223/2009 of the European Parliament and of the Council on cosmetic products (Benzophenone-3) was published in the OJL36 on 11.2.2017, p. 37:

http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1486978094623&uri=CELEX:32017R0238

The new legislative acts are posted on the website of the scientific committees with a link to DG GROW website: <u>http://ec.europa.eu/growth/sectors/cosmetics/legislation_en</u>

 D4/D5 in rinse off products (0.1%): REACH Annex XVII might be changed (vote foreseen in June) to lower the concentration for environmental safety –A Public consultation on Tagetes minuta, Tagetes patula and Tagetes erecta extracts and essential oils –Cosmetics Regulations has been launched by GROW:

<u>http://ec.europa.eu/growth/tools-databases/newsroom/cf/itemdetail.cfm?item_id=9033</u> The deadline to submit contributions is 08/03/2017.

• NEW REQUESTS/MANDATES

- Quantitative Risk Assessment (QRA 2)
- Submission I on cosmetic ingredients HEMA (CAS 868-77-9) and Di HEMA Trimethylhexyl Dicarbamate (CAS 41137-60-4 /72869-86-4)
- Submission II on Aluminium in antiperspirant/deodorant and other cosmetic products following the SCCS opinion of 2014

Rapporteurs were selected for each Opinion and will be appointed by the Commission.

Mandates are published:

http://ec.europa.eu/health/scientific committees/consumer safety/requests/index en.htm

• **OPINIONS ADOPTED ON**

COSMETIC INGREDIENTS (including Hair Dyes/Fragrances)

- UV filter S87 - SCCS/1587/17

Based on the data provided, the SCCS is of the opinion that genotoxic potential of Methoxypropylamino Cyclohexenylidene Ethoxyethylcyanoacetate (S87) cannot be excluded. Therefore, the SCCS cannot conclude on the safety of S87.

On the basis of the studies provided, skin and eye irritation potential of the test item cannot be excluded. More evidence is needed to exclude the genotoxicity concern regarding S87.

Dermal penetration data using 5% of the test material should also be provided.

This is the preliminary version opened for comments until 14 May 2017: https://ec.europa.eu/health/sites/health/files/scientific_committees/consumer_safety/docs/sccs_o_208.pdf

- Zinc salts in oral hygiene - SCCS/1586/17

The SCCS considers that the use of zinc in toothpaste and mouthwash per se is safe for adults and children aged 7-17 years.

The SCCS considers that the use of zinc in toothpaste per se is safe for children aged 0.5-6 years. This is the preliminary version opened for comments until 14 May 2017: https://ec.europa.eu/health/sites/health/files/scientific committees/consumer safety/docs/sccs o 207.pdf

- Hair Dye A164 – SCCS/1584/17

The SCCS considers Dimethylpiperazinium Aminopyrazolopyridine HCl (A164) safe when used in oxidative hair colouring products up to a maximum on-head concentration of 2%. This is the preliminary version opened for comments until 14 May 2017: https://ec.europa.eu/health/sites/health/files/scientific_committees/consumer_safety/docs/sccs_o_209.pdf

- Hair Dye Basic Blue 99 - C059 - SCCS/1585/17

The SCCS cannot assess the safety of a mixture which has a variable composition (mixture of up to 40 substances and variable isomeric composition) as shown by the data provided on six batches of Basic Blue 99.

This is the preliminary version opened for comments until 14 May 2017: https://ec.europa.eu/health/sites/health/files/scientific_committees/consumer_safety/docs/sccs_o_205.pdf

- Hair Dye C183 – SCCS/1573/16

Because of the large discrepancies noted between the specifications provided for the representative market quality batch intended for commercial use and that used in toxicological testing, SCCS cannot conclude on the safety of C-183. This is the final Opinion.

https://ec.europa.eu/health/sites/health/files/scientific committees/consumer safety/docs/sccs o 197.pdf

