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 PRODUCTS
5TH PLENARY MEETING

Held on 20 September 2005
in Brussels
MINUTES

1. WELCOME AND APOLOGIES

Dr. I.R. White welcomed all the participants. Apologies were received from Dr. C. Chambers, Prof C. Galli and Prof. G. Speit.

2. DECLARATION OF INTEREST ON MATTERS ON THE AGENDA

There were no declarations of interest concerning items on the agenda.

3. APPROVAL OF THE AGENDA

The draft agenda was approved.

4. PRESENTATION BY COLIPA OF DATA ON EXPOSURE TO COSMETIC INGREDIENTS

COLIPA was represented by Mrs. Manuela Coroama (COLIPA), Dr. Barbara Hall (L'Oréal), Dr. Cronan McNamara (Trinity College, Dublin) and by Dr. Sarah Tozer (P&G).

In addition to the presented data, the Committee asked for access to the existing, comprehensive exposure data used for in-house risk assessment by the cosmetic industry. L'Oreal, P&G and Unilever agreed to submit the data on all available product categories by the end of November 2005.

The Committee said that further data is also needed on skin surface area.

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

Minutes of the 4th plenary meeting were approved.

6. INFORMATION FROM CHAIRMAN/MEMBERS

Dr. White informed the members about the meeting of the Chairmen of the three non-food committees (SCCP, SCHER and SCENIHR) of 22 June 2005 and 14 September 2005
7 April 2005.

He said that the SCENIHR was finalising its opinion on nanotechnologies, which will be used as the basis for an opinion on the use of nanotechnology in cosmetic products.
New requests for scientific opinions are foreseen on allergenicity and on a framework for risk assessment methodologies for mutagenicity/genotoxicity and carcinogenicity.

He also mentioned that EFSA had finalised its work on Genotoxicity.

7. EMERGING ISSUES

No issues were raised.

8. 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

8.1. ALTERNATIVES

Report of the Co-ordinator

In her report, Prof. Rogiers said that:

- a meeting with COLIPA, industry experts and external scientists had taken place on 5 July 2005 in order to solve frequent problems with dermal absorption studies submitted for evaluation;
- a WG Meeting on genotoxicity is scheduled on 30 September 2005 where also external experts are invited to share their views on the issue.

Prof. V. Rogiers expressed her concerns that no presentation from academia will be given at the conference “Europe goes Alternative”, hosted by DG ENTR on 7 November in Brussels.

7.2. HAIR DYES AND COLORANTS

Report of the Co-ordinator

Prof. T. Platzek reported that one meeting of the WG had taken place since the last plenary of 21 June 2005 and that about 50 safety dossiers were submitted by industry in compliance with DG ENTR second step of the strategy on the evaluation of hair dyes.

Draft opinions were prepared on:

A74, 4-Amino-m-cresol, doc. n° SCCP/0898/05

The SCCP was asked to answer the following questions:

1. *On the basis of currently available information, the SCCP is asked to assess the risk to consumers of 4-Amino-m-cresol when used in hair dye formulations.*

2. *Does the SCCP recommend any further restrictions with regard to the use of 4-Amino-m-cresol in hair dye formulations?*

The SCCP concluded that the use of 4-Amino-m-cresol itself as an oxidative hair dye at a maximum concentration of 1.5% in the finished cosmetic product (after mixing with hydrogen peroxide) does not pose a risk to the health of the consumer, apart from its sensitising potential.

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

The opinion was adopted.

A101, 2,6-Dimethoxy-3,5-pyridinediamine HCl, doc. n° SCCP/0908/05

The SCCP was asked to answer the following questions:

1. *Is 2,6-Dimethoxy-3,5-pyridinediamine dihydrochloride safe for use in hair dye formulations taken into account the data provided ?*

2. *Does the Scientific Committee on Consumer Products (SCCP) recommend any restrictions with regard to the use of 2,6-Dimethoxy-3,5-pyridinediamine dihydrochloride in hair dye formulations ?*

The SCCP concluded that the use of 2,6-Dimethoxy-3,5-pyridinediamine HCl itself as an oxidative hair dye at a maximum concentration of 0.25% in the finished cosmetic product (after mixing with peroxide) does not pose a risk to the health of the consumer, apart from its sensitising potential.

However:
- data on the stability of 2,6-Dimethoxy-3,5-pyridinediamine HCl in typical hair dye formulations should be provided, and
- studies on genotoxicity/mutagenicity in finished hair dye formulations should be undertaken following the relevant SCCNFP opinions and in accordance with its Notes of Guidance.

