



EUROPEAN COMMISSION
 HEALTH & CONSUMERS DIRECTORATE-GENERAL
 Public Health and Risk Assessment
Risk assessment

Scientific Committee on Consumer Safety
 5th Plenary Meeting

Held on 8 December 2009 in Brussels

MINUTES

1. WELCOME AND APOLOGIES

Dr. I.R. White, the chairman of the SCCS, welcomed all the participants. Apologies were received from Prof. G. Degen, Prof. C.L. Galli, Prof. K. Savolainen and Prof. R. Waring.

2. DECLARATIONS OF INTEREST

No member declared any interest that could prevent him/her from participating in the discussion of the items on the agenda.

3. APPROVAL OF THE DRAFT AGENDA

SCCS/1285/09

The agenda was approved without changes.

4. ADOPTION OF THE DRAFT MINUTES OF THE 4TH PLENARY MEETING

SCCS/1273/09

The minutes of the 4th plenary meeting of 13 October 2009 were approved.

5. INFORMATION FROM CHAIRMAN/MEMBERS

5th meeting of chairmen of EU Scientific Committees on 18 and 19 November 2009

The Chairman reported from the 5th meeting of chairmen of EU Scientific Committees on 18 and 19 November 2009. The main items were:

- discussion on the follow-up of the previous meeting;
- presentation on the next generations of nanotechnology and on synthetic biology;
- ongoing projects on emerging risks, terminology/weight of evidence/uncertainty and exposure assessment;
- further issues for collaboration
- special session on alternative test methods.

Commission follow-up to earlier opinions

A representative of the cosmetics unit of DG ENTER informed that the following legal implementations for cosmetic ingredients were made since the last plenary of 13 October 2009:

- Allyl phenyl ether: insertion of an entry in Annex III, part 1 (entry n° 155a)
- Hair dyes: prolongation of the deadline of the hair dyes listed in Annex III, part 2
- Hair dyes: additional warning on the risk of sensitisation.
- Terpene terpenoids sinpine: these words are replaced by 'Terpenes and terpenoids' in Annex III, part 1, entry n° 130
- Verbena oil: modification of its entry in Annex II (entry n° 450) and insertion of Verbena absolute in Annex III, part 1 (entry 155)

Restructuring of Commission services

The Secretariat informed that some re-arrangements in the European Commission structure will take place with the start of the new Commission. DG SANCO will become responsible for Pharmaceuticals, Cosmetics and Medical Devices (currently Units F2 and F3 at DG Enterprise) and Biotechnology, Pesticides and Health (currently Unit D4 at DG Environment).

6. NEW REQUESTS

6.1. BORATES AND PERBORATES

Two mandates for assessments of cosmetics ingredients were submitted in relation to the recent CMR classification of boron compounds, one concerning sodium perborate and perboric acid, the other the remaining classified boron compounds.

6.2. ALTERNATIVE TEST METHODS

The Secretariat informed that a joint mandate is planned for SCCS, SCHER and SCENIHR. Expressions of interest for participation were invited from the members.

6.3. POSSIBLE IMPROVEMENTS IN RISK ASSESSMENT APPROACHES IN VIEW OF RISK MANAGEMENT NEEDS AND EFFECTIVE RISK ASSESSMENT

A joint mandate for the three Scientific Committee, under the lead of SCHER, has been issued.

7. REPORTS FROM THE WORKING GROUPS

7.1. COSMETIC INGREDIENTS

The Chairperson of the WG reported on the ongoing work of the Working Group. He said that a draft opinion on the new classification of substances as carcinogenic, mutagenic or toxic to reproduction according to the Commission Regulation 790/2009 was prepared, which was tabled for formal adoption.

7.2. HAIR DYES

The Chairperson of the WG reported on the ongoing work of the Working Group. He said that draft opinions on 5-Amino-6-chloro-o-cresol (A94), Hydroxyethyl-3,4-methylenedioxyaniline HCl (A98), HC Red n° 7 (B36) and on HC Yellow n° 4 (B38) were prepared, which were tabled for formal adoption.

7.3. METHODOLOGIES

The Chairperson of the WG said that no Working Group meeting had taken place since the plenary meeting of 13 October 2009.

