Scientific Committee on Consumer Safety (SCCS)

6th PLENARY

Venue: Luxembourg

Meeting date: 18 June 2014

Minutes

1. WELCOME AND APOLOGIES

The Chair welcomed all the participants. There were two apologies.

2. ADOPTION OF THE AGENDA

The agenda was adopted as presented.

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

These minutes were adopted on 22/04/2014 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

- Following the resignation of Vice-Chair *Prof. D. Gawkrodger*, the process for the election of a new Vice-Chair took place and Dr Qasim Chaudhry was elected. The record of the election procedure is included in Annex II.

- Prof *P.J. Coenraads* reported on his participation in the IDEA workshop on QRA Methodology & Possibilities of Further Refinement held in Brussels on 13-15 May 2014. For further details, see:

  http://www.ideaproject.info/eventsmanager/8/16/IDEA-Workshop-Validity-of-the-QRA-Methodology-Possibilities-of-Further-Refinement-May-2014

- The Chair notified to the group that one of the dermatologists should represent SCCS and participate in the next two-day IFRA workshop dedicated to the characterization and the categorization of fragrance allergens and taking place on September 23-25, 2014 in Brussels. The final decision will be taken according to respective commitments/agenda and will be forwarded to the SCCS Secretariat.

- The Chair reported on his participation in the Cosmetics Europe annual conference and his presentation on "*Cosmetics at the Crossroads of Science and Regulation*" held in Brussels on 10-11 June 2014.

- The Commission informed that, as last year, the IDEA annual meeting (IFRA) is planned to be organised back to back with December SCCS Plenary meeting, i.e. on 17/12/2014.

- The Commission informed that, in agreement with the Chair and the Vice-Chair, due to specific needs of SCCS work and according to the rules of procedures three new external experts have been selected (general toxicologist, expert in alternative and in vitro methods, dermatologist) and will rapidly join the different SCCS WG meetings.

- *SYNBIO joint opinion SCCS/SCHER/SCENIHR*: the SCCS expressed a minority opinion on a part of the preliminary opinion on Synthetic Biology (definition) prior to the public consultation launched on 6 June and lasting until 21 July. To reach a consensus on the controversial part, some SCCS members have volunteered for the follow-up of the work together with SCHER/SCENIHR, after receiving all comments from public consultation. Audio meetings will be set before and after the summer period, to start the joint work on the second opinion on Synbio (methodological and safety aspects).

- A need to have an expert in oncology, epidemiology and animal studies was discussed. The SCCS will consult SCHER and SCENIHR colleagues to see if one of them would be ready to assist SCCS, on *ad hoc* basis, for these issues.

6. NEW MANDATES

Mandates were adopted; rapporteurs appointed for:

Hair Dyes

- Di-[2-[4-[(E)-2-[2,4,5-trimethoxyphenyl]vinyl]pyridinin-1-ium]butanoyl]aminoethyl]disulfanyl dichloride - HC Yellow No. 17 (B121)
- 1-Hexyl-1H-pyrazole-4,5-diamine hemisulfate (COLIPA A163) Submission I
- 3-Amino-7-(dimethylamino)-2-methoxyphenoxazin-5-ium chloride (Basic Blue 124) Submission I

Nano

- Hydroxyapatite (nano)

The group has also been informed about the mandate for an addendum to scientific opinion on Ethyl Lauroyl Arginate HCl (ELA) (P95) which will be discussed at the next plenary meeting (23/9).

7. DRAFT OPINIONS ON

Cosmetic Ingredients

- SCCS/1535/14 **POLYAMINOPROPYL BIGUANIDE** – PHMB

The SCCS was asked to answer the following questions:

Taking into account the scientific data provided, SCCS is requested to give its opinion on the safety of Polyaminopropyl Biguanide (PHMB) when used as a preservative in cosmetics products up to a maximum concentration of 0.3%.

The SCCS cannot assess the safety of Polyaminopropyl Biguanide (PHMB) as no firm conclusion on the genotoxic potential can be drawn based on the available data. Before any further consideration, adequate data (i.e. a properly performed gene mutation study) are required to rule out the genotoxic potential of PHMB.

In the absence of a valid dermal absorption study, a 10 % dermal absorption might be taken as default according to SCCS Notes of Guidance. Deviation from the default assumption of 10 % dermal absorption would be possible if a valid dermal absorption study according to SCCS Notes of Guidance is submitted.

