



Scientific Committee on Consumer Safety (SCCS) 10th PLENARY

Venue: Luxembourg

Meeting date: 25 June 2015

Minutes

1. WELCOME AND APOLOGIES

The Chair welcomed all the participants. Prof Ana PROYKOVA (from SCENIHR) and Dr Jan LINDERS (from SCHER) participated as well.

2. ADOPTION OF THE AGENDA

The agenda was adopted as presented.

3. MINUTES OF THE PREVIOUS PLENARY MEETING – 25 MARCH 2015

The minutes were adopted on 13/05/2015 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

- New Decision for setting up the Scientific Committees (2016-2021) -> the Commission briefly updated the group on the progress of this document. The adoption by the College is foreseen late July and the call for members is planned to be launched immediately after.
- Ongoing evaluation of the Scientific Committees (2009-2014) -> the inception report has been received from the contractor.
- Nomination of new Vice-Chair following Resign from Vice-Chair *Suresh Rastogi* from 1st July 2015, four names were suggested: but two confirmed their interest before proceeding to the vote by secret ballots. *Gisela Degen* was elected 6 / 4 (see AnnexII). The Committee expressed to Gisela their congratulations for the new appointment.
- Feedback from Secretariat on JRC/EFSA visit on 17->19 June 2015:
The Secretariat informed about the exchanges of information that took place during these visits from 17 to 19 June 2015.

- EFSA Draft guidance on uncertainty in risk assessment: a workshop is planned to be held in Brussels on 29-30/06 -> SCCS / SCHER / SCENIHR representatives will participate. The deadline of the ongoing public consultation is 10/09.
- EFSA Working Group meeting on Benchmark Dose (BMD), Amsterdam 15/04/2015 and Brussels 28-29 /05/2015 -> *Christophe Rousselle* presented his report from these events.
- CoE annual Conference, Brussels 16-17/06/2015-> *Gisela Degen*, new Vice-Chairperson of the SCCS, presented her report/presentation made at this event about safety of Endocrine Disruptors, based on the SCCS Memorandum. The way SCCS is dealing with controversial topics and involvement of observers from industry (representatives from Cosmetics Europe) in methodology working groups' meetings was highly appreciated.
- IDEA workshop on Pre and Pro-Haptens, Genval (BE), 16-17/06/2015 -> *Pieter-Jan Coenraads* reported on this event where *in vitro* testing model and knowledge gaps were identified. The next IDEA workshop in October will focus on clinical dermatology and SCCS agreed he'll represent SCCS again.
- Survey on prioritisation of new or enhanced test methods for identifying endocrine disruptors (from DG ENV – held by JRC) -> DG ENV agreed to invite members of SCs to the planned Workshop on 17-19/11-> three members are volunteers.
- Scientific Journal "Regulatory Toxicology and Pharmacology" : two SCCS Opinions have been sent for publication on the Journal: Peanut Oil and Hydrolysed Wheat protein.
- SCCS comments on ECHA paper on using read-across and categories to improve safety of nanomaterials were sent to ECHA and GROW. SCCS agreed to prepare a Memorandum at the next nano WG meeting (04/09).

6. NEW REQUESTS/MANDATES

Mandates were adopted; rapporteurs appointed for:

Hair Dyes

- N,N'-Bis-(2-hydroxyethyl)-2-nitro-p-phenylenediamine (B34) (Submission IV)
- HC Red No.18 (B124 Colipa number) (Submission I)

Cosmetic ingredient

- Vitamin A CAS n. 68-26-8 / 11103-57-4/ 116-31-4 (Retinol, Retinyl Acetate, Retinyl Palmitate, Retinyl Linoleate and Retinal)

7. DRAFT OPINIONS ON

Joint opinion SCCS/SCENIHR/SCHER

- **SYNBIO 3RD OPINION**: the preliminary Opinion was discussed and adopted by the members.

Cosmetic Ingredients

- **ALPHA-ARBUTIN** (SCCS/1552/15) was adopted by written procedure on 27 May (and published) -> commenting period until 22/7.

