EUROPEAN COMMISSION
HEALTH & CONSUMERS DIRECTORATE-GENERAL

Public Health and Risk Assessment
Risk assessment

SCIENTIFIC COMMITTEE ON CONSUMER SAFETY
3RD PLENARY MEETING

Held on 8 July 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 Dr. M.Q. Chaudhry, Prof. C.L. Galli, Prof. G. Eisenbrand and Prof. K. Savolainen.

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.

The Committee discussed the declarations of interest of external experts recently recruited for SCCS working groups.
On the basis of these declarations, the Committee decided that there were no conflicts of interest and that these experts could participate in the discussions of the respective Working Groups.

3. APPROVAL OF THE DRAFT AGENDA SCCS/1220/09

The agenda was approved.

4. ADOPTION OF THE DRAFT MINUTES OF THE 2ND PLENARY MEETING SCCS/1221/09

The minutes of the 2nd plenary meeting of 28 April 2009 were approved.

5. INFORMATION FROM CHAIRMAN/MEMBERS

The Chairman and the secretariat reported on the 1st meeting of the Inter-Committee Coordination Group (ICCG) meeting of 25 June 2009, in particular on the following topics:

- the 5th meeting of Chairmen of the Risk Assessment Bodies of the EU on 18-19 November 2009; the meeting will be followed by a workshop on alternative methods on 19 November, pm. On 20 November 2009, the annual Risk Assessment Day will take place.

- Rules of Procedure & interim opinions: the various types of documents produced by the Committees and the types and modalities of public/stakeholders consultations were discussed. It was agreed to simplify the terminology used. The rules of procedure referring to "interim opinions" and related consultation procedures will be revised.

- A scientific hearing on the risk assessment of nanomaterials will be held on 10 September 2009 in Brussels.

6. INFORMATION ON FOLLOW-UP ON OPINIONS

No information was given under this agenda point.

7. NEW REQUESTS AND OTHER EMERGING ISSUES

7.1. VITAMIN K1

The Chairman presented the general background information and the opinions adopted so far. At present, vitamin K1 is banned. However, new data were submitted for evaluation.

8. REPORTS FROM THE WORKING GROUPS

8.1. COSMETIC INGREDIENTS

The Chairperson of the WG said that work is on-going on:

- chloro methyl isothiazolinone / methyl isothiazolinone (CMI/MI)
- cyclomethicone (D4/D5)
- borate classified as CMR substances)

and on the responses/objections to previous opinions on:

- alkyl (C16, C18, C22) triethylammoniumchloride
- benzophenone-3 (public consultation)
- camphor benzalkonium methosulfate (public consultation)
- tea tree oil

8.2. HAIR DYES

The Chairperson of the WG reported on the work of the Working Group. 11 hair dyes are presently under evaluation.

8.3. METHODOLOGIES

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

- EPISKIN-SM™ *in vitro* skin irritation test

The test was recently validated as a full replacement for the *in vivo* Draize test by ESAC (ECVAM Scientific Advisory Committee).

In a memorandum on the EPISKIN-SM™ method (SCCP/1145/07, 18 December 2007), the former SCCP expressed specifically its concern about the interference of colorants and coloured hair dyes with the MTT colorimetric method used in the test.

Additional data, addressing the concern of the SCCS, have been submitted and are currently being evaluated.

- Dermal absorption

The WG will review and update the current SCCNFP/SCCP basic criteria on dermal absorption.

- Revision of the Notes of Guidance

The points that need to be updated in the 6th revision of the Notes of Guidance (2006) were discussed.

- Status report on alternatives

On 19 June 2007, the former SCCP adopted a memorandum on the actual status of alternative methods to the use of experimental animals. Directive 76/768/EEC on cosmetic products prohibits the testing of cosmetic ingredients on animals (testing ban) as from 11 March 2009. A draft update of this memorandum will be presented to the next plenary meeting of 13 October.

- Inhalation exposure

A presentation on inhalation exposure was given. The Committee recognised the need for external expertise on this topic.

8.4. NANO-MATERIALS IN COSMETICS

As the chairperson of this group was absent, Dr. I.R. White said that the Working Group met once and that the discussions focussed on the mandates on TiO_2 and ETH50. He reported that the WG plans to address also some general questions e.g. on the delineation of nano-materials and the applicability of testing methods regarding nano-materials in cosmetics.

8.5. TRICLOSAN (ANTIMICROBIAL RESISTANCE)

The Chairperson of the WG reported that one meeting of the Working Group had taken place. The discussion focussed mainly on the scope of work and on the mandate. The WG stated that the environmental safety of triclosan was not covered by this mandate.

The WG agreed that the scope of the work would cover the issues of resistance and cross-resistance linked to triclosan that could have relevance for human health, both directly and indirectly (i.e. through the environment). It would also address the issue of related data gaps and research needs.

8.6. TTC (THRESHOLD OF TOXICOLOGICAL CONCERN)

The secretariat said that a scientific hearing on the TTC approach is planned in Brussels on 24 September 2009. For this targeted hearing the contributors to the public consultation will be invited. A meeting of the Working Group to update the opinion according to the outcome of the hearing is planned for 25 September.

9. FUTURE PLANNING FOR WORKING GROUPS

9.1. SENSITISATION & FRAGRANCES

The Chairperson of the WG informed that the first meeting of the Working Group will take place on 14 July 2009. The main point is the mandate on the review of the opinion on fragrance allergy in consumers of 8 December 1999.

