



## **Scientific Committee on Consumer Safety (SCCS) 12<sup>th</sup> PLENARY**

**Venue: Luxembourg**

**Meeting date: 15 December 2015**

### **Minutes**

#### **1. WELCOME AND APOLOGIES**

The Chair welcomed all the participants. *Prof Ana PROYKOVA* (from SCENIHR) participated as well. There were three apologies.

#### **2. ADOPTION OF THE AGENDA**

The agenda was adopted as presented.

#### **3. MINUTES OF THE PREVIOUS PLENARY MEETING – 29 SEPTEMBER 2015**

The minutes were adopted on 21 October 2015 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 CHAIR/MEMBERS/COMMISSION**

- The SCCS was invited to send any comment on the Rules of procedure that is foreseen to be updated: [http://ec.europa.eu/health/scientific\\_committees/docs/rules\\_procedure\\_2013\\_en.pdf](http://ec.europa.eu/health/scientific_committees/docs/rules_procedure_2013_en.pdf)
- The deputy head of unit of DG SANTE C2 informed about the status of the ongoing evaluation of the scientific committee (SCs) and the ongoing internal reorganisation within DG SANTE.
- A list with all opinions adopted by all three SCs was distributed for information.
- GROW D4 informed about legislative measures published in 2015 following SCCS adoption of opinions, and in particular the following updates:
  1. <http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32015R1298&from=EN>
  2. <http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32015R1190&from=EN>

- *Ana Proykova* informed about the SYN BIO workshop held in Luxembourg on 10 December 2015: [http://ec.europa.eu/health/scientific\\_committees/events/ev\\_20151210\\_en.htm](http://ec.europa.eu/health/scientific_committees/events/ev_20151210_en.htm)
- The members were informed on the ongoing working group of SCENIHR on sunbeds and on the status of the draft Opinion.
- HEARINGS – the SCCS met with the industry representatives and reported on nano silica on 4 December. It will also meet with applicant of BMHCA fragrance ingredient on 16 December.
- A DG GROW Workshop on cosmetic product preservation was held on 21 October in Brussels. SCCS representatives and Secretariat were participating and *Werner Lilienblum*, SCCS member, reported on the event highlighting the importance of the quality of a safety dossier to start a risk assessment. GROW D4 reported on DG GROW Workshop on cosmetic product preservation explaining the foreseen follow-up actions
- *Werner Lilienblum*, SCCS member, reported on the JRC meeting of "The read-across case study for safer assessment contributing to the SEURAT-1 Proof in Concept - Part II" held on 5-6 October. The project will end in December 2015 and final results will be presented in Brussels.
- *Tamara Vanhaecke*, SCCS external expert, participated in the JRC meeting of the preliminary assessment of regulatory relevance Network (PARERE) on 20-21 October 2015. Her report was already sent to all SCCS members.
- *Pieter-Jan Coenraads*, SCCS member, participated in ECVAM stakeholders' meeting and also in IDEA Workshop on pre- and pro-haptens in Brussels on 20-21 October 2015 and reported on both events.
- *Christophe Rousselle*, SCCS member, participated in the Benchmark Dose (BMD) meeting in EFSA on 4-5 November 2015. His report was already distributed to all SCCS members. This topic is planned to be further discussed at next methodology WG meeting on 15 March 2016.
- *Christophe Rousselle*, SCCS member, participated in the Commission workshop to present methodology for evidence screening of chemicals developed by the JRC in the context of an impact assessment (IA) on criteria to identify Endocrine Disruptors (EDs), on 6 November 2015. His report was already distributed to all SCCS members. The European list of EDs has been published and 45 cosmetic ingredients have been selected:  
[http://ec.europa.eu/health/endocrine\\_disruptors/impact\\_assessment/index\\_en.htm](http://ec.europa.eu/health/endocrine_disruptors/impact_assessment/index_en.htm)
- *Thomas Platzek*, SCCS Chair, reported on the Inter Committee Coordination Meeting (ICCG) held 4 December 2015. Minutes will be made available later on the website: [http://ec.europa.eu/health/scientific\\_committees/inter\\_committee/minutes/index\\_en.htm](http://ec.europa.eu/health/scientific_committees/inter_committee/minutes/index_en.htm)
- SCCS Opinions on Aluminium, TiO<sub>2</sub> (nano), Polyaminopropyl Biguanide (PHMB), Silica (nano), and beta - alpha and deoxyarbutin have been published in the Regulatory Toxicology Pharmacology Journal. The two last ones for 2015 are planned

to be on 2,2'-methylene-bis-(6-(2H-benzotriazol-2-yl)-4-(1,1,3,3-tetramethylbutyl)phenol -S79 (nano) and Methylisothiazolinone (P94): [http://ec.europa.eu/health/scientific\\_committees/scientific\\_journals/index\\_en.htm#cat\\_cosmetic](http://ec.europa.eu/health/scientific_committees/scientific_journals/index_en.htm#cat_cosmetic)

