



## Scientific Committee on Consumer Safety (SCCS) 2nd PLENARY

Venue: Luxembourg

Meeting date: 18 June 2013

### Minutes

#### 1. WELCOME AND APOLOGIES

The Commission welcomed the participants and a tour de table was made to introduce each other. Three apologies were announced by the Chair. Two members were connected via audio.

#### 2. ADOPTION OF THE AGENDA

The agenda was adopted as presented.

#### 3. DECLARATION OF INTEREST ON MATTERS ON THE AGENDA

No declaration of potential conflict of interest was made.

The Plenary members took note of the fact that one member is not taking part in discussion related to a specific nanofile under the WG on Nanomaterials in Cosmetic products (see minutes of that WG dated 31/05).

#### 4. NEW INFORMATION FROM THE COMMISSION, CHAIR AND THE MEMBERS OF SCCS

- A WG members' participation list was tabled for final checking
- SCCS Chair has been invited to draft an editorial for the "special edition SC newsletter" of the Health-EU Newsletter
- IFRA meeting on fragrances allergy was held on 28-29 May 2013 in Brussels. One member of SCCS was participating. Outcome documents from previous IFRA meeting were sent to all members. One SCCS member is planning to participate in the next meeting on definition of allergens on 17-18 September 2013
- OECD next meeting of the Task Force on Hazard Assessment will be on 25 – 26 June 2013 with a view to endorsement of the proposal and establishment of the drafting group (deadline for submission of experts was 24 April)
- WHO/IPCS Workshop on Uncertainty in Hazard Assessment, 19-20 November 2013: one SCCS member is planning to participate

#### 5. NEW REQUESTS

##### Cosmetic ingredients:

- *Mandate on S86, UV filter Phenylene Bis Diphenyltriazine*: this mandate is blocked due to absence of a toxicological file. SANCO B2 will require additional data to the applicant cf. point 9)

- *Mandate on preservative Ethyl Lauroyl ArginateHCl (P95 - submission IV)*: the members took note of the Rapporteur appointed during the WG meeting
- *Mandate on Thioglycolic acid and its salts*: a Rapporteur was appointed and it was decided that the dossier will be dealt with by the WG on Cosmetic Ingredients

### Hair Dyes

- *Submission IV on Hair Dye Dispersion Red 17 (B005)*: a mandate is still expected from SANCO B2

### Nanomaterial in Cosmetic Products:

- *ZnO revision (UV filter)*: the members took note of the rapporteur appointed during the WG meeting (see also point 6-nano)
- A short discussion on the future submissions of nano dossiers to SCCS took part

## **6. DRAFT OPINIONS FOR FINALISATION ON**

### Cosmetic Ingredients

The Chair of the WG informed about the two other draft opinions, still under WG discussion, i.e. EcoG+ (the applicant has been requested to submit missing data), and Cetylpyridinium Cl (Subm II).

#### • **P81, ZINC PYRITHIONE** **SCCS/1512/13**

The SCCS was asked to answer the following question:

1. Based on the scientific data provided, does the SCCS consider that zinc pyrithione, when used in a concentration up to 2.0% as anti-dandruff agent in rinse-off hair care products, is safe for the consumer? [The request should be seen as additional to the currently authorized use].

The SCCS concluded that the previous opinion (SCCNFP/0671/03) on the safe use of zinc pyrithione for preservative purposes in cosmetic rinse-off hair care products at a maximum concentration of 1.0 % is confirmed.

SCCS considers that zinc pyrithione, when used in a concentration up to 2.0% as anti-dandruff agent in rinse-off hair care products, is not safe for the consumer. This conclusion is based on the fact that a MOS below 100 was obtained based on the information available. The data provided by the applicant is incomplete in order to enable risk assessment based on PBPK modelling.

Aggregate exposure to Zinc Pyrithione from non-cosmetic sources has not been considered.

The opinion was adopted.

Editorial work is still needed prior to publication.

#### • **S61, 3-BENZYLIDENE CAMPHOR** **SCCS/1513/13**

The SCCS was asked to answer the following questions:

1. Does the SCCS consider 3-benzylidene camphor safe for use as a UV-filter in cosmetic products in a concentration up 2.0% taken into account the scientific data provided?

2. Does the SCCS have any further scientific concerns with regard to the use of 3-benzylidene camphor as a UV-filter in cosmetic products taking into account the concern about its potential endocrine disruptor properties?

The SCCS concluded that due to MoS < 100, the use of 3-benzylidene camphor (3-BC) as a UV-filter in cosmetic products in a concentration up to 2.0% is not safe.

Concerning the potential endocrine disruptor properties of 3-BC, multiple hormonal activities of 3-BC have been reported in vitro: estrogenic and anti-estrogenic effects as well as anti-androgenic activities. In vivo, the expression of target genes (ER $\alpha$ , ER $\beta$ , SRC-1 and PR (progesterone receptor)) has been shown to be altered in both males and females rats at doses lower than the NOAEL used to calculate the MoS. Due to some shortcomings in the studies, the results need to be confirmed.

The opinion was adopted.

Editorial work is still needed prior to publication.

### Hair Dyes

The Chair of the WG informed about three draft opinions still under WG discussion, i.e. C169, *Lawsonia inermis* (Henna) as the next WG has to assess the new analytical part received from the applicant (analytical specification of the requested batch and the non-mutagenic profile) a few days before the Plenary, A8 (2-Chloro-p-phenylenediamine), and Bismuth citrate.

