

EUROPEAN COMMISSION HEALTH & CONSUMER PROTECTION DIRECTORATE-GENERAL

Directorate C – Public Health and Risk Assessment C7 Risk assessment Scientific Committee on Consumer Products

SCIENTIFIC COMMITTEE ON CONSUMER SAFETY 2ND PLENARY MEETING

Held on 28 April 2009 in Brussels

MINUTES

1. WELCOME AND APOLOGIES

Dr. I.R. White welcomed all the participants. Apologies were received from Prof. J. Angerer, Dr. M.Q. Chaudhry, Prof. G. Degen, Prof. K. Savolainen and Dr. J. van Engelen.

2. DECLARATIONS OF INTEREST

Fluoridation of drinking water: Dr. C.M. Chambers said that she was involved in the work of the Irish Society of Toxicology on the issue of fluoridation of drinking water in Ireland.

3. APPROVAL OF THE DRAFT AGENDA

SCCS/1218/09

The agenda was approved as proposed.

4. Adoption of the draft minutes of the 1^{st} plenary meeting SCCS/1216/09

The minutes of the 1st plenary meeting of 27 March 2009 were approved.

5. INFORMATION FROM CHAIRMAN/MEMBERS

No items were raised.

6. INFORMATION ON FOLLOW-UP ON OPINIONS

6.1 **REGULATION OF COSMETIC INGREDIENTS**

Mrs. A. Orloff reported on recent adaptations to technical progress of Directive 76/768/EEC on cosmetic products:

- 17 hair dyes, for which a final opinion was adopted by the SCCP, were inserted in Annex III;
- Diethylene glycol (except for traces in ingredients) and phytonadione (vitamin K1), for which the SCCP concluded that they should not be used in cosmetic products, were inserted in Annex II;
- Butoxydiglycol (DEGBE), butoxyethanol (EGBE) and toluene, for which opinions were adopted, were inserted in Annex III.
- 4-Amino benzoic acid was removed from Annex VII (list of permitted UV-filters) and inserted in Annex II. The SCCP concluded that no risk assessment could be performed because of the lack of data.

6.2 AGGREGATE RISK ASSESSMENT OF SILVER

In its opinion n° SCCP/1196/08, 21 January 2008, on citric acid and silver citrate, the SCCP strongly recommends the consideration of an aggregate exposure and risk assessment for silver. 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, medical products).

A first meeting with relevant Commission services (e.g. ENTR cosmetics and chemicals, ENV biocides, SANCO food contact materials) has taken place in March 2009 to follow-up to this opinion.

7. LEGAL BACKGROUND OF COSMETIC SAFETY EVALUATIONS – CURRENT SITUTATION AND FUTURE CHANGES

Mrs. S. Lecrenier, Head of Unit DG ENTR-F3 - responsible for Directive 76/768/EEC on cosmetic products, was invited to meet the members of the renewed SCCS. She briefly illustrated the legal background of the requests for scientific opinions and expressed her appreciation for and importance of the work of the Committee.

Mrs. B. Mentre presented the EU cosmetic legislation: the purpose of the directive and its basic principles.

Particular attention was given to the 'recast' of the directive. She said that the European Parliament and the Council might adopt the regulation on cosmetic products before the summer break.

8. NEW REQUEST AND OTHER EMERGING ISSUES

8.1 SCHER MANDATE

Mr. T. Daskaleros presented the request for a critical review of any new (after 2005) evidence on the hazard profile, health effects, and human exposure to fluoride, and assessment of the risks that may be associated with the use of most common drinking water fluoridation agents like silicofluorides.

9. **REPORTS FROM WORKING GROUPS**

9.1. COSMETIC INGREDIENTS

- Report of the Co-ordinator

One WG-meeting had taken place since the renewal of the Committee. As this was the 1st meeting of the new WG, it was dedicated to a description of the work and distribution of tasks to the members.

The following issues were treated:

- Chloromethyl isothiazolinone/methyl isothiazolinone: a full toxicological dossier needs to be evaluated.

- Choline salts and esters: entry n° 168 of Annex II to the cosmetic Directive bans the use of choline salts and their esters. The SCCS was asked whether certain substances currently mentioned in the CosIng-database are considered covered by this entry.

- Cyclomethicone: additional information, as requested by opinion n° SCCP/0893/05 needs to be evaluated.

- Erythrosine: Erythrosine is currently regulated as a cosmetic colorant in Annex IV of the Cosmetics Directive. In order to reduce the intake of iodine from cosmetic products, the Commission proposed to ban erythrosine if no safety dossier was submitted. A dossier was submitted applying for use in toothpaste at 0.0025%.

