



## Scientific Committee on Consumer Safety (SCCS)

2<sup>nd</sup> PLENARY term 2016-2021

Venue: Luxembourg

Meeting date: 06 October 2016

### Minutes

- **WELCOME AND APOLOGIES (CHAIR: QASIM CHAUDHRY)**

The Chair, Dr Qasim Chaudhry, welcomed the members including one representative from SCHEER, Mrs Renate Krätke. Apologies were received from five members.

- **ADOPTION OF THE AGENDA**

The agenda was adopted as presented.

- **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.

- **INFORMATION FROM COMMISSION**

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

#### **Adopted opinions and mandates**

- Both final Opinion on Cyclopentasiloxane (D5) and on hair dye N'-Bis-(2-hydroxyethyl)-2-nitro-p-phenylenediamine (B34) have been adopted by written procedure, respectively on 29 July 2016 and on 16 September 2016
- The following mandates were adopted by written procedure on 19 August 2016:
  - 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
  - Colloidal Silver (nano) CAS No 7440-22-4, EC No 231-131-3

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

#### **Administrative information**

- The annual Declaration of Interests will have to be filled in this month, using a new form in compliance with the new Horizontal Rules applying to all expert groups of the European Commission.
- Tattooing: the Joint Research Centre has recently published a Science for Policy report. It provides evidence-based scientific support to the European policy-making process. Implications for the Committees will be discussed at the next ICCG meeting (16/11).
- A Call for independent panel in order to advise on tobacco flavours has been published:

[http://ec.europa.eu/dgs/health\\_food-safety/dyna/enews/enews.cfm?al\\_id=1713](http://ec.europa.eu/dgs/health_food-safety/dyna/enews/enews.cfm?al_id=1713)

- 29-30 August 2016: the Secretariat participated in a symposium organised by Korea Centre for Cosmetics Risk Assessment (CCRA) funded by the National Institute of Food and Drug Safety evaluation to promote the Scientific Committees activities, and in particular SCCS. The focus was on risk assessment of cosmetics performed by the SCCS and the revision of the SCCS Notes of Guidance for the testing of the cosmetic ingredients and their safety evaluation. The SC's opinions are very often used and referred to in Asia and Australia.
- The EFSA guidance on the use of the benchmark dose approach in risk assessment went through a public consultation process from 14 July until 20 September 2016.  
<http://www.efsa.europa.eu/en/press/news/160714a>  
It has been discussed at the Methodology WG meeting on 5/10. Training on this topic could be organised at the Methodology WG meeting to be held on 2 May 2017.
- The Database of Experts of the Scientific Committees (SCs) has been re-launched:  
[http://ec.europa.eu/health/scientific\\_committees/experts/database/index\\_en.htm](http://ec.europa.eu/health/scientific_committees/experts/database/index_en.htm)
- A Workshop to accelerate the acceptance of mathematical models as evidence in safety and efficacy decision making was held on 14&15/09/2016 in London by the UK's national Centre to promote 3Rs to reduce/refine/replace animal testing. SCCS provided a short description to the workshop organisers on what are the basic elements that would help acceptance of estimated values derived from *in silico* methods in regulatory assessments. The content of this paper has been included into an SCCS Statement technically adopted at this plenary (see below) and foreseen for publication on the SC website. The link will also be provided to the organiser.
- The Secretariat reported on the ECHA and SCs' Secretariat bilateral (videoconference) held on 28 September 2016 to exchange information on Opinions of common interest and events.
- The report on 'Using (eco) toxicological data between nanoforms of the same substance: Elements to consider' (ECHA/RIVM/JRC) was published:  
[http://echa.europa.eu/documents/10162/13630/eco\\_toxicological\\_for\\_bridging\\_grouping\\_nanoforms\\_en.pdf](http://echa.europa.eu/documents/10162/13630/eco_toxicological_for_bridging_grouping_nanoforms_en.pdf)

#### **Future events:**

- A DG GROW Workshop on carcinogens is scheduled on 22 November 2016 in Brussels. A representative from SCCS will give a presentation on cosmetic ingredients' cases studies. Participation via registration:  
[http://ec.europa.eu/growth/tools-databases/newsroom/cf/itemdetail.cfm?item\\_id=8936](http://ec.europa.eu/growth/tools-databases/newsroom/cf/itemdetail.cfm?item_id=8936)
- DG ENV is organising a European Commission Scientific Conference: "Non-Animal Approaches - The Way Forward" on 6-7 December 2016. SCCS is considering sending a representative. Participation via registration:  
<http://www.euconf.eu/non-animal-approaches-the-way-forward/en/registration/index.html>
- SCCS received an invitation from BfR (DE) to participate in 1-day expert meeting on "mineral oil aromatic hydrocarbons (MOAH) in cosmetics" on 25 November. One member is already participating for BfR and will brief SCCS afterwards. SCCS therefore declined this invitation.
- 13 December 2016: SCCS Vice-Chair, Vera Rogiers, will participate in the IDEA working group meeting on pre- and pro haptens, representing SCCS as an observer.
- The International Dialogue for the Evaluation of Allergens (IDEA) annual review meeting is planned in Luxembourg back to back with March plenary, on 6 March 2017. A mandate to assess

the developed Qualitative Risk Assessment tool (2) is expected to be sent to SCCS by the end of this year.