- The SCCS was informed that a public consultation on recommendations for Formaldehyde from the Scientific Committee on Occupational Exposure Limit (SCOEL) is ongoing (deadline 17/02/2016). The ICCG will first check if there is a need for the three SCs to reply: <https://circabc.europa.eu/w/browse/1934303f-58d8-40b4-a84f-f931a0d3980c>
- Two Factsheets on hair dyes risk assessment and on the 9<sup>th</sup> revision of the Notes of Guidance on the testing of cosmetic ingredients and their safety evaluation were finalised and will be sent for translation before the publication foreseen in January 2016. [http://ec.europa.eu/health/scientific\\_committees/policy/opinions\\_plain\\_language/index\\_en.htm](http://ec.europa.eu/health/scientific_committees/policy/opinions_plain_language/index_en.htm)

## 6. NEW REQUESTS/MANDATES

Mandates were adopted; rapporteurs appointed for:

- Preservative 'Hydroxyethoxyphenyl Butanone' (HEPB) - **P 98**  
[http://ec.europa.eu/health/scientific\\_committees/consumer\\_safety/docs/sccs\\_q\\_125.pdf](http://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_q_125.pdf)
- Hair dye Tetrabromophenol Blue, 4,4'-(4,5,6,7-tetrabromo-1,1-dioxido-3H-2,1-benzoxathiol-3-yliden)bis-2,6-dibromophenol (**C183**) (CAS 4430-25-5). **Submission III**  
[http://ec.europa.eu/health/scientific\\_committees/consumer\\_safety/docs/sccs\\_q\\_123.pdf](http://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_q_123.pdf)
- **Three coatings for Titanium Dioxide (nano form)** as UV-filter in dermally applied cosmetic products  
[http://ec.europa.eu/health/scientific\\_committees/consumer\\_safety/docs/sccs\\_q\\_124.pdf](http://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_q_124.pdf)
- International Cooperation on Cosmetic Regulations' Report on **Traces of 1,4-dioxane**  
[http://ec.europa.eu/health/scientific\\_committees/consumer\\_safety/docs/sccs\\_q\\_126.pdf](http://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_q_126.pdf)

In addition, a mandate on scientific comments on the cosmetics part of the **FDA guidance for industry related to sunscreens** was presented and discussed. This point is foreseen to be further discussed at next working group (WG) meeting on cosmetic ingredients (19-20 January 2016).

## 7. DRAFT OPINIONS ON

Joint opinion SCCS/SCENIHR/SCHER

- **SYNBIO 3RD OPINION** WAS adopted by written procedure and published on 9 December 2015:  
[http://ec.europa.eu/health/scientific\\_committees/emerging/docs/scenihr\\_o\\_050.pdf](http://ec.europa.eu/health/scientific_committees/emerging/docs/scenihr_o_050.pdf)

### Cosmetic Ingredients

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

- **Phenoxyethanol** progress report was presented by the rapporteur. Missing references are still expected from the Applicant. Tasks to SCCS members were allocated. The draft Opinion will be further discussed at the next WG meeting on cosmetic ingredients (19-20 January 2016).

### Hair Dyes/Fragrances

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

- **HC Yellow 16 (B123)** - Submission I: the Opinion was adopted.  
[http://ec.europa.eu/health/scientific\\_committees/consumer\\_safety/docs/sccs\\_o\\_192.pdf](http://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_o_192.pdf)
- **HC Red 18 (B124)** - Submission I: the Opinion was adopted.  
[http://ec.europa.eu/health/scientific\\_committees/consumer\\_safety/docs/sccs\\_o\\_179.pdf](http://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_o_179.pdf)
- **N,N''-Bis-(2-hydroxyethyl)-2-nitro-p-phenylenediamine (B34)** - Submission I: data requested to the Applicant have not been received yet and the draft Opinion was sent back to the appropriate WG for further discussion.

### Nanomaterial in cosmetic ingredients

A representative of the WG made a report on the ongoing work in absence of the Chair.