7.4. NANO-MATERIALS IN COSMETICS

The Chairperson of the WG reported on the ongoing work of the Working Group in relation to safety evaluations of nano-sized cosmetic ingredients.

7.5. TRICLOSAN (ANTIMICROBIAL RESISTANCE)

The Chairperson of the WG reported on the ongoing work of the Working Group. A draft opinion might be presented during the next plenary meeting.

7.6. TTC

The Chairman of the Working Group said that the draft opinion had been revised further to the outcome of the public hearing September 2009. This draft is under discussion in the WG.

7.7. SENSITISATION & FRAGRANCES

The Chairperson of the WG reported on the work of the Working Group.

7.8. FOOD IMITATING PRODUCTS

The Chairperson of the WG said that an initial meeting will take place shortly to discuss the mandate and define the scope of the work.

7.9. PARTICIPATION OF MEMBERS IN ACTIVITIES OF OTHER SCIENTIFIC COMMITTEES

The members involved in the activities of SCHER and SCENIHR reported on the progress of the draft opinions on:

- anti-microbial resistance
- heavy metals in jewellery
- CMR in toys, and
- Fluoride in drinking water.

8. DRAFT OPINIONS - DISCUSSION AND POSSIBLE ADOPTION

8.1. A94, 5-AMINO-6-CHLORO-O-CRESOL

The SCCS was asked to assess the safety of 5-amino-6-chloro-o-cresol in any hair dye formulation with a concentration on the scalp of maximum 2.0%.

The SCCS concluded that, because of the low margin of safety for the use in both oxidative and non-oxidative hair dye formulations, the use of 5-amino-6-chloro-o-cresol as a hair dye ingredient up to a final on-head concentration of 2.0% under oxidative and non-oxidative conditions poses a risk to the health of the consumer.

The opinion was adopted.

8.2. A98, HYDROXYETHYL-3,4-METHYLENEDIOXYANILINE HCL

The SCCS was asked to assess the safety of Hydroxyethyl-3,4-methylenedioxyaniline hydrochloride as an oxidative hair dyes with an on-head concentration of maximum 1.5%.

The SCCS concluded that, based on the information provided, the use of hydroxyethyl-3,4-methylenedioxyaniline HCl itself as an oxidative hair dye substance at a maximum concentration on the head of 1.5% does not pose a risk to the health of the consumer, apart from its strong sensitising potential.

Hydroxyethyl-3,4-methylenedioxyaniline HCl is a secondary amine and thus prone to nitrosation. It should therefore not be used in combination with nitrosating substances. The nitrosamine content should be less than 50 ppb.

Studies on genotoxicity/mutagenicity in finished hair dye formulations should be undertaken following the relevant SCCNFP/SCCP opinions and in accordance with its Notes of Guidance.

The opinion was adopted.

8.3. B36, HC RED N° 7

The SCCS was asked to assess the safety of HC Red n° 7 as a non-oxidative hair dye with a concentration of maximum 1.0%.

The SCCS concluded that, based on the data provided, the use of HC Red n° 7 as a non-oxidative hair dye with a maximum concentration on the head of 1.0% does not pose a risk to the health of the consumer, apart from its strong sensitising potential.

HC Red n° 7 is a secondary amine, and thus is prone to nitrosation. It should not be used in combination with nitrosating substances. The nitrosamine content should be < 50 ppb.

The opinion was adopted.

8.4. B38, HC YELLOW N° 4

The SCCS was asked to assess the safety of HC Yellow n° 4 as a non-oxidative hair dye with a concentration of maximum 1.5%.

The SCCS concluded that, based on the data provided, the use of HC Yellow n° 4 as a non-oxidative hair dye with a maximum concentration on the head of 1.5% does not pose a risk to the health of the consumer.

A sensitising potential of HC Yellow n° 4 cannot be excluded.

HC Yellow n° 4 is a secondary amine, and thus is prone to nitrosation. It should not be used in combination with nitrosating substances. The nitrosamine content should be < 50 ppb.

The opinion was adopted.