- 7 June 2017: a session will be organised in Luxembourg on methodology to assess uncertainty, inviting also EFSA expert to explain EFSA Guidance. This is back to back with SCCS Plenary of 6 June.

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 or a real conflict of interest.

- **CHAIR'S / MEMBER'S REPORT**

- *Qasim Chaudhry*, Chair of SCCS, reported on his participation in the event organised by the new scientific advice mechanism (SAM) "*Science and Policy-Making: towards a new dialogue*" held in Brussels on 29-30 September.
- *Pieter-Jan Coenraads*, Vice-Chair of SCCS, reported on his participation together with *Christophe Rousselle*, in the DG GROW workshop on preservatives held on 22 September in Brussels. The challenges faced by SCCS when safety dossiers are submitted were presented. It helped Member States to better understand the above challenges and will also help industry to submit safety dossier of better quality.
- JRC organised the International Cooperation on Alternative Test Methods (ICATM) workshop on 04-05 October in Ispra and one SCCS representative, *Leonardo Celleno*, participated. He will report during the next WG meetings.

- **FOLLOW-UP OF ADOPTED OPINIONS BY DG GROW**

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

**1. Commission Regulation (EU) 2016/1198 amending Annex V to Regulation (EC) No 1223/2009 of the European Parliament and of the Council on cosmetic** has been adopted on 22 July 2016 and published in the OJ L198 of 23.07.2016, p. 10.

[http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L\\_.2016.198.01.0010.01.ENG&toc=OJ:L:2016:198:TOC](http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2016.198.01.0010.01.ENG&toc=OJ:L:2016:198:TOC)

**2. Commission Regulation (EU) 2016/1120 amending Annex IV to Regulation (EC) No 1223/2009 of the European Parliament and of the Council on cosmetic products (Carbon Black)** has been adopted on 11 July 2016 and published in the OJ L187 of 12.07.2016, p. 1.

**3. Commission Regulation (EU) 2016/1121 amending Annex V to Regulation (EC) No 1223/2009 of the European Parliament and of the Council on cosmetic products (Ethyl Lauroyl Arginate HCl)** has been adopted on 11 July 2016 and published in the OJ L187 of 12.07.2016, p. 4.

<http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=OJ:L:2016:187:TOC>

**4. Commission Regulation (EU) 2016/1143 amending Annex VI to Regulation (EC) No 1223/2009 of the European Parliament and of the Council on cosmetic** has been adopted on 13 July 2016 and published in the OJ L189 of 14.07.2016, p. 40. (cf. UV-filter-TiO<sub>2</sub>)

[http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L\\_.2016.189.01.0040.01.ENG&toc=OJ:L:2016:189:TOC](http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2016.189.01.0040.01.ENG&toc=OJ:L:2016:189:TOC)

The new legislative acts are posted on the website of the scientific committees on DG GROW website: [http://ec.europa.eu/growth/sectors/cosmetics/legislation\\_en](http://ec.europa.eu/growth/sectors/cosmetics/legislation_en)

5. A Report from High Court of Justice on non-animal testing of cosmetics was released:  
[http://www.wort.lu/en/luxembourg/european-court-of-justice-no-exceptions-to-cosmetics-animal-testing-ban-says-luxembourg-court-57e25e5bac730ff4e7f66b9c?utm\\_source=en\\_daily&utm\\_medium=email-0800&utm\\_content=newsLink&utm\\_campaign=dailyNewsletter](http://www.wort.lu/en/luxembourg/european-court-of-justice-no-exceptions-to-cosmetics-animal-testing-ban-says-luxembourg-court-57e25e5bac730ff4e7f66b9c?utm_source=en_daily&utm_medium=email-0800&utm_content=newsLink&utm_campaign=dailyNewsletter)

6. A report from the Commission to the European Parliament and the Council on the development, validation and legal acceptance of methods alternative to animal testing in the field of cosmetics (2013-2015) was adopted on 19 September 2016  
<http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1474371485850&uri=COM%3A2016%3A599%3AFIN>

7. A report from the Commission to the European Parliament and the Council on product claims made based on common criteria in the field of cosmetics was adopted on 19 September 2016  
<http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1474371584966&uri=COM:2016:580:FIN>

- **NEW REQUESTS/MANDATES**

- Propylamino biguanide (PHMB) Submission III (dermal penetration)
- Water-soluble Zinc salts used in oral hygiene products. Submission II
- Hair dye A164 - Submission I
- Fragrance Acetylated Vetiver Oil - Submission III

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

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

The draft mandate on Hair dye A165- Hydroxypropyl P-Phenylenediamine - Submission I was not submitted to the SCCS for adoption and might be adopted through written process.

