



Scientific Committee on Consumer Safety (SCCS)

5th PLENARY

Venue: Luxembourg

Meeting date: 27 March 2014

Minutes

1. WELCOME AND APOLOGIES

The Chair welcomed all the participants. There was no apology.

2. ADOPTION OF THE AGENDA

The agenda was adopted as presented.

3. MINUTES OF THE PREVIOUS PLENARY MEETING – 12 DECEMBER 2013

These minutes were adopted on 17/01/2014 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

- The commission informed about three resignations from the SCCS members due to new supervening time limitations: *Prof. N.Monteiro-Riviere*, *Prof. M. Metzler*, *Prof. D.Gawkrodger (V-C)*. The process for their replacement by pool advisors has started.
- *Prof D. Gawkrodger* reported on his participation in the IDEA workshop on QRA method held in Brussels on 13-14 March 2014. For further details, see:
<http://www.ideaproject.info/eventsmanager/5/16/IDEA-Workshop-Validity-of-the-QRA-Methodology-Possibilities-of-Further-Refinement>
- The Chair reported on the ICCG meeting – minutes of the ICCG will be on-line soon. The group was also informed about the results of the feedback questionnaire sent out by the SCCS Secretariat in order to evaluate the smoothness of the move to Luxembourg and to identify areas for improvement.
- Members reiterated the need for joint meetings of 2 days/ back to back meetings in the future.

6. NEW MANDATES

Mandates were adopted; rapporteurs appointed and priorities were set for:

Cosmetic Ingredients

- Preservative Phenoxyethanol
- Polyaminopropyl Biguanide PHMB
- Cyclopentasiloxane (D5)
- o-phenylphenol OPP
- Formaldehyde in nail hardener

Hair Dyes

- Addendum to the scientific opinion on the safety of oxidative hair dye substances and hydrogen peroxide in products to colour eyelashes
- Acid Orange 7 (C15)

7. DRAFT OPINIONS ON

Cosmetic Ingredients

- SCCS 1525/14 **Aluminium**

The SCCS was asked to answer the following questions:

1. In view of the above, SCCS is requested to assess the possible risk for human health from the presence of Aluminium in cosmetics, in particular in products such as antiperspirants and deodorants, lipsticks and toothpastes, considering the exposure from other sources, such as food and food supplements.

2. In the event the estimated exposure to Aluminium from specific types of cosmetic products is found to be of concern, SCCS is asked to recommend safe concentration limits for the presence of Aluminium in those cosmetic products or other risk reducing measures.

Aluminium is a known systemic toxicant at high doses.

The SCCS is of the opinion that due to the lack of adequate data on dermal penetration to estimate the internal dose of aluminium following cosmetic uses, risk assessment cannot be performed.

Therefore internal exposure to aluminium after skin application should be determined using a human exposure study under use conditions.

Confusion exists with respect to the correct terminology for under-arm deodorants that are actually present on the market since they often contain both, typical deodorant as well as typical antiperspirant ingredients.

- **SCCS 1526/14 Peanut oil**

The SCCS was asked to answer the following questions:

1. Does the SCCS consider the use of peanut oil and/or its derivatives to be safe for consumers in cosmetic products on the basis of the provided scientific data?

The SCCS is of the opinion that since it is not possible to define the level of peanut protein allergens in peanut oils (there being no standard for the refinement of peanut oil), and since cases of potentially life-threatening peanut allergy have occurred on the contact of peanut-allergic subjects with peanut oil-containing topical products, peanut oil or peanut oil derivatives containing peanut proteins cannot be used safely in cosmetic products, based on the scientific evidence that currently is available.

2. And/or does the SCCS has any scientific concerns with regard to the use of peanut oil and/or its derivatives in cosmetic products?

There is no known safe threshold currently defined at which peanut allergic subjects can safely be exposed to peanut proteins.

- **SCCS 1527/14 Potassium hydroxide - KOH**

The SCCS was asked to answer the following questions:

1. Does SCCS consider Potassium Hydroxide KOH safe for use as callosity softener/remover with a concentration of maximum 1.5 % taking into account the information provided?

In addition to those uses already regulated by the Cosmetics Regulation (EC) n. 1223/2009, the SCCS is of the opinion that potassium hydroxide is safe for use as callosity softener/ remover with a concentration of maximum 1.5% by weight.

2. And/or does the SCCS recommend any further scientific concerns with regard to the use of Potassium Hydroxide KOH in cosmetic products?

Other potential uses of potassium hydroxide in cosmetic products cannot be evaluated without further documentation.

The safe use of cosmetic products containing free potassium hydroxide in concentrations from 0.5% depends on responsible risk management (warnings and extensive guidance for use).

- **SCCS 1528/14 Trimethylbenzoyl diphenylphosphine oxide - TPO**

The SCCS was asked to answer the following questions:

1. In view of the above, and taking into account the scientific data provided, SCCS is requested to give its opinion on the safety of Trimethylbenzoyl diphenylphosphine oxide (TPO) when used as a nail modelling product at a concentration of at maximum 5.0%.

The SCCS is of the opinion that Trimethylbenzoyl diphenylphosphine oxide (TPO) is safe when used as a nail modelling product at a concentration of at maximum 5.0%. However, TPO is considered a moderate skin sensitizer.

2. SCCS is requested to address any further scientific concerns with regard to the use of Trimethylbenzoyl diphenylphosphine oxide (TPO) in cosmetic products.

Other potential uses of Trimethylbenzoyl diphenylphosphine oxide in cosmetic products cannot be evaluated without further documentation.

Hair Dyes

- SCCS 1529/14 **A162** 3-amino-2,6-dimethylphenol

The SCCS was asked to answer the following questions:

1. Does the SCCS consider 3-amino-2,6-dimethylphenol safe for use as oxidative hair dye formulations with an on head concentration of maximum 2.0% taken into account the scientific data provided?