8.5. P56, MIXTURE OF 5-CHLORO-2-METHYL-ISOTHIAZOLIN-3(2H)-ONE AND 2-METHYLISOTHIAZOLIN-3(2H)-ONE

The SCCS was asked to assess whether the preservative mixture of 5-chloro-2-methyl-4-isothiazolin-3-one and 2-methyl-4-isothiazolin-3-one in a ratio of 3:1 is safe for the consumers when used as a preservative up to a maximum authorised concentration of 0.0015% in rinse-off cosmetic products.

The SCCS concluded that the mixture of 5-chloro-2-methyl-4-isothiazolin-3-one and 2-methyl-4-isothiazolin-3-one in a ratio of 3:1 is well recognised as an important skin sensitiser at current conditions of use and applications. Hitherto, it has been used in both leave-on and rinse-off products in Europe.

Induction and elicitation would be less likely in a rinse-off product than when the same concentration is present in a leave-on product.

On the basis of the data submitted, the SCCS concluded that the mixture of 5-chloro-2-methyl-4-isothiazolin-3-one and 2-methyl-4-isothiazolin-3-one in a ratio of 3:1 does not pose a risk to the health of the consumer when used as a preservative up to a maximum authorised concentration of 0.0015% in rinse-off cosmetic products, apart from its sensitising potential.

The opinion was adopted.

8.6. CMR SUBSTANCES

The SCCS was asked to consider whether, in relation to a list of chemicals recently classified as CMR there are new elements that would lead it to amend its opinion on CMR substances of 25 September 2001, and if so, to revise it accordingly.

The SCCS concluded that there are no new elements that would lead it to amend the opinion of the SCCNFP on CMR substances of 25 September 2001 (doc. n° SCCNFP/0474/01).

The opinion was adopted.

8.7. P72, ALKYL (C16, C18, C22) TRIETHYLAMMONIUM, BROMIDE AND CHLORIDE

The SCCS was asked to assess the safety of Alkyl (C16, C18, C22) trimethylammonium, bromide and chloride when used in cosmetic products for non-preservative purposes in the specified concentrations.

The SCCS concluded that, as far as systemic and local toxicity are concerned, the chemical analogy between the three compounds seems to permit a read-across approach for cetrimonium chloride, stearammonium chloride and behentrimonium chloride.

The calculation of the Margin of Safety under 3.3.13 leads to a value of 192.

Apart from the fact that quaternary ammonium derivative formulations have the potential to be irritative, especially when combinations of the concerned compounds are used, the SCCS concluded that the use of *cetrimonium chloride*, *stearammonium chloride* and *behentrimonium chloride* does not pose a risk to the health of the consumer under the following concentration limits:

Cetrimonium chloride (C₁₆), *stearammonium chloride* (C₁₈):

Rinse-off hair care products up to	2.5%
Leave-on hair care products up to	1.0%
Leave-on facial cream products: sum of cetrimonium chloride and stearammonium chloride up to	0.5%

Behentrimonium chloride (C₂₂):

Rinse-off hair care products up to	5.0%
Leave on hair care and facial cream products up to	3.0%

The opinion was adopted

9. MEMORANDUM ON ALTERNATIVE METHODS IN SAFETY ASSESSMENT OF COSMETIC INGREDIENTS IN THE EUROPEAN UNION – FOR APPROVAL

Pending some smaller discussion points that will be clarified by written exchange, the memorandum was approved.

10. ANY OTHER BUSINESS

- Next Plenary meeting: 23 March 2010

Annex 1: List of Participants

Annex 1

List of Participants**Members of the SCCS**

Prof. J. Angerer, Dr. U. Bernauer, Dr. C. Chambers, Dr. M.Q. Chaudhry, Prof. G. Eisenbrand, Prof. T. Platzek, Dr. S.C. Rastogi, Prof. V. Rogiers (vice-Chairman), Dr. C. Rousselle, Prof. T. Sanner (vice-Chairman), Dr. J. van Benthem, Dr. J. van Engelen, Prof. M.P. Vinardell, Dr. I.R. White (Chairman)

Apologies

Prof. G. Degen, Prof. C.L. Galli, Prof. K. Savolainen, Prof. R. Waring

SCCS Secretariat (DG SANCO)

Mr. T. Daskaleros, Mrs K. Kilian, Mr. A. Van Elst

DG ENTR F3

Mrs. A. Orloff