EUROPEAN COMMISSION
HEALTH & CONSUMERS DIRECTORATE-GENERAL

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

SCIENTIFIC COMMITTEE ON CONSUMER PRODUCTS
16TH PLENARY MEETING

Held on 24 June 2008 in Brussels
MINUTES

1. WELCOME AND APOLOGIES

Dr. I.R. White welcomed all the participants. Apologies were received from Prof. R. Dubakiene, Prof. Kapoulas, Prof. J. Krutmann and Prof. G. Speit.

2. DECLARATION OF INTEREST ON MATTERS ON THE AGENDA

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 AGENDA

The agenda was approved as proposed.

4. APPROVAL OF THE MINUTES OF THE 15TH PLENARY MEETING

The Minutes of the 15th plenary meeting were approved.

5. INFORMATION FROM CHAIRMAN/MEMBERS

Dr. White said that the chairmen of the 3 Scientific Committees met members of the EP STOA panel (Science and Technology Options Assessment) in Strasbourg on 19 June 2008. Brief presentations of the 3 committees were followed by a discussion on points of mutual interest.

6. EMERGING ISSUES

No issued were raised.

7. DISCUSSION AND POSSIBLE ADOPTION OF A SCIENTIFIC OPINION

The adopted opinions will be published at:
http://europa.eu.int/comm/health/ph_risk/committees/04_sccp/sccp_opinions_en.htm

7.1. ALTERNATIVES

Report of the Co-ordinator

Prof. V. Rogiers reported on the following:

- At its 28th meeting on 7-8 May 2008, the Non-Commission members of the ECVAM Scientific Advisory Committee (ESAC) unanimously endorsed the following statement: "*The ESAC members recommend to use non-animal serum substitutes of foetal calf serum (FCS) and other animal derived supplements, whenever possible. For new in vitro culture test methods to be developed the ESAC strongly suggests the use of non animal alternatives to FCS.*"

- ECVAM business plan.

- request from ECVAM for a SCCP opinion on validation of new alternative method

- EpiSkin: SCCP is waiting for a reaction from ECVAM on its opinion on the EpiSkin method.

Next WG meeting is planned on 1 September 2008. The aim of the meeting is to discuss the issue of dermal absorption together with external experts.

7.2. HAIR DYES AND COLORANTS

Report of the Co-ordinator

There was a report on the work done during the meetings of the WG that had taken place since the last plenary of 15 April 2008.

Draft opinions were prepared on:

A84, 2-Amino-4-hydroxyethylaminoanisole sulfate, doc. n° SCCP/1172/08

The SCCP was asked to answer the following questions:

1. *Does SCCP consider 2-Amino-4~hydroxyethylaminoanisole sulphate safe for use as a substance in oxidative hair dye formulations with an on-head concentration of maximum 1.5 % taken into account the scientific data provided?*

2. *And/or does the SCCP have any further scientific concerns with regard to the use 2-Amino-4-hydroxyethylaminoanisole sulphate as a substance in oxidative hair dye formulations?*

In its opinion n° SCCP/0958/05 of 28 March 2006, the SCCP requested a skin penetration test using 2-amino-4-hydroxyethylamino-anisole sulfate and conforming to current Notes of Guidance for Safety Evaluation.

The SCCP concluded that the study included in the present submission did not follow these SCCP guidelines. Consequently, opinion SCCP/0958/05 of 28 March 2006 remains unchanged.

The opinion was adopted.

C177, Acid Red 52, doc. n° SCCP/1115/07

The SCCP was asked to answer the following questions:

1. *Does SCCP consider Acid Red 52 safe for consumers when used as an ingredient in oxidative hair dye products with a maximum concentration of 1.5% on the scalp, taken into account the scientific data provided?*

2. *Does the SCCP recommend any further restrictions with regard to the use of Acid Red 52 in any hair dye formulations?*

The SCCP concluded that the use of Acid Red 52 as an ingredient in oxidative hair dye formulations, at a maximum concentration of 1.5% on the head or in non-oxidative hair dye formulations at a maximum concentration of 0.6% on the head, does not pose any risk to the health of the consumer.

Its use as a colorant was not evaluated.

The opinion was adopted.

7.3. PRESERVATIVES AND FRAGRANCES

Report of the Co-ordinator

Dr. White said that the following opinions had been prepared by the Working Party since the plenary meeting of 15 April 2008.

