



Scientific Committee on Consumer Safety (SCCS)

7th PLENARY

Venue: Luxembourg

Meeting date: 23 September 2014

Minutes

1. WELCOME AND APOLOGIES

The Chair welcomed all the participants. There was one apology.

2. ADOPTION OF THE AGENDA

The agenda was adopted as presented.

3. MINUTES OF THE PREVIOUS PLENARY MEETING – 27 MARCH 2013

The minutes were adopted on 22/08/2014 through written procedure and published on the website.

4. DECLARATION OF INTEREST ON MATTERS ON THE AGENDA

No declaration of potential conflict of interest was made.

5. INFORMATION FROM CHAIRMAN/MEMBERS/COMMISSION

- *Th. Platzek* and *J. van Benthem* informed about their participation in the *EPAA workshop* "Knowledge sharing to facilitate regulatory decision making" (September 22, 2014).
- The *Commission* reminded that, as last year, *the IDEA annual meeting (IFRA)* is planned to be organised back to back with the December SCCS Plenary meeting (16/12), i.e. on 17/12/2014.
- The *Chair* also informed about the Commission invitation to participate in the European Health Forum in Gastein event on 1-3 October (fragrance allergens) together with the Head of unit SANCO C2, as well as in the ICADA meeting on 27 November (endocrine disruptors in cosmetics) and in an EFSA stakeholders' meeting in Brussels on Threshold of Toxicological Concern - TTC (2 December).
- The *Commission and Chair* informed about the next ICCG meeting on 16 October 2014.
- *Referring to the Plenary meeting dated June 2014*, the SCCS consulted SCHER and SCENIHR members to check if an expert in oncology, epidemiology and animal studies would be ready to assist SCCS, on an *ad hoc* basis, for these issues. Two members replied positively and can be contacted on an ad-hoc basis.

6. NEW MANDATES

Mandates were adopted; rapporteurs appointed for:

Cosmetic ingredients

- Addendum to scientific opinion on Ethyl Lauroyl Arginate HCl (P95)

Hair Dyes

- C059 Basic Blue 99
- B122 HC Blue 18
- HC Red 17 (B120)

Nanomaterial in cosmetic ingredients

- Request for clarification on the meaning of the term "sprayable applications/products" for the nano forms of Carbon Black CI 77266, Titanium Oxide and Zinc Oxide

SANCO B2 informed the SCCS about mandates under preparation and a discussion took place about the requested identification of priority files. Due to the increasing workload of the SCCS, SANCO B2 will try to prioritize the mandates. SANCO B2 agreed to continue to send info on mandate under preparation so that SCCS can manage its workload better.

7. DRAFT OPINIONS ON

Joint opinion SCCS/SCENIHR/SCHER

- **SYNBIO – OPINION I, DEFINITION PART**

The SCCS adopted the joint opinion I on definition part together with the replies to the comments received during public consultation.

Cosmetic Ingredients

- **FORMALDEHYDE IN NAIL HARDENER**

The SCCS discussed the draft opinion and is planning to finalise it during the next WG meetings on cosmetic ingredients in October (7 and 23/10). A written procedure for adoption is foreseen by the end of October.

Hair Dyes/Fragrances

- **FRAGRANCE 2-(4-TERT-BUTYLBENZYL) PROPIONALDEHYDE (BMHCA))**

The SCCS discussed the draft opinion and is planning to finalise it during the next working group meetings on hair dyes/fragrances in October/November. A written procedure for adoption is foreseen by the end of November.

- **C059 BASIC BLUE 99**

The SCCS adopted its opinion that will be published.

The SCCS was asked to answer the following questions:

(1) In light of the new data provided, does the SCCS consider Basic Blue 99 (C059) safe as direct hair dye substance in hair dye formulations with a concentration on-head of maximum 1.0%?

(2) Does the SCCS have any further scientific concerns with regard to the use of Basic Blue 99 (CO59) in cosmetic products?

Basic Blue 99 is a mixture of up to 40 substances of varying concentrations as demonstrated by the HPLC analysis of six batches (See Figures 1-3 and Tables 2, 3 and 5).

Due to the highly variable composition of Basic Blue 99 in six batches, the safety of Basic Blue 99 cannot be evaluated.

Nanomaterial in cosmetic ingredients

- **SILICA (NANO)** CAS No 112945-52-5; *Hydrated Silica (nano)* CAS No. 112926-00-8; *Silica silylate* CAS No. 68909-20-6; *Silica Dimethyl silylate (nano)* CAS No. 68611-44-9:

The request for information and questions to applicants were sent out through the CPNP portal on 21 March 2014 – deadline for reply by 22 September 2014 – One applicant replied and submitted an updated dossier. This new information will be sent back to the working group on Nanomaterial in cosmetic ingredients for further assessment.

- **TiO₂- SUBMISSION 2014:** the Chair informed about the new dataset and reviews/expert reports submitted by the applicant for an eventual new mandate (question from Commission). The SCCS view on this new data has been adopted by the group and will be forwarded to Commission. No new mandate is planned yet.
- **HYDROXYAPATITE:**
The request for information and questions to applicants need further discussion during the next working group on Nanomaterial in cosmetic ingredients (31/10).
- **CLARIFICATION REQUEST** from Member States on the meaning of the term “*sprayable applications/products*” for the nano forms of carbon Black, TiO₂ and ZnO

The SCCS adopted its opinion that will be published.

The SCCS was asked to answer the following questions:

(1) In light of the different definitions of spray, could the SCCS clarify the product types included in the term “*sprayable applications/products*” used in the conclusions of the safety assessments for the nano forms of Carbon Black CI 77266, Titanium Oxide and Zinc Oxide?