The representative of DG ENTR gave some background information regarding the request for review of the opinion: (i) during a public consultation concerning the limitation of the use concentrations of these allergenic substances, recent scientific publications were submitted indicating a need for review, (ii) many other allergens do not have concentration restrictions and the need to set limits also for these substances should be envisaged and (iii) labelling requirements for other allergens than those currently labelled might be relevant due to changed fragrance compositions in consumer products.

9.2. FOOD IMITATING PRODUCTS

The Chairman informed the Committee about the mandate on the potential health risks posed by food-imitating and child-appealing chemical consumer products. Be it because of their inherent toxicity properties, be it from other characteristics (viscosity, foaming potential, vomiting induction potential), ingestion of these products may pose a risk to the health of consumers.

The secretariat said that DG SANCO B3 has established contacts with the national poisoning centres.

10. DRAFT OPINIONS FOR DISCUSSION AND POSSIBLE ADOPTION

10.1. 2-HYDROXYETHYLAMINO-5-NITROANISOLE (B52)

The SCCS was asked to answer the following questions:

1. *Does SCCS consider 2-Hydroxyethylamino-5-nitroanisole safe for use in non-oxidative hair dyes with a concentration of maximum 0.2 % taken into account the scientific data provided?*

2. *And/or does the SCCS has any further scientific concerns with regard to the use of 2-Hydroxyethylamino-5-nitroanisole in non-oxidative hair dye formulations?*

The SCCS concluded that the use of 2-Hydroxyethylamino-5-nitroanisole as an ingredient in non-oxidative hair dye formulations with an on-head concentration of 0.2% does not pose a risk to the health of the consumer. This risk assessment relates to the use of 2-Hydroxyethylamino-5-nitroanisole in non-oxidative hair dye formulation only.

2-Hydroxyethylamino-5-nitroanisole is a secondary amine. It should not be used in combination with nitrosating substances. The nitrosamine content should be < 50 ppb

The opinion was adopted.

10.2. Clarification on Choline Salts and Esters

As a result of the discussion, the SCCS decided to refer the draft opinion back to the Working Group for further consideration.

11. Draft Responses for Discussion and possible approval

11.1. Draft response to Objection to Alkyl (C16, C18, C22) triethylammoniumchloride

The SCCS was asked whether on the basis of the newly provided information/argumentation the conclusions of SCCP/1087/07 need to be adapted. A draft response was discussed and will be adapted accordingly by the Rapporteur.

11.2. Draft response to comments from public consultation on benzophenone-3

Further to the public consultation on the opinion adopted on benzophenone-3 (opinion n° SCCS/1201/08, 16 December 2008), comments were received by member states concerning mainly the possible adverse effects on human reproduction, on endocrine disrupting properties and on the safe use by children.

The SCCS concluded that, unless new, relevant and scientifically sound information becomes available, it maintains the conclusions formulated in its opinion n° SCCP/1201/08 of 16 December 2008. A written response will be provided to DG ENTR.

11.3. Draft response to comments from Applicant on Tea Tree oil

The European Commission received on 25 March 2009 a letter from the applicant expressing his concern about the conclusion of the opinion of the SCCS on Tea Tree Oil (TTO), and in particular on the cosmetic function of TTO, on the content of methyleugenol and on the request for adequate dermal absorption data. As a result of the discussion on the issues raised in this letter, the SCCS concluded that there is no reason to changes opinion n° SCCS/1155/08 of 16 December 2008. DG ENTR will respond to the applicant accordingly.

12. Any other business

No issues were raised.

Next Plenary meeting: 13 October 2009

Annex 1: List of Participants

Annex 2: Draft agenda

Annex 1

List of Participants

Members of the SCCS
Prof. J. Angerer, Dr. U. Bernauer, Dr. C.M. Chambers, 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

Dr. M.Q. Chaudhry, Prof. C.L. Galli, Prof. G. Eisenbrand, Prof. K. Savolainen

SCCS Secretariat (DG SANCO)
Mr. T. Daskaleros, Mrs. A. Kanellopoulou, Mr. A. Van Elst, Mrs. M. Viitaniemi

DG ENTR F3
Mrs. A. Orloff

Annex 2

3rd Plenary meeting of the
Scientific Committee on Consumer Safety (SCCS)

Draft agenda - 8 July 2009

1. Welcome and apologies

2. Declarations of interest

3. Approval of the draft agenda

4. Adoption of the draft minutes of the 2nd plenary meeting

5. Information from Chair

6. Information on follow-up on opinions

7. New request and other emerging issues

8. Reports from Working Groups

   8.1. Cosmetic Ingredients
   8.2. Hair Dyes
   8.3. Methodologies
   8.4. Nano-materials in Cosmetics
   8.5. Triclosan (Antimicrobial resistance)
   8.6. TTC

9. Future Planning for Working Groups

   9.1. Sensitisation & Fragrances
   9.2. Food imitating products

10. Draft Opinions for Discussion and possible adoption

    10.1. 2-Hydroxyethylamino-5-nitroanisole (B52)
    10.2. Clarification on Choline Salts and Esters

11. Draft Responses for Discussion and possible approval

    11.1. Draft response to Objection to Alkyl (C16, C18, C22) triethylammoniumchloride
    11.2. Draft response to comments from public consultation on benzophenone-3
    11.3. Draft response to comments from Applicant on Tea Tree oil

12. Any other business