Dermal Quantitative Risk Assessment, doc. n° SCCP/1153/08

The SCCP is requested to critically review the QRA methodology to answer the following questions:

1. *Taking into account the description of the methodology as well as the application to three example fragrances (Citral, Farnesol, Phenylacetaldehyde), does the SCCP consider the QRA approach appropriate to assess the sensitisation potential of fragrance substances in cosmetic products and set use restrictions on the basis of these calculations?*

2. *Could this approach also be used for assessing the risk posed by sensitising cosmetic ingredients other than fragrances?*

3. *If the answers to questions 1 and/or 2 are negative, can the SCCP identify additional scientific work (data generation, method development) that would support the use of the Dermal Sensitisation QRA approach for fragrances and/or other sensitising cosmetic ingredients?*

In response to question 1, the SCCP concluded that:

The dermal sensitization QRA model is based primarily on data from experimental sensitization tests in humans e.g. Human Repeated Insult Patch Tests (HRIPT). There is a lack of in-depth method description and the experience with this test, its validity, sensitivity and reliability is sparse outside industry. Such experimental sensitization tests in humans are considered unethical to perform.

Epidemiological and experimental data, providing information on sensitization/elicitation reactions in consumers by fragrance ingredients in marketed products, are not integrated in the dermal sensitization QRA model. It is of concern that the model operates with multiple product categories without considering risk from aggregated exposures and that scientific consensus has not been achieved concerning the choice of safety factors. Occupational exposures are not considered although they have been identified as an important area of development of the dermal sensitization QRA.

The data provided shows that the application of the dermal sensitization QRA approach would allow increased exposures to allergens, already known to cause allergic contact dermatitis in consumers. The model has not been validated and no strategy of validation has been suggested. There is no confidence that the levels of skin sensitizers identified by the dermal sensitization QRA are safe for the consumer.

Identification of safe levels of exposure to existing substances known to cause allergic contact dermatitis in the consumer should be based on clinical data and/or elicitation low-effect levels. Currently these are the only methods, which have proven efficient in reducing/preventing existing problems of sensitization/allergic contact dermatitis in the consumer.

In view of the comments above, the SCCP cannot endorse the industry proposed QRA-approach for setting safe levels of exposure to citral, farnesol and phenylacetaldehyde.

In response to question 2, the SCCP concluded that:

The strategy has been developed for fragrance ingredients, but could in principle be applied to other cosmetic ingredients provided that the concerns stated above, are addressed.

In response to question 3, the SCCP concluded that:

From a scientific point of view, models like the dermal sensitization QRA approach may, after refinement and validation, in the future be applicable for risk assessment of new substances to

suggest a safe level of exposure prior to incorporation into products. In such cases an independent post-marketing surveillance system would be essential.

Aggregated exposures must be incorporated in the dermal sensitization QRA model. Validation must be performed employing a broad range of different chemicals and data from substantial clinical investigations.

Scientific consensus must be obtained, especially concerning the choice of safety factors in the model.

Further development of dermal sensitization QRA models and establishment of scientific consensus are encouraged to improve the risk assessment of new substances for consumer protection.

The opinion was adopted.

P82, Parabens, doc. n° SCCP/1183/08

The SCCP was asked to answer the following question:

Does the SCCP consider the continued use of propyl, isopropyl, butyl and isobutylparaben in a concentration up to the existing 0.4% weight/weight as individuals or 0.8% when used in combination in cosmetic products safe for the consumer?

The SCCP concluded that, based upon the available data, the safety assessment of Propyl and Butyl Paraben cannot be finalised yet.

Parabens are important cosmetic preservatives and they have wide use in multiple product types. Since no unequivocal conclusion can be drawn with regards to the contradictory reproductive toxicity studies available, of which none appears to be scientifically acceptable, the SCCP welcomes the proposal made by industry to conduct further work in the field of skin penetration/metabolism and pharmacokinetics to further support existing data. It is, however, recommended to supplement the envisaged studies in the rat with toxicokinetic studies in human volunteers after dermal application of representative cosmetic products containing Propyl and Butyl Paraben, since these may deliver essential information.

In case significant systemic exposure to Propyl and/or Butyl Paraben is measured in the requested human volunteer study, a rodent generation toxicity study may be unavoidable, although it is the opinion of the SCCP that this should only be performed as a last resort.

Safety data need to be provided for all authorised parabens, including iso-alkyl and phenyl parabens.

As already concluded in earlier opinions, Methyl Paraben and Ethyl Paraben are not subject of concern.

The opinion was adopted.