- Melatonin: A safety dossier was submitted to support the use of melatonin in hair products at a concentration of 0.0033%.

- P72, Alkyl trimethylammonium chloride: Alkyl trimethyl ammonium chloride is currently authorised as a preservative at a maximum concentration of 0.1%. The applicant submitted an objection to the opinion, arguing that the restrictions made are not compatible with the current use levels of the substances.

- P81, zinc pyrithione: A mandate was issued applying for an extension of the authorised concentration from 1.0% to 2.0% in rinse-off antidandruff hair care products.

For this task, the need for external expertise in PBPK modelling was identified. No suitable expert was identified in the Pool or the Database, therefore a search in the scientific literature was conducted. The members agreed on a shortlist of experts. The secretariat will inquire about the availability of the experts for this task.

- S74, Polysilicone-15: Polysilicone-15 is currently authorized as an UV-filter at a concentration up to 10%. The applicant has informed the Commission that polysilicone-15 was tested via inhalation route in an acute exposure scenario and that polysilicone-15 was found to be toxic by inhalation. In order to evaluate whether this founding has any influence on the current authorisation, the Commission has requested the study to have it evaluated by the SCCP.

9.2. METHODOLOGIES

- Report of the Co-ordinator

No meeting of the WG had taken place since the renewal of the Committee. A first meeting is planned on 7 May 2009.

- Alternative methods in cosmetic safety testing

Prof. V. Rogiers illustrated the alternative methods which are available today for the testing of cosmetic ingredients.

9.3 TTC

- Report of the Co-ordinator

This joint task is ongoing for the previous term of the Scientific Committees. Especially for the new members, the 'Background' and 'Terms of References' of the opinion were described. The three former Scientific Committees, namely the SCCP, SCHER and SCENIHR approved on 19 November 2008 a preliminary report which was put on the web for public consultation. Subsequently, a revised version was made based upon the comments received.

Further meeting would be required to finalise the document.

10. PLANNING OF WORKING GROUPS

10.1. HAIR DYES & COLORANTS

- Report of the Co-ordinator

The first meeting of the renewed WG is planned on 12 May 2009. The work of the WG and the list of hair dyes to be evaluated were briefly presented.

To initiate the work, a first distribution of tasks was done.

10.2. SENSITISATION & FRAGRANCES

No meeting of this WG has yet taken place. The upcoming tasks were considered and the need for external expertise stated.

10.3. NANO-MATERIALS

No meeting of the WG has yet taken place. Due to the absence of the group's chairman, provisions for the first WG meeting, including coordination with SCENIHR and selection of external experts, will be made in writing.

10.4. TRICLOSAN (ANTIMICROBIAL RESISTANCE)

The 'Background' and 'Terms of References' of the opinion were illustrated. To answer the question on anti-microbial resistance, co-ordination with SCENIHR is needed.

10.5. FOOD IMITATING PRODUCTS

A preliminary mandate was received on the potential health risks posed by food-imitating and child-appealing chemical consumer products.

The data base currently available for this evaluation is considered inadequate. The Commission will initiate data gathering from EU Poison Centres, public literature and other sources through direct contact, a data mining project and a call for information.

A first meeting is planned end of June 2009.

11. WORKING PROCEDURES: LIST OF QUESTIONS/INTERIM OPINIONS

Dr. I.R. White said that this issue was already sufficiently discussed during the 1st plenary meeting.

12. ANY OTHER BUSINESS

Mrs A. Orloff said that comments were received on the opinions on:

- Tea Tree Oil
- Benzophenone-3
- camphor benzalkonium methosulfate

The questions asked will be further discussed in the respective Working Groups.

The SCCS agreed on the following dates for meetings:

7 May 2009:	WG on Methodologies
12 May 2009:	Hair Dyes
19 May 2009:	WG on Cosmetic Ingredients
16 June 2009:	WG on Hair Dyes
8 July 2009:	Plenary meeting
13 October 2009:	Plenary meeting
8 December 2009:	Plenary meeting

Annex I: List of Participants

Annex I

List of Participants

Members of the SCCS

Dr. U. Bernauer, Dr. C.M. Chambers, Prof. G. Eisenbrand, Prof. C.L. Galli, Prof. T. Platzek, Dr. S.C. Rastogi, Prof. V. Rogiers (vice-Chairman), Dr. C. Rousselle, Prof. T. Sanner (vice-Chairman), Prof. M.P. Vinardell, Prof. R. Waring, Dr. I.R. White (Chairman)

Apologies

Prof. J. Angerer, Dr. M.Q. Chaudhry, Prof. G. Degen, 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. S. Lecrenier, Mrs. S. Hoeke, Mrs. B. Mentre, Mrs. A. Orloff