- **DRAFT OPINIONS ON**

**COSMETIC INGREDIENTS (including Hair Dyes/Fragrances)**

- Propylamino biguanide (PHMB): Submission III – dermal penetration. A request to the applicant has been prepared concerning issues on the purity of batches and on requested information regarding inhalation/spray formulation.
- B125 HC Orange N°6 – submission I. The draft opinion was discussed and will be finalised in order to be adopted by written procedure.

**NANOMATERIAL IN COSMETIC INGREDIENTS**

- Titanium Dioxide (nano) as UV-Filter in sunscreens and personal care spray products: Discussions are still open and the draft opinions will be further discussed at the next WG nano meeting (07/12)
- Three coatings for Titanium Dioxide (nano form) as UV-filter in dermally applied cosmetic products: The draft opinion will be finalised and adopted through written process.

**METHODOLOGIES**

The SCCS Chair of the Working Group reported on the meeting held on 05 October (see minutes). Issues planned for the next meeting(s) have been presented by the Chair and will be discussed at the next WG meetings.

- **COMMENTS ON OPINIONS ADOPTED**

Phenoxyethanol – SCCS/1575/16

Comments received have been discussed and SCCS responses have been adopted. They'll be sent out. The revised Opinion was adopted.

[http://ec.europa.eu/health/scientific\\_committees/consumer\\_safety/docs/sccs\\_o\\_195.pdf](http://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_o_195.pdf)

Vitamin A – SCCS/1576/16

Comments received have been discussed and SCCS responses have been adopted. They'll be sent out. The revised Opinion was adopted.

[http://ec.europa.eu/health/scientific\\_committees/consumer\\_safety/docs/sccs\\_o\\_199.pdf](http://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_o_199.pdf)

EcoG+ – SCCS/1577/16

Comments received have been discussed and SCCS responses have been adopted. They'll be sent out. There is no change in the Opinion and the final version was adopted.

[http://ec.europa.eu/health/scientific\\_committees/consumer\\_safety/docs/sccs\\_o\\_198.pdf](http://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_o_198.pdf)

Fragrance ingredients Tagetes minuta and T. patula extracts and essential oils (phototoxicity only) – SCCS/1551/15

The SCCS agrees with the proposal of DG GROW to set the maximum concentration level of 0.1 % of Tagetes minuta and Tagetes patula extracts and essential oils in rinse-off products.

- **ANY OTHER BUSINESS**

**Dates of next meetings:**

November 2016: Cosmetic WG meeting on 15/11

December 2016: Nano WG meeting on 07/12, Methodology WG meeting on 08-09/12 (*including PBPK modelling training*) and Cosmetic WG meeting on 15/12

January 2017: Methodology WG meeting on 18/01 (*in silico*) and Cosmetic WG meeting on 19/01

February 2017: Cosmetic WG meeting on 14/02

March 2017: IDEA annual review meeting on 06/03, Plenary meeting 07/03/2017, Methodology WG meeting on 08/03 (*aggregate dermal exposure*), and Cosmetic WG meeting on 28-29/03

May 2017: Methodology WG meeting on 02/05 (*BMD*) and Cosmetic WG meeting on 03/05

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

October 2017: Plenary meeting 24-25/10

## **Annex: List of Participants**

### **Members of the SCCS**

Ulrike Bernauer, Laurent Bodin, , Qasim Chaudhry (Chair), Pieter-Jan Coenraads (2nd Vice-Chair), Maria Dusinska, Janine Ezendam Eirini Panteri, Vera Rogiers (1st Vice-Chair), Christophe Rousselle, Maciej Stepnik, Tamara Vanhaecke, Susan Wijnhoven.

### **Apologies**

Leonardo Celleno, Jeanne Duus-Johansen, Corrado Lodovico Galli, Berit Granum, Eric Gaffet.

### **Member of the SCHEER**

Renate Krätke.

### **SCCS Secretariat (DG SANTE C2)**

Donata Maroni, Natacha Grenier and Diana Herold.

### **DG GROW D4**

Gaetano Castaldo.