7.4. UV FILTERS AND AD HOC SUBSTANCES

Prof. Sanner said that the following opinion had been prepared:

Diethylene glycol, doc. n° SCCP/1181/08

The SCCP was asked to answer the following questions:

1. *Does SCCP consider that a limit for the safe use of DEG as an ingredient in cosmetic products including oral care products can be set taken into account the provided risk assessments and the fatal cases reported in the enclosed literature?*

2. *If no safe limit for DEG as an ingredient in cosmetic products can be set, and taken into account that DEG exists as an impurity in commonly used cosmetic ingredients like glycerine and polyethylene glycols, does SCCP consider a maximum concentration up to 0.1% of DEG in a finish cosmetic product as safe?*

The SCCP concluded that diethylene glycol (DEG) should not be used as an ingredient in cosmetic products including oral care products. This opinion is based on the fact that more than 600 deaths have occurred due to DEG mass poisonings. Although most of the deaths have occurred after oral intake, deaths are also reported after dermal exposure. In addition, reliable data in line with present guideline requirements on non-lethal repeated dose toxicity and dermal absorption, which would allow assessment of the safety of use in cosmetic products, is not available.

SCCP is of the opinion that a maximum concentration of up to 0.1% DEG from impurities in ingredients like glycerine and polyethylene glycols in the finished cosmetic products can be considered to be safe.

The opinion was adopted.

Vitamin K1, doc. n° SCCP/1182/08

The SCCP was asked to answer the following questions:

1. *Does the SCCP consider that the concern by this substance in a concentration up 1.0% to cause allergy is superseded by the scientific data submitted?*

2. *If yes, does the SCCP consider that vitamin K1 is safe when used in cosmetic product in a concentration up to 1%?*

The studies provided on the allergenic potential of Vitamin K1 did not supersede the concerns stated in opinion SCCP/1105/07.

The SCCP maintains the view that use of Vitamin K1 in cosmetic products is not safe, since it may cause cutaneous allergy and individuals so affected may be denied an important therapeutic agent.

The opinion was adopted.

S60, 4-Methylbenzylidene Camphor (4-MBC), doc. n° SCCP/1184/08

The SCCP was asked to answer the following questions:

Does the SCCP, on the basis of the additional data submitted to it after its opinion of 10 October 2006 (SCCP/1042/06), maintain its view that the safe use of a maximum concentration of 4% 4-MBC in sunscreens cannot be established?

The SCCP concluded that, using the toxicokinetic data for 4-MBC (rat, human), the toxicokinetic factor present in the calculation of the MoS can be reduced from 4 to 1, bringing the requested MoS value for 4-MBC to 25.

As such, it is concluded that 4-MBC can be considered safe for use in finished cosmetic products (whole body application) at a concentration of up to 4%.

It must be emphasized that this opinion is restricted to the safety evaluation of 4-MBC after dermal application of a cosmetic product containing this UV filter. Exposure scenarios via the inhalation route (through aerosols, sprays, etc.) or the oral route (through e.g. lip care products) are not covered. In these cases, risk cannot be excluded.

The opinion was adopted.

Note added after adoption of the Opinion:
"The SCCP is aware of a newly published review article related to the developmental toxicity of 4 MBC (Schlumpf et al. 2008). The raw data forming the basis of this article and of previous publications cited in the review have not been made available to the SCCP and their relevance could not be assessed. The publication does therefore not affect the opinion as it is currently formulated."

8. NEXT PLENARY MEETING

The 17th plenary meeting of the SCCP will take place on 30 September 2008.

9. ANY OTHER BUSINESS

- **Dates of WG meetings:**

8 July	*in vitro* Mutagenicity Testing
15 July	Hair Dyes
22 July	ad hoc substances + Fragrances & Preservatives
2 September	Hair Dyes
16 September	ad hoc substances + Fragrances & Preservatives
17 September	TTC (Threshold of Toxicological Concern)

Annex I: List of Participants.

Scientific Committee on Consumer products
16th Plenary Meeting

Held on 24 June 2008
in Brussels

Members of the SCCP
Dr. C.M. Chambers, Prof. G. Degen, Dr. B. Jazwiec-Kanyion, Prof. C. Lidén, Prof. J.-P. Marty, Prof. T. Platzek, Dr. S.C. Rastogi, Prof. J. Revuz, Prof. V. Rogiers (Vice chair), Prof. T. Sanner (Vice chair), Dr. J. van Engelen, Dr. I.R. White (Chair)

SCCP Secretariat (DG SANCO)
Mrs. I. Coppola, Mr. T. Daskaleros, Mrs. K. Kilian, Mr. A. Van Elst

DG ENTR F3
Mrs. A. Orloff