



EUROPEAN COMMISSION
HEALTH & CONSUMERS DIRECTORATE-GENERAL

Public Health and Risk Assessment
Risk assessment

Scientific Committee on Consumer Safety
4th Plenary Meeting

Held on 13 October 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. J. Angerer, Dr. C. Chambers, Prof. G. Eisenbrand, Prof. C.L. Galli, Prof. K. Savolainen and Dr. J. van Engelen.

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/1268/09

The agenda was approved without changes.

4. ADOPTION OF THE DRAFT MINUTES OF THE 3RD PLENARY MEETING

SCCS/1258/09

The minutes of the 3rd plenary meeting of 8 July 2009 were approved.

5. INFORMATION FROM CHAIRMAN/MEMBERS

Inter-Committee Coordination Group (ICCG) meeting 12 Oct 2009

The Chairman said that a meeting of the Inter-Committee Coordination Group (ICCG) had taken place on 12 Oct 2009. The following items were discussed:

- the new commission decision concerning indemnities was adopted in July, adjusting the daily indemnities and rapporteur's indemnities as well as introducing a staged system for rapporteurs indemnities.
- The preliminary 2010 work programme was presented and the Committees were asked for comments.

- During the 5th meeting of chairmen of EU Scientific Committees on 18 and 19 November 2009, a session on "Methods, New Approaches and Methods for Hazard Identification and Assessment and their implications for Risk Assessment" will take place. The members were asked whether they would like to participate.
- A SANCO representative summarised the first experience in terms of the participation in meetings and discussions and appropriate written contributions to the committee documents. The Commission will monitor attendance at meetings until the end of the year and will carry out an assessment of the situation with the aim to address members that do not manage to meet the Commission requirements.

Commission follow-up to earlier opinions

The Commission service responsible for Cosmetics reported that no new legal implementations for cosmetic ingredients were made since the last plenary of 8 July 2009.

6. APPOINTMENT OF A SCIENTIFIC ADVISOR

According to Article 3 of Commission Decision 2008/721/EC of 5 August 2008 setting up an advisory structure of Scientific Committees, the SCCS may associate, at its own initiative, up to 5 scientific advisors from the Pool to contribute to the Committee work on specific issues or disciplines.

Dr. J. van Benthem (RIVM, the Netherlands) was appointed by the SCCS as a scientific advisor on genotoxicity issues.

7. NEW REQUESTS

7.1. REVIEW OF OPINION ON TRICLOSAN

Arguments regarding an alternative interpretation of the available safety data on triclosan were received. A mandate to consider these arguments will be submitted.

7.2. OPINION ON DIHYDROXYACETONE

The SCCS was asked to evaluate the use of dihydroxyacetone (DHA) in cosmetic products and in "spray cabin" applications.

7.3. OPINION ON BORON COMPOUNDS CLASSIFIED AS CMR

The Commission reported that the mandate for these substances is under revision.

7.5. OPINION ON MERCURY IN ENERGY SAVING LIGHT BULBS (SCHER WITH SCCS PARTICIPATION)

A mandate on the environmental and health impact of mercury in certain types of light bulbs has been issued to SCHER. The SCCS will be asked to nominate member(s) for this WG depending on expertise needed.

7.6. OPINION ON CMR SUBSTANCES IN TOYS (SCHER WITH SCCS PARTICIPATION)

A mandate to SCHER is under discussion. SCCS will be asked to nominate member(s) for the WG.

8. REPORTS FROM THE WORKING GROUPS

8.1. COSMETIC INGREDIENTS

The Chairperson of the WG reported on the ongoing work of the Working Group. He said that i.a. draft opinions on choline chloride and on citric acid and silver citrate were prepared and are tabled for formal adoption.

8.2. HAIR DYES

The Chairperson of the WG reported on the ongoing work of the Working Group. He said that i.a. draft opinions on 2-amino-4-hydroxyethylaminoanisole sulfate and on hydroxypropyl bis(N-hydroxyethyl-p-phenylenediamine) HCl were prepared and are tabled for formal adoption.

8.3. METHODOLOGIES

The Chairperson of the WG said that the next meeting of the WG will take place on 27 October 2009.

8.4. NANO-MATERIALS IN COSMETICS

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

8.5. TRICLOSAN (ANTIMICROBIAL RESISTANCE)

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

8.6. TTC

The Chairman of the Working Group said that a public hearing had taken place in September 2009 followed by a meeting of the WG. An additional meeting in November has been set to finalise the opinion.

8.7. SENSITISATION & FRAGRANCES

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

8.8. FOOD IMITATING PRODUCTS

A chairman for this working group was nominated and members were asked to confirm their previously expressed interest in joining this group with the aim to organise a first meeting in the near future.