- **C117, HYDROXYANTHRAQUINONE-AMINOPROPYL METHYL MORPHOLINIUM METHOSULFATE** **SCCS/1505/13**

The SCCS was asked to answer the following question:

1. Does the SCCS consider Hydroxyanthraquinone-aminopropyl methyl morpholinium methosulfate safe for use in non-oxidative hair dye formulations with a maximum concentration of 0.5% taken into account the new scientific data provided?

2. Does the SCCS recommend any further restrictions with regard to the use of Hydroxyanthraquinone-aminopropyl methyl morpholinium methosulfate in any non-oxidative hair dye formulations?

The SCCS concluded that the use of Hydroxyanthraquinone-aminopropyl methyl morpholinium methosulfate with a maximum concentration of 0.5% in non-oxidative hair dye formulations does not pose a risk to the health of the consumer, apart from its sensitising potential.

Hydroxyanthraquinone-aminopropyl methyl morpholinium methosulfate is a secondary amine, and thus it is prone to nitrosation. It should not be used together with nitrosating agents. The nitrosamine content should be <50 ppb.

This hair dye is a strong skin sensitiser.

The opinion was adopted.

Editorial work is still needed prior to publication.

### Nanomaterial in cosmetic ingredients

The Chair of the WG informed about draft opinions still under WG discussion, i.e. Carbon Black.

- **S75, TiO2 DRAFT OPINION**

**SCCS/1516/13**

The opinion has been provisionally adopted but needs some additional work in particular regarding references and double checking of data. It is planned to be circulated for adoption through written procedure during summer.

- **CRITERIA TO IDENTIFY NANOMATERIALS OF CONCERN**

This point was discussed among members and a proposal tabled has been adopted. It will be submitted to SANCO B2 after editorial work.

- **ADDENDUM TO THE OPINION SCCS/1489/12 ON ZINC OXIDE (NANO FORM)**

The addendum to the opinion needs some additional check of data. It is planned to circulate it soon for written procedure or to put it back to the agenda of the next WG meeting should major needs for change be identified.

**7. JOINT OPINIONS (SCCS/SCENIHR/SCHER)**

Synbio: the information on the mandate was provided to the members and one member volunteered for WG membership. SCENIHR will lead the future WG.

**8. COMMENTS ON PREVIOUS OPINIONS**

Cosmetic Ingredients

- **DEGEE**

**SCCS/1507/13**

The members agreed that conclusion 3 will be clarified in 3 (a) and (b). A revised version of the opinion will be published.

- **CLIMBAZOLE**

**SCCS/1506/13**

The members agreed with replies to two questions that are not amending the opinion and with a third one which calls for a revision of the addendum of the opinion clarifying when it is referring to preservative and anti-dandruff use in shampoo or preservative use only. A revised version of the addendum to the opinion will be published.

- **P72 SOYTRIMONIUM CHLORIDE**

**SCCS/1464/12**

The members agreed with the reply to the question that is not amending the opinion.

Hair Dyes

- **ACID BLACK 1, B15**

**SCCS/1492/12**

The members agreed to send the reply to the applicant's question back to the WG in order to finalise it.

- **ACID VIOLET 43, C63**

**SCCS/1494/12**

The members agreed with the reply to the two questions that are not amending the opinion.

Nanomaterial in cosmetic ingredients

- **2,2-METHYLENE-BIS-(6(2H-BENZOTRIAZOL-2-YL)-4-(1,1,3,3-TETRAMETHYLBUTYL)PHENOL)**

**SCCS/1443/11**

The members agreed with the amendment of some chapters such as acute inhalation toxicity, dermal penetration, discussion (dermal sensitization) and conclusion. However a last check is needed as well as editorial work; therefore the revised version of the opinion will be put back on the agenda of the next WG on Nanomaterial in Cosmetic products (5 July) prior to its publication.

**9. TOXICOLOGICAL DOSSIERS**

The Memorandum on Scientific Evaluations and Opinions was adopted by the SCCS.

**10. ANY OTHER BUSINESS**

The SCCS provisionally agreed on the following dates for meetings:

19 September 2013 : Plenary meeting  
12 December 2013 : Plenary meeting

04 July 2013: WG on Methodology (via audio)  
05 July 2013: WG on Nanomaterials in Cosmetic products  
26 August 2013: WG on Hair Dyes  
27 August 2013: WG on Cosmetic Ingredients  
05 September 2013: WG on Nanomaterials in Cosmetic products  
18 September 2013: WG on Methodology (genotoxicity)  
08 October 2013: WG on Cosmetic Ingredients

**11. ANNEX : LIST OF PARTICIPANTS**

## **Annex**

### **List of Participants**

#### **Members of the SCCS**

Dr Ulrike Bernauer, Dr Qasim Chaudhry, Prof. Gisela Degen, Dr Elsa Nielsen, Prof. Thomas Platzek (Chair), Dr Suresh Chandra Rastogi (Vice-Chair), Dr Christophe Rousselle, Dr Jan van Benthem, Prof. Pieter-Jan Coenraads, Dr Maria Dusinska, Dr Werner Lilienblum and Prof. Nancy Monteiro- Rivière (via audio)

#### **Apologies**

Prof. David Gawkrödger (Vice-Chair), Prof. Andreas Luch, Prof. Manfred Metzler

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

Mrs Donata Meroni, Ms Natacha Grenier  
Observers: Mrs Mihaela Haratau, Mrs Diana Herold

#### **DG SANCO B2**

Mrs Federica de Gaetano