- **Carbon Black (nano)**: revision of the opinion was adopted.  
[http://ec.europa.eu/health/scientific\\_committees/consumer\\_safety/docs/sccs\\_o\\_144.pdf](http://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_o_144.pdf)

### Methodologies

- A Memorandum on human data in risk assessment of skin sensitisation was adopted.  
[http://ec.europa.eu/health/scientific\\_committees/consumer\\_safety/docs/sccs\\_s\\_010.pdf](http://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_s_010.pdf)
- The draft Agenda of the next meeting on 15 March 2016 was discussed and some amendments were made.

## 8. COMMENTS ON OPINIONS ADOPTED

### Cosmetic Ingredients

- **METHYLISOTHIAZOLINONE – MI ( P94) – SCCS/1557/15**  
The SCCS answers to comments received were adopted and will be sent out. The final Opinion remains unchanged:  
[http://ec.europa.eu/health/scientific\\_committees/consumer\\_safety/docs/sccs\\_o\\_178.pdf](http://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_o_178.pdf)

- **O-PHENYLPHENOL – OPP – SCCS/155/15**  
The SCCS answers to comments received were adopted and will be sent out. The final Opinion has been revised accordingly, mainly in section 3.3.14 Discussion - Special investigations - Potential endocrine disruptor properties (p. 51).  
[http://ec.europa.eu/health/scientific\\_committees/consumer\\_safety/docs/sccs\\_o\\_177.pdf](http://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_o_177.pdf)
- **CETYLPIRIDINIUM CHLORIDE - P97 – SCCS/1548/15**  
The SCCS answers to comments received were adopted and will be sent out. The final Opinion has been revised accordingly, and in particular: the overall SCCS comment to oral mucosal irritation on page 16 has been revised, the section 3.3.11 human data now includes the pharmacovigilance information provided by the applicant (pages 44-45), the section 3.3.13 oral and dermal application (including the tables) have been revised, the section 3.3.14 discussion was modified under section irritation/sensitisation on page 49, and finally the conclusion 1 on page 51 was revised too.  
[http://ec.europa.eu/health/scientific\\_committees/consumer\\_safety/docs/sccs\\_o\\_171.pdf](http://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_o_171.pdf)
- **PHMB – SCCS/1535/14**  
The SCCS adopted a reply to be sent to the applicant regarding future studies.

#### Hair Dyes

- **A163 – SCCS/1562/15**  
The SCCS answer to comments received was adopted and will be sent out. The final Opinion has been revised accordingly:  
[http://ec.europa.eu/health/scientific\\_committees/consumer\\_safety/docs/sccs\\_o\\_181.pdf](http://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_o_181.pdf)
- **B120 – SCCS/1558/15**  
The SCCS answer to comment received was adopted and will be sent out. The final Opinion has been revised accordingly.  
[http://ec.europa.eu/health/scientific\\_committees/consumer\\_safety/docs/sccs\\_o\\_182.pdf](http://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_o_182.pdf)
- **B121 - SCCS/1559/15**  
The SCCS answer to comment received was adopted and will be sent out. The final Opinion has been revised accordingly.  
[http://ec.europa.eu/health/scientific\\_committees/consumer\\_safety/docs/sccs\\_o\\_186.pdf](http://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_o_186.pdf)
- **B122 - SCCS/1560/15**  
The SCCS answer to comment received was adopted and will be sent out. The final Opinion has been revised accordingly:  
[http://ec.europa.eu/health/scientific\\_committees/consumer\\_safety/docs/sccs\\_o\\_180.pdf](http://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_o_180.pdf)

## 9. ANY OTHER BUSINESS

1. There will be a Human Biomonitoring Conference that will take place in Germany in April: conference website: [www.uba.de/en/hbm-conference-berlin2016n](http://www.uba.de/en/hbm-conference-berlin2016n) )

2. GROW D4 informed about the possibility to organise a new workshop before future meetings of the Standing Committee on Cosmetic Products in 2016.

Next working group meetings

19-20/1 and 24/2/2016:

26/1/2016

15/3/2016

WG on cosmetic ingredients and hair dyes (joint)

WG on nano in cosmetics

WG on methodology

Next plenary meetings

16 March 2016

## **Annex I: List of Participants**

### **Members of the SCCS**

Ulrike Bernauer, Pieter-Jan Coenraads, Gisela Degen (Vice-Chair), Maria Dusinska, Werner Lilienblum, Elsa Nielsen, Thomas Platzek (Chair).

### **Apologies**

Qasim Chaudhry (Vice-Chair), Christophe Rousselle and Jan van Benthem.

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

Donata Meroni, Natacha Grenier and Diana Herold.

### **DG GROW D4**

Federica de Gaetano, Gaetano Castaldo.