2. And/or does the SCCS recommend any restrictions with regard to the use of 3-amino-2,6-dimethylphenol in oxidative hair dye formulations (e.g. max conc. in the finished cosmetic product, dilution ratio with hydrogen peroxide, warning)?

The SCCS is of the opinion that 3-amino-2,6-dimethylphenol is safe for use in oxidative hair dye formulations with an on head concentration of maximum 2.0% taken into account the scientific data provided.

A sensitisation potential cannot be excluded.

- SCCS 1531/14 **B007** Basic Brown 17

The SCCS was asked to answer the following questions:

1. Does SCCS consider Basic Brown 17 safe for use in non-oxidative hair dyes with a concentration of maximum 2.0% taken into account the scientific data provided?

SCCS considers Basic Brown 17 safe for use in non-oxidative hair dye formulations with a concentration of maximum 2.0%, apart from its possible sensitisation potential.

2. And/or does the SCCS recommend any further restrictions with regard to the use of Basic Brown 17 in non-oxidative hair dye formulations?

Basic Brown 17 may contain up to 4.5 % (w/w) Basic Red 118, corresponding to maximum 0.09% in a hair dye formulation. Basic Red 118 according to the Cosmetic

Regulation (Regulation 1223/2009) is not permitted for use in cosmetics except as an impurity in Basic Brown 17.

- SCCS 1530/14 **A161** Hydroxyethoxy aminopyrazolopyridine HCl

The SCCS was asked to answer the following questions:

1. Does the SCCS consider Hydroxyethoxy aminopyrazolopyridine HCl safe for use in oxidative hair dye formulations with a concentration on-head of maximum 2.0% taken into account the scientific data provided?

2. And/or does the SCCS recommend any restrictions with regard to the use of Hydroxyethoxy aminopyrazolopyridine HCl in oxidative hair dye formulations (e.g. max conc. in the finish cosmetic product, dilution ratio with hydrogen peroxide, warning)?

The SCCS is of the opinion that, apart from its sensitising potential, hydroxyethoxy aminopyrazolopyridine HCl is safe for use in oxidative hair dye formulations with a concentration on-head of maximum 2.0%.

Hydroxyethoxyamino pyrazolopyridine HCl is a strong sensitiser.

Nanomaterial in cosmetic ingredients

SILICA (NANO) CAS n.112945-52-5; *Hydrated Silica (nano)* CAS n. 112926-00-8; *Silica silylate* CAS n. 68909-20-6; *Silica Dimethyl silylate (nano)* CAS n. 68611-44-9:

The request for information and questions to applicants have been adopted on 19/03 through written procedure. They were sent out via e-mail on 20 March 2014 and through the CPNP portal on 21 March 2014 – deadline for reply by 22 September 2014.

Methodology

The Chair of that Working Group reported briefly on the content of the meeting held on 17/02 that focused on sensitisation. Minutes have been published already. The follow-up of this meeting is foreseen on 28/03/2014 together with a discussion on BMD approach and the possible revision of the SCCS Notes of Guidance; a next meeting is foreseen on 21 May.

The revision of the mutagenicity/carcinogenicity part of the SCCS Note for Guidance is planned to be adopted via written procedure, as Addendum to SCCS Note for Guidance SCCS/1501/12.

8. COMMENTS ON OPINIONS FROM PLENARY IN 2013

- **CARBON BLACK** (SCCS/1515/13)

The SCCS modified the content of the opinion in accordance to comments received mainly on particle size, acute oral toxicity, skin and eye/mucous membrane irritation, reproductive toxicity, human data, and related conclusions.

Replies to comments will be sent out. Revised version of the opinion on carbon black will be replacing the previous one and will be published.

- **METHYLISOTHIAZOLINONE II – P94** (SCCS/1521/13)
The SCCS did not modify the content of the opinion following the comments received. Replies to comments will be sent out. A revised version will nevertheless be (re)published, dated on 27 March 2014, acknowledging that all comments received have been taken into consideration.
- **ADDENDUM OF ZINC OXIDE (NANO)**
The SCCS decided to revise the opinion. However, it needs some additional discussion at the next WG on nanomaterials in cosmetic products' meeting (07 April).
- **ZINC PYRITHIONE - ZPT (P81)**
The SCCS decided to revise the opinion. However, it needs additional discussion at the next WG on cosmetic ingredients' meeting (25 April).
- **REVISION OF MEMORANDUM “RELEVANCE AND QUALITY OF DATA IN SAFETY DOSSIERS ON NANOMATERIALS”** (SCCS/1524/13)
The SCCS modified the content of the opinion in accordance to comment received on point 12. The reply will be sent out. The revised version of the Memorandum will be replacing the previous one and will be published.

9. ANY OTHER BUSINESS

- Next Working group meetings

28 March 2014: WG on methodology (low bioavailability and notes of guidance)
07 April 2014: WG on nanomaterials in cosmetic products (audio)
25 April 2014: WG on cosmetic ingredients
20 May 2014: WG on cosmetic ingredients
21 May 2014: WG on methodology
3-4 June 2014: WG on cosmetic ingredients + hair dyes

- Next Plenary meetings

18 June 2014
23 September 2014
16 December 2014

11. ANNEX: LIST OF PARTICIPANTS

Annex

List of Participants

Members of the SCCS

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

Resigns before the Plenary

Prof. Nancy Monteiro- Rivière

Prof. Manfred Metzler

SCCS Secretariat (DG SANCO C2)

Ms Diana Herold

DG SANCO B2

Ms Federica de Gaetano, Mr Gateano Castaldo