NANOMATERIAL IN COSMETIC INGREDIENTS

- TiO2 (nano) in sprayable products SCCS/1583/17
 The SCCS has concluded that the information is insufficient to allow assessment of the safety of the use of nano- TiO2 in sprayable application.
 This is the preliminary version opened for comments until 14 May 2017: https://ec.europa.eu/health/sites/health/files/scientific committees/consumer_safety/docs/sccs_o_206.pdf
- Styrene/Acrylates copolymer (nano) CAS No 9010-92-8, EC No 927-710-1 and Sodium styrene/Acrylates copolymer (nano) CAS No 9010-92-8 and Colloidal Silver (nano) CAS No 7440-22-4, EC No 231-131-3. Letters with a request for data was sent to the Applicants with a deadline for replying by 30 September 2017.
- The draft ECHA guidance on nano read-across is available online for public consultation. SCCS will discuss its possible contribution during a nano Working Group meeting. <u>https://echa.europa.eu/support/guidance/consultation-procedure/ongoing-reach.</u>

METHODOLOGIES

The checklists to inform how to complete a dossier before submission, respectively for the cosmetic ingredients and the nano materials used in cosmetic ingredients, have been discussed. Last comments need to be taken into account before finalisation. They are planned to be published and to be annexed later on to the next revision of the SCCS Notes of Guidance on the testing of cosmetic ingredients and their safety evaluation $(10^{th} \text{ revision})$.

The SCCS Chair of the Working Group reported on the meeting held on 18 January focusing on *In Silico* methods (see minutes available on the web).

Issues planned for the next meeting(s) have been presented by the Chair and will be discussed at the next Working Group meetings.

• COMMENTS ON OPINIONS ADOPTED

- <u>Opinion on HC Orange No. 6 (B125) SCCS/1579/16</u>
 No comment has been received and the final version has been published.
 <u>https://ec.europa.eu/health/sites/health/files/scientific_committees/consumer_safety/docs/sccs_o_201.pdf</u>
- <u>Opinion on additional coatings for Titanium Dioxide</u> (nano form) as UV-filter in dermally applied cosmetic products SCCS/1580/16 Replies to comments and the final Opinion have been adopted. <u>https://ec.europa.eu/health/sites/health/files/scientific_committees/consumer_safety/docs/sccs_o_202.pdf</u>
- <u>Propylamino biguanide (PHMB) SCCS/1581/16- Submission III</u> *dermal penetration* Comments received have been presented. The deadline is 10 March; SCCS will wait to have the complete list before discussing the responses.
- <u>Ethylzingerone 'Hydroxyethoxyphenyl Butanone' (HEPB)</u> (Cosmetics Europe No P98) SCCS/1582/16
 Comments received have been presented. The deadline is 10 March; SCCS will wait to have the complete list before discussing the responses.

• INFORMATION FROM COMMISSION

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

Administrative information

- The Health Policy Platform was presented by the Commission since it is foreseen to replace the actual platform (Circa B).
- Member Prof Jeanne Duus-Johansen resigned in January 2017 for personal reasons due to other commitments. However she expressed her intention to remain in the reserve list.
- Dr von Goetz was appointed as external expert in the Working Group nanomaterials used in cosmetics and in Working Group methodology. Dr Simonnard has been appointed as external expert in the Working Groups of cosmetic ingredients, methodology and nanomaterials used in cosmetics. Dr Varvaresou has been appointed as external expert in the Working Groups of cosmetic ingredients.
- The Secretariat informed the group about an internal survey of the first year evaluation of new Scientific Committees and Secretariat support.
- Draft EURL ECVAM Recommendation on the use of non-animal approaches for skin sensitisation assessment: SCCS drafted a reply to the consultation with minor remarks that will be sent to JRC.
- The JRC report on 3Rs knowledge was shared: <u>https://ec.europa.eu/jrc/en/news/reducing-animal-testing-through-better-knowledge-sharing</u>
- The EFSA Scientific Committee guidance <u>"Update: use of the benchmark dose approach in risk</u> <u>assessment</u>" was published on the EFSA Journal.
- EFSA published the news story <u>'EFSA to live webstream open scientific meetings in 2017</u>, which is available in English, French, German and Italian. A <u>calendar of open plenary meetings in 2017</u> was published at the same time, in the 'Engage' section of our website.
- The report on 'Using (eco) toxicological data between nanoforms of the same substance: Elements to consider' (ECHA/RIVM/JRC) was published: <u>http://echa.europa.eu/documents/10162/13630/eco_toxicological_for_bridging_grouping_nanoforms_en.pdf</u>