The following Opinions were adopted:

- **O-PHENYLPHENOL (OPP)**

o-Phenylphenol as preservative with a maximum concentration of 0.2 % in leave-on cosmetic products is not safe. Also, in view of further exposures including noncosmetic uses (see Anses, 2014), the maximum concentration of o-Phenylphenol in leave-on cosmetic products should be lowered. However, the proposed maximum use concentration of up to 0.15% by the applicant can be considered safe.

The use of o-Phenylphenol as preservative with a maximum concentration of 0.2 % in rinse-off cosmetic products is considered safe.

Based on the information provided, no conclusions of safe use can be drawn for Sodium o-phenylphenate and Potassium o-phenylphenate.

In vitro data indicate an absent or very weak binding affinity of OPP to the oestrogen receptor, in line with limited stimulation of proliferation in oestrogen responsive cells. No information is available on androgenic and anti-androgenic effects of OPP in vitro. Agonistic or antagonistic effects on thyroid hormones were not observed with OPP. There might be a potential of injury to the vision system attributable to OPP. Aggregate exposure to OPP should be considered.

http://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_o_177.pdf

- **DEOXY-ARBUTIN**

Although on the basis of the provided scientific data the use of deoxyarbutin as such can be considered safe for consumers in cosmetic products in a concentration up to 3% in face creams, hydroquinone will be formed at levels which raise concerns with regard to the safety of such products during life-cycle of the product (e.g. storage conditions and stability under in-use conditions). Therefore, the overall conclusion of the SCCS is that the use of deoxyarbutin up to 3% in face creams is not safe.

http://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_o_183.pdf

- **METHYLISOTHIAZOLINONE (MI) (P94)** -> *in rinse-off and leave-on hair products up to concentration limit of 100ppm*

The information provided does not support the safe use of MI as a preservative in rinse-off cosmetic products up to a concentration limit of 100 ppm from the view of induction of contact allergy.

For rinse-off cosmetic products, a concentration of 15 ppm (0.0015%) MI is considered safe for the consumer from the point of view of induction of contact allergy.

The information provided does not support the safe use of MI as a preservative in leave-on hair cosmetic products up to a concentration limit of 100 ppm from the point of view of induction of contact allergy.

The concerns and opinions raised in SCCS Opinion SCCS/1521/13 (12 December 2013 with revision 27 March 2014) remain. The results of the recent Scandinavian study do not support safety of MI in rinse-off products at either 100 ppm or at 50 ppm for elicitation or induction.

http://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_o_178.pdf

The following Opinion was presented and needs further discussion at the next WG meeting (02/07):

UV FILTER – S86 - PHENYLENE BIS-DIPHENYLTRIAZINE

The SCCS considers Phenylene bis-diphenyltriazine, S86, not safe for use as a UV-filter in sunscreen products in a concentration up to 10.0% taking into account the scientific data provided. SCCS cannot exclude that Phenylene bis-diphenyltriazine may have a genotoxic potential. An adequate physico-chemical characterisation should be provided. The tests conducted on eye irritation and skin sensitisation are considered inconclusive. The phototoxicity potential can as yet not be excluded.

This Opinion does not apply to inhalation exposure of Phenylene bis-diphenyltriazine since no adequate information on chronic or sub-chronic toxicity after inhalation was provided.

The SCCS noted that due to the poor biodegradation potential and the very high octanol-water partition coefficient, long-term effects or bioaccumulation of Phenylene bis-diphenyltriazine, S86, in the environment cannot be excluded. The use of Phenylene bis-diphenyltriazine as an ingredient in sunscreen products might lead to environmental exposure.

http://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_o_184.pdf

Hair Dyes/Fragrances

The following Opinions were adopted:

- **Basic Blue 124** (following modification of the mandate)

The safety of Basic Blue 124 cannot be assessed since no final conclusion on mutagenicity can be drawn without further studies to exclude gene mutation potential.

The SCCS considers Basic Blue 124 as a strong skin sensitiser.

Basic Blue 124 is a tertiary amine. It should not be used together with nitrosating agents.

Total nitrosamine content should be < 50 ppb.