In view of the foregoing, the SCCS view is that dispensing devices for single-dose cream that do not generate airborne particles or droplets that are either respirable as such, or dry off while airborne to become small enough to be respirable, should be excluded from the term ‘spray’ or ‘sprayable’. However, the proposed term “pump dispenser” is too inclusive, since not only the type of dispenser, but also the formulation that is dispensed together with the nozzle size, determine the droplet size after dispensing. To reflect this, and for the purpose of clarity, the SCCS will use the following harmonised terminology in the existing and future opinions when describing various dispensing methods as follows:

- The term ‘spray’ or ‘sprayable’ will mean that a formulation is either dispensed by the use of propellant gas as defined in Directive 75/324, or by a spray bottle with a pump dispenser that forces a liquid through a nozzle generating a spray stream or a mist of a liquid. Where this term is used in an SCCS opinion, further clarification will be added. For example, instead of [the use of nano.... in sprayable applications is not recommended.] the recommendation will state [the use of nano.... in sprayable applications that could lead to lung exposure of the consumer to nano.... by inhalation is not recommended.]
- The term ‘pump dispenser for dosing cream’ will mean a formulation is dispensed through a mechanical pump in the form of a single dose, where the process does not generate a significant quantity of airborne particles or droplets that are either respirable as such, or become respirable as a result of drying while airborne.

(2) For clarity of the future safety assessment, could the SCCS adopt a harmonised terminology that will allow a distinction between aerosol (with propellant), spray (spray bottles) and pump dispensers (single-dose cream)?

This clarification should prevent any confusion, misinterpretation or unnecessary queries on the issue, and the SCCS suggests to replace the relevant text in the current opinions on nano-forms of Carbon black, Titanium dioxide and Zinc oxide.

Then the SCCS include proposals to incorporate specific changes to each of the existing Opinions, in details (see the opinion).

Methodology

The Chair of that Working Group reported briefly on the content of the meeting held on 8 July and 22 August that focused on substances with low absorption and the 9th revision of the SCCS Notes for Guidance document. Minutes have been published already. The follow-up of these meetings is foreseen for 8 October and 4-5 November with a possible revision of SCCS the Notes of Guidance text to be tabled at December plenary for discussion and may be adoption.

8. COMMENTS ON OPINIONS FROM PLENARY IN 2013

The SCCS reminded the Commission that comments should be received in due time and in the language of the opinion. The Commission will also remind the Authorities.

Cosmetic Ingredients

- **HAA299** – SCCS/1533/14
The SCCS modified the content of the opinion in accordance to comments received mainly on separating nano batches from non-nano batches (instead of micronized and non-micronised forms), and related conclusions.
Replies to comments will be sent out. Revised version of the opinion will be published.
- **PEANUT OIL** - SCCS/1526/14
The SCCS modified the content of the opinion in accordance to comments received mainly on the induction of sensitisation, safe skin exposure level, standard for the level of protein and related conclusions.

Replies to comments will be sent out and a revised version of the opinion will be published as soon as the WG on cosmetic ingredients will have dealt with the last request from SCCS (07/10).

- **HYDROLYSED WHEAT PROTEIN - SCCS/1534/14**

The replies along with the revised opinion will be forwarded to the working group meeting on 7/10, for further discussion and most probably finalisation.

Hair Dyes

- **ACID ORANGE 7 (COLIPA C15) – SCCS/1536/14**

The SCCS modified the content of the opinion in accordance to comments received mainly on dermal absorption, stability data under oxidative conditions, and related conclusions.

Replies to comments will be sent out. Revised version of the opinion will be published.

FOR INFO ONLY

- **A8 - SCCS/1510/13**

New data on log Pow was sent by the applicant. This could be considered in a next submission but there is no change foreseen in the opinion text for the moment. Reply to comment was sent out.

- **B007- BASIC BROWN 17 - SCCS/1531/14:** adopted version dated March 2014, revised version dated June 2014, now corrigendum made in September 2014 (minor change).

Methodology

- **ADDENDUM TO OPINION ON NOTES OF GUIDANCE (SCCS/1501/12) - SCCS/1532/14**

The SCCS forwarded the comments received to the Methodology WG for discussion (meeting of 08/10): the SCCS replies to comments were adopted and the Addendum still needs a revision, accordingly.

9. ANY OTHER BUSINESS

Next working group meetings

7 October 2014: WG on cosmetic ingredients

8 October 2014: WG on methodology

23 October 2014: WG on cosmetic ingredients

24 October 2014: WG on hair dyes

31 October 2014: WG on nano in cosmetics (pm audio only)

4-5 November 2014: WG on methodology (BfR-BERLIN-DE)

25 November 2014: WG on cosmetic ingredients

26 November 2014: WG on hair dyes

01 December 2014: WG on nano in cosmetics

Next plenary meetings

16 December 2014

25 March 2015

25 June 2015

29 September 2015

15 December 2015

Annex I: List of Participants

Members of the SCCS

Ulrike Bernauer, Qasim Chaudhry (Vice-Chair), Pieter-Jan Coenraads, Maria Dusinska, Werner Liliënblum, Andreas Luch, Elsa Nielsen, Thomas Platzek (Chair), Suresh Chandra Rastogi (Vice-Chair), Gisela Degen and Jan van Benthem

Apologies

Christophe Rousselle

SCCS Secretariat (DG SANCO C2)

Natacha Grenier and Diana Herold

DG SANCO B2

Gaetano Castaldo