Future events:

- BfR workshop on validation and regulatory acceptance of alternative methods on 23-24 March 2017: SCCS Vice-Chair is planning to participate.
- The objective of the DG ENV workshop "setting priorities for further development and validation of test methods and testing approaches for evaluating Endocrine Disruptors" is to discuss and prioritise where to invest as regards test methods development in the next 5 years in order to make the biggest contribution to improvement of protection of human health and the environment. It will be from 30 May 2017 to Thursday 1 June 2017 in Brussels. SCCS decided to send a representative. Secretariat informed DG ENV already.
- Genotoxicity Task Force of Cosmetics Europe (CE) invited SCCS to an all-day international workshop which planned to hold on April 26 or April 27 in Brussels, Belgium. SCCS decided to send a representative.

All members are invited to send information to the Secretariat about their (future) participation in any relevant meeting in case there could be a potential conflict of interest.

• CHAIR'S / MEMBER'S REPORT

- Ulrike Bernauer participated in the seminar organised by the German Cosmetic, Toiletry, Perfumery and Detergent Association (IKW) and German Society for Scientific and Applied Cosmetics) (DGK) on 30 January 2017, and reported.
- *Ulrike Bernauer* participated in the plenary of the Scientific Committee on Exposure Occupational level Limits (SCOEL) held on 8 to 10 February 2017 in Berlin, and reported.
- Pieter-Jan Coenraads, SCCS Vice-Chair, participated in the International Dialogue for the Evaluation of Allergens (IDEA) workshop meeting held on 15 February, as observer, and reported.
- *Laurent Bodin* participated in the EFSA workshop on Benchmark-Dose approach (BMD) on 1-2 March 2017, and will report. Both SCCS and SCHEER were represented.
- *Qasim Chaudhry*, SCCS Chair, reported briefly on the fourth International Dialogue for the Evaluation of Allergens (IDEA) annual review meeting held on 6 March 2017 in Luxembourg as half of the members were present too.
- *Qasim Chaudhry*, SCCS Chair, received a letter from the Scientific Advisory Board of EU-ToxRisk Project funded under Horizon 2020 (DG RTD) to which a response was sent after the plenary meeting: the Scientific Advisory Board could start a discussion whether the current interaction could be improved (invitation to project meetings and/or reception of progress reports).

• ANY OTHER BUSINESS

Dates of next meetings:

March 2017: Cosmetic WG meeting on 28-29/03

<u>May 2017</u>: Cosmetic WG meeting on 02/05, Methodology WG meeting on 03/05 (*BMD*) and nano WG meeting on 04/05

June 2017: Plenary meeting 06/06 and Training on Uncertainty on 07/06

<u>August 2017</u>: nano WG meeting on 29/08, Methodology WG meeting on 30/08 (*inhalation exposure*) and Cosmetic WG meeting on 31/08

September 2017: Methodology WG meeting on 26/09 (general issues) and Cosmetic WG meeting on 27 September 2017.

October 2017: Plenary meetings on 24-25/10.

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February 2018: Plenary meeting on 22/02.

Annex: List of Participants

Members of the SCCS

Ulrike Bernauer, Laurent Bodin, Leonardo Celleno, Qasim Chaudhry (Chair), Pieter-Jan Coenraads (2nd Vice-Chair), Janine Ezendam, Eric Gaffet, Corrado Lodovico Galli, Berit Granum, Eirini Panteri, Vera Rogiers (1st Vice-Chair), Christophe Rousselle, Maciej Stepnik, Tamara Vanhaecke, Susan Wijnhoven.

Apologies

Maria Dusinska

Member of the SCHEER Renate Krätke.

SCCS Secretariat (DG SANTE C2) Donata Maroni and Diana Herold.

DG GROW D4

Gaetano Castaldo.