The purity determination of Basic Blue 124 should be performed adequately.

http://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_o_179.pdf

- **A163** 1-Hexyl-1H-pyrazole-4,5-diamine hemisulfate

The SCCS is of the opinion that 1-hexyl 4,5-diamine pyrazole sulfate is safe for use in oxidative hair dye formulations with an on-head concentration of maximum 1.0% taken into account the scientific data provided. 1-hexyl 4,5-diamine pyrazole sulfate is a moderate skin sensitiser.

http://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_o_181.pdf

- **B120** HC Red 17

The SCCS considers the hair dye HC Red No. 17 safe when used in non-oxidative hair colouring products at concentrations up to 0.5%. A skin sensitising potential of HC Red No. 17 cannot be excluded. HC Red 17 is a tertiary amine. It should not be used together with nitrosating agents. Nitrosamine content should be <50 ppb.

http://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_o_182.pdf

- **B121** HC Yellow No. 17

The SCCS considers the hair dye HC Yellow No. 17 (B121) safe when used in non-oxidative hair colouring products at concentrations of up to 0.5%, except for its sensitisation potential. HC Yellow No. 17 is considered a strong sensitiser.

http://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_o_186.pdf

- **B122** HC Blue 18

In light of the data provided, SCCS considers that the use of 2 HC Blue 18 (B122) as an ingredient in non-oxidative hair dye formulations at a maximum concentration of 0.35% on the head is safe.

Concerning oxidative conditions, the safety cannot be assessed because stability assessment was not adequately performed.

The purity of HC Blue 18 and impurities in it are not adequately quantified.

SCCS considers HC Blue 18 as a moderate sensitiser.

http://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_o_180.pdf

- **A143** 2,5,6-Triamino-4-pyrimidinol sulfate. Submission III

In the light of the new data provided, the SCCS considers the use of 2,5,6-triamino-4-pyrimidinol sulfate as an ingredient in oxidative hair dye formulations at a maximum concentration of 0.5% on the head is safe.

A skin sensitising potential of 2,5,6-triamino-4-pyrimidinol sulfate cannot be excluded.

http://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_o_185.pdf

- **A138** - 2,6-dihydroxyethylaminotoluene. Submission III

In the light of the new data provided, SCCS considers that the use of 2,6-dihydroxyethylaminotoluene as an ingredient in oxidative hair dye formulations at a maximum concentration of 1.0% on the head is safe.

2,6-Dihydroxyethylaminotoluene is a secondary amine, and thus, it is prone to nitrosation. It should not be used together with nitrosating agents. Nitrosamine content should be <50 ppb.

http://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_o_188.pdf

The following Opinion was presented and needs further discussion at the next WG meeting (02/07):

- **BMHCA**, fragrance 2-(4-tert butylbenzyl)propionaldehyde

Nanomaterial in cosmetic ingredients

The Chair of that Working Group reported briefly on the content of the last meeting held on 4 June 2015. The minutes are published on the website:

http://ec.europa.eu/health/scientific_committees/consumer_safety/minutes_wg_meetings/index_en.htm

Methodologies

The next meeting will be held on 1st July (sensitisation and SCCS Notes of Guidance). The minutes will be published on the website:

http://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_miwg_226.pdf

8. COMMENTS ON OPINIONS ADOPTED

This point was postponed to respective WG meetings due to lack of time.

9. ANY OTHER BUSINESS

Next working group meetings

02/07 - 27/08 – 29/10 and 02/12/2015:

WG on cosmetic ingredients

02/07 - 26/08 – 28/10 and 03/12/2015:

WG on hair dyes

01/07 - 09/09 and 04/11/2015:

WG on methodology

03/09 (audio) and 28/09/2015

WG on nano in cosmetics

Next plenary meetings

29 September 2015, 15 December 2015

Annex I: List of Participants

Annex II: Election Procedure of second SCCS Vice-Chair

Annex I: List of Participants

Members of the SCCS

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

Apologies

None.

SCCS Secretariat (DG SANCO C2)

Donata Meroni, Natacha Grenier and Diana Herold

DG GROW D4

Federica de Gaetano, Gaetano Castaldo

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

Prof. Pieter-Jan Coenraads and Prof. Gisela Degen expressed their interest in becoming Vice-Chairperson of SCCS.

Prof. Gisela Degen was elected as Vice-Chairperson in one separate vote by majority of SCCS members. The members voted by secret ballot.