SCCS is requested to address any further scientific concerns on the ingredient Polyaminopropyl Biguanide (PHMB) in particular regarding its use in spray formulation.

Neat PHMB is a respiratory irritant and exerts adverse effect to the respiratory system after acute and repeat exposure. As the vapour pressure is low, no respiratory irritation or toxic effects are expected from the evaporation of PHMB when present in 0.3% in cosmetic formulation. In the absence of additional information required to determine the toxic effects of spray products according to the SCCS Notes of Guidance, the use of PHMB in spray formulation is not recommended.

PHMB is used in a variety of applications, not only in cosmetics. Therefore information on exposures from all possible sources is required for safety calculation as PHMB is a CMR substance.

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

The SCCS was asked to answer the following questions:

Does the SCCS consider the use of hydrolysed wheat proteins to be safe for consumers in cosmetic products on the basis of the provided scientific data?

The SCCS considers the use of hydrolysed wheat proteins (HWP) safe for consumers in cosmetic products except in soaps and liquid soaps.

And/or does the SCCS have any scientific concerns with regard to the use of hydrolysed wheat proteins in cosmetic products?

The SCCS is of the opinion that, in view of the numbers of reported cases of immediate-type contact urticaria and systemic allergic reactions, the overall risk of sensitization to HWP appears to be low, with the exception of an ‘epidemic’ in Japan associated with one particular product.

Scientific concerns with regard to the use of HWP in cosmetic products include that

- there is evidence that sensitisation to HWP is via exposure to cosmetics, not via food
- there is evidence to indicate that the risk of sensitisation is higher when HWP are used on the skin as ingredient of soaps and liquid soaps; this combination can lead to sensitisation.

- SCCS/1533/14 **UV FILTER HAA299 (FAT 75'808)**

The SCCS was asked to answer the following questions:

Does SCCS consider that the use of FAT 75'808 (HAA299) in its micronized and non-micronized form as an UV-filter in cosmetic products in a concentration up to maximum 10.0 % is safe for the consumers taken into account the scientific data provided?

The calculation of margin of safety (MoS) is not justified given the low dermal penetration when applied on human skin, and in consideration of the low observed systemic toxicity (NOAEL for oral administration of HAA299 to rats is 1000 mg/kg bw/d).

The SCCS is of the opinion that the use of HAA299 in non-micronized and micronized (with median particle size distribution around 134 nm or larger, as measured by FOQELS), at a concentration up to 10% as an UV-filter in cosmetic products, does not pose any risk of systemic toxicity in humans.

The results of genotoxicity testing were negative *in vitro* as well as *in vivo* but exposure of target cells was not proven. However, in light of the low bioavailability, the mutagenicity risk for the consumer is considered negligible.

This opinion does not apply to inhalation exposure of HAA299 since no information on chronic or sub-chronic toxicity after inhalation is provided.

Does SCCS have any other scientific concerns for the safe use of the new UV-filter HAA299 in finished cosmetic products?

This opinion is based on the currently available scientific evidence, which shows an overall very low or lack of dermal absorption of HAA299 in human skin. If any new evidence emerges in the future to show that HAA299 used as UV-filter in cosmetic products can penetrate human skin (healthy, compromised, sunburnt or damaged skin) to reach viable cells, then the SCCS may consider revising this assessment.

<u>Hair Dyes</u>

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

The SCCS was asked to answer the following questions:

In light of the new data provided, does the SCCS consider Acid Orange 7 (C15) safe at on-head concentrations up to 0.5% under non-oxidative conditions?

Does the SCCS consider Acid Orange 7 (C15) safe at on-head concentrations up to 0.8% under oxidative conditions? If not, does the SCCS suggest maximum

concentrations under oxidative and non-oxidative conditions for which Acid Orange 7 (C15) could be considered safe for consumers?

The SCCS is of the opinion that the use of Acid Orange 7 as a hair dye ingredient up to a final on-head concentration of 0.8% under oxidative conditions and 0.5% under non-oxidative conditions does not pose a risk to the health of the consumer.

Does the SCCS have any further scientific concerns with regard to the use of Acid Orange 7 (C15) in cosmetic products particularly as it is used as colorant agent with the name of CI 15510?

The SCCS has no information on the use concentrations of Acid Orange 7 as a colorant in other cosmetic products. The aggregate exposure is not known and, therefore, the safety of Acid Orange 7 as a cosmetic colorant cannot be assessed.