9. DRAFT OPINIONS - DISCUSSION AND POSSIBLE ADOPTION

9.1. CLARIFICATION ON CHOLINE SALTS AND ESTERS

The SCCS was asked to answer the question, whether various choline compounds, based on the chemical structure and/or behaviour of the substances following questions should be considered to be covered by entry II/168 of the Cosmetics Directive:

The SCCS concluded that, based on their structural and chemical properties the following substances listed in the Terms of Reference should fall under the scope of entry II/168:

Choline fenofibrate, choline salicylate, choline gluconate, choline theophylline, choline esters of stearic acid and other long alkyl chain carboxylic acids, methylcholine and its salts and esters.

The following substances, based on their structural and chemical properties, should not be considered to fall under the scope of entry II/168:

Glycerophosphocholine, phosphatidylcholine, lecithin, hydrogenated lysophosphatidylcholine, hydrogenated phosphatidylcholine, polyphosphorylcholine glycol acrylate

The opinion was adopted.

9.2. CITRIC ACID (AND) SILVER CITRATE

The SCCS was asked to answer the questions whether the novel cosmetic preservative Citric acid (and) Silver Citrate can be considered safe for consumers when used in cosmetic products except oral care products and products intended to be used in the vicinity of the eyes in a concentration up to 0.2%, and as the "active" ingredients in deodorants also in a concentration up to 0.2%.

The SCCS concluded that the use of citric acid (and) silver citrate in cosmetic products, at a concentration up to 0.2%, as a preservative does not pose a risk to the health of the consumer. For deodorants and anti-perspirants, it is also considered safe when used up to a total concentration of 0.2% as a preservative and/or an active ingredient.

The critical aspect in the safety evaluation of silver containing compounds, like citric acid (and) silver citrate, is possible long-term effects of the silver released, in particular in relation to argyria. The available toxicity data in relation to silver, on which various regulatory limits (RfD by US-EPA, lifetime NOAEL by WHO and group restriction limit for food contact material by EFSA) are based, are very limited and old. The SCCS is aware that additional silver toxicity information has been generated to address other regulatory needs and recommends a review of these data once they become accessible should they be relevant for the safety of silver-containing cosmetic ingredients.

The SCCS pointed out that its opinion is limited to the evaluation of the potential exposure and risks associated with the use of citric acid (and) silver citrate in cosmetic products at the proposed use concentration. It did not consider uses of other silver containing cosmetic ingredients or exposure to silver from other non-cosmetic sources. Evidence in the public domain suggests an increase in the exposure of consumers to silver from sources other than cosmetics (e.g. textiles, cleaning products and medical products). Therefore, the SCCS strongly recommends to the Commission services that there should be an assessment on aggregate exposure to silver.

The opinion was adopted.

9.3. 2-AMINO-4-HYDROXYETHYLAMINOANISOLE SULPHATE (A84)

The SCCS was asked to answer the questions whether the hair dye substance 2-Amino-4-hydroxyethylaminoanisol sulphate can be considered safe for use in oxidative hair dye formulations with an on-head concentration of maximum 1.5 %.

The SCCS concluded that the use of 2-amino-4-hydroxyethylamino-anisole sulphate as an ingredient in oxidative hair dye formulations with a maximum on-head concentration of 1.5% will not pose a risk to the health of the consumer.

A possible sensitising potential of 2-amino-4-hydroxyethylamino-anisole sulphate cannot be excluded.

2-amino-4-hydroxyethylamino-anisole sulfate is a secondary amine. It should not be used in combination with nitrosating substances. The nitrosamine content should be < 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.

9.4. HYDROXYPROPYL BIS(N-HYDROXYETHYL-P-PHENYLENEDIAMINE) HCL (A121)

The SCCS was asked to answer the questions whether the hair dye substance hydroxypropyl bis(N-hydroxyethyl-p-phenylenediamine) tetrahydrochloride can be considered safe for the consumers when used in oxidative hair dye products with a concentration on the head up to 0.4%.

The SCCS concluded that, based on the information provided, the use of Hydroxypropyl bis(N-hydroxyethyl-p-phenylenediamine) itself as an oxidative hair dye substance at a maximum concentration on the head of 0.4% does not pose a risk to the health of the consumer, apart from its strong sensitising potential.

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.

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

The memorandum was discussed and some further suggestions were made, which will be included by the Rapporteur. The memorandum will be circulated for final approval.

11.1. RESPONSES TO MEMBER STATE COMMENTS ON UV FILTERS FROM ENTR PUBLIC CONSULTATION – FOR APPROVAL AND DISCUSSION

The Committee approved the responses to the comments received on the opinions on Benzophenone-3 and on Camphor benzalkonium methosulfate. The response will be forwarded to DG ENTR.

12. ANY OTHER BUSINESS

- A letter from the Danish Hairdresser Union concerning the occupational exposure of hair dressers to cosmetic hair products was discussed. A response letter will be drafted

- Next Plenary meeting: 8 December 2009

Annex 1: List of Participants

Annex 1

List of Participants

Members of the SCCS

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

Apologies

Prof. J. Angerer, Dr. C.M. Chambers, Prof. G. Eisenbrand, Prof. C.L. Galli, Prof. K. Savolainen, Dr. J. van Engelen

SCCS Secretariat (DG SANCO)

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

DG ENTR F3

Mrs. A. Orloff