Nanomaterial in cosmetic ingredients

SILICA (NANO) *CAS No 112945-52-5; Hydrated Silica (nano) CAS No.. 112926-00-8; Silica sylilate 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 – no reply has been received yet.
Regarding the call for information launched in parallel with deadline of 31 May, 7 submissions were been received. These will be considered while performing risk assessment of nano silica by the SCCS WG on nanomaterials in cosmetic products.

Methodology

The Chair of that Working Group reported briefly on the content of the meeting held on 28 March and 21 May that focused respectively on low bioavailability and use of HPLC for *in vitro* test methods, such as Episkin (skin irritation), SkinEthic RHE (skin corrosion) and EpiOcular (eye irritation). Minutes have been published already. The follow-up of these meetings is foreseen on 8 July and 8 October with a discussion on the possible revision of the SCCS Notes of Guidance.

8. COMMENTS ON OPINIONS FROM PLENARY IN 2013

Cosmetic Ingredients

- **ALUMINIUM IN COSMETIC PRODUCTS** – SCCS/1525/14

  The group agreed with the SCCS replies to comments. The documents will be finalised shortly after the meeting, together with the help of the secretariat. The SCCS agreed to have a meeting with industry on 7 July (cf. WG meeting on cosmetic ingredients) to discuss the study protocol concerning dermal absorption of Al.

- **ZINC PYRITHIONE - ZPT (P81)** – SCCS/1512/13
  The SCCS updated the preliminary opinion based on the new data submitted after public consultation. The reply will be finalised after the meeting with the help of the

Secretariat and sent out. The updated version of the opinion will be replacing the previous one and will be published.

Hair Dyes

- **BASIC BROWN 17** (COLIPA B7) – SCCS/1531/14

The SCCS comment on water solubility has been deleted in accordance to comment received and some values have been re-entered in a table as requested. No further change has been made except for some typos. The reply will be sent out. The revised version of the opinion will be replacing the previous one and will be published.

- **3-AMINO-2,6-DIMETHYLPHENOL** (COLIPA A162) – SCCS/1529/14

The SCCS changed the SCCS comments on skin and eye irritation. The reply will be sent out. No further change has been made. The revised version of the opinion will be replacing the previous one and will be published.

- **HYDROXYETHOXY AMINOPYRAZOLOPYRIDINE HCL** (COLIPA A161) - SCCS/1530/14

The SCCS included the EC number in the opinion in accordance to the comment received. No further change has been made. The reply will be sent out. The revised version of the opinion will be replacing the previous one and will be published.

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 at the next meeting (08/07).

9. ANY OTHER BUSINESS

Next working group meetings
7 July 2014: WG on cosmetic ingredients
8 July 2014: WG on methodology
21 August 2014: WG on hair dyes
02-03 September 2014 WG on cosmetic ingredients and hair dyes (3 September PM only)
7 October 2014: WG on cosmetic ingredients
8 October 2014: WG on methodology

Next plenary meetings
23 September 2014
16 December 2014
25 March 2015
25 June 2015

10. ANNEX I: LIST OF PARTICIPANTS

11. ANNEX II: ELECTION PROCEDURE OF SECOND SCCS VICE-CHAIR

Annex I: List of Participants

Members of the SCCS
Dr Ulrike Bernauer, Dr Qasim Chaudhry, Prof. Pieter-Jan Coenraads, Dr Maria Dusinska, Dr Werner Lilienblum, Prof. Andreas Luch, Dr Elsa Nielsen, Prof. Thomas Platzek (Chair), Dr Suresh Chandra Rastogi (Vice-Chair), Dr Christophe Rousselle.

Apologies
Prof. Gisela Degen and Dr Jan van Benthem.

SCCS Secretariat (DG SANCO C2)
Ms Donata Meroni, Natacha Grenier and Mr Stefan Schreck.

DG SANCO B2
Ms Federica de Gaetano, Mr Gateano Castaldo and Mr Jean-François Roche.

Annex II: Election Procedure of second SCCS Vice-Chair

Appointed members of the Committee were asked to express an interest of candidature for Vice-chairmanship prior to the meeting. In addition, during the meeting members were given an opportunity to announce their candidature or to nominate other members. Nominated candidates were asked whether they agreed to stand in the election.
The second vice-chair was elected in separate, secret, votes.

Vice-Chairperson
Dr Qasim Chaudhry and Prof. Gisela Degen expressed their interest in becoming Vice-Chairperson of SCCS.
Dr Qasim Chaudhry was elected as Vice-Chairperson in one separate vote by majority of SCCS members. The members voted by secret ballot.