The opinion was adopted.

Personal Use of Hair Dyes and Cancer Hazard, doc. n° SCCP/0930/05

The SCCP was asked to answer the following questions:

1. *On the basis of currently available information and taking into account the data provided, the SCCP is asked if the data provided in the attached publications change the overall assessment of the use of hair dyes and cancer risk as stated in the opinion SCCNFP/0484/01, updated in the opinion SCCNFP/0797/04?*

2. *On the basis of currently available information and taking into account the data provided, does the SCCP recommend any other requirements for assessing hair dyes than already recommended in its opinion "Assessment Strategies for Hair Dyes" (SCCNFP/0553/02, Opinion of the SCCNFP adopted during the 22nd plenary meeting of 17 December 2002)?*

SCCP focussed in its assessment on leukaemia and bladder cancer since no evidence was found linking personal use of hair dyes to a cancer risk at other sites.

Although the published data are conflicting, especially, when all types of hair dyes were considered, it was concluded that some studies indicated excess risks for acute leukaemia and chronic lymphoid leukaemia for users of hair dyes. Also, there was an indication of excess risk of bladder cancer for women in USA using permanent hair dyes frequently and for long time.

The SCCP decided not recommend any other requirements for assessing hair dyes than already recommended in the opinion "Assessment Strategies for Hair Dyes" (SCCNFP/0553/02, 17 December 2002).

The opinion was adopted.

7.3. PRESERVATIVES AND FRAGRANCES

Report of the Co-ordinator

Dr. White said that the following opinions had been prepared:

P64, Climbazole, doc. n° SCCP/0918/05

The SCCP was asked to answer the following questions:

1. *On the basis of provided data the SCCP is asked to assess the risk to consumers when Climbazole is used for non-preservative purposes as an anti-dandruff active ingredient in hair care formulation up to a maximum concentration of 2.0% in rinse-off products and up to a maximum concentration of 0.5% in leave-on products.*

2. *And/or does the SCCP recommend any further restrictions or conditions for its use in cosmetic products?*

The SCCP concluded that the dossier was inadequate. Due to the many shortcomings mentioned under section 3.3.14 of the opinion, it was impossible to assess whether Climbazole is safe for use in rinse-off (2.0%) and leave-on (0.5%) anti-dandruff cosmetic products.

The SCCP noted that Climbazole is taken up in Annex VI of the cosmetic directive and consequently used as a preservative.

In view of the poor quality of the toxicological data presented in the dossier, the SCCP recommended a re-evaluation of the safety of this compound for preservative uses.

The opinion was adopted.

Memorandum on the classification and categorisation of skin sensitisers and grading of test reactions, doc. n° SCCP/0919/05

Animal and human assays for skin sensitisation are used in research and by industry. They are used in hazard identification and risk assessment for regulatory purpose (Directives on Cosmetics 76/768/EEC, Dangerous Substances 67/548/EEC, Dangerous Preparations 1999/45/EC).

Guideline methods are described for animal assays (ref OECD 406, OECD 429) and international recommendations for human assays. Deviations from the guideline methods are frequent; interpretation of results and terminology are often not harmonised. Some key issues for interpretation of the quality and results of tests are addressed below.

Allergic contact dermatitis is the clinical disease caused by skin exposure to skin sensitising substances (contact allergens). Skin exposure of humans and test animals to contact allergens may cause induction of contact allergy (sensitisation). Re-exposure of a sensitised individual or animal to the substance may result in elicitation of a response (allergic contact dermatitis or positive test reaction). The dose sufficient for induction is generally larger than the dose sufficient for elicitation. To avoid allergic contact dermatitis the sensitised individual has to avoid further exposure to the substance at levels causing elicitation.

The scope of this memorandum is to clarify issues essential for interpretation of data and dossier results in risk assessment of potential skin sensitisers.

The memorandum was adopted.

7.4. UV FILTERS AND AD HOC SUBSTANCES

Prof. Sanner reported on the work done since the previous plenary meeting.

Statement on Zinc oxide, doc. n° SCCP/0932/05

The SCCNFP previously adopted an opinion on the safety of zinc oxide when used as a sunscreen (doc. n° SCCNFP/0649/03, 24-25 June 2003). This was in response to the question: *Is Zinc oxide safe for use in cosmetic products as a UV filter up to 25 %?*

The dossier reviewed at the time contained data primarily derived from pigment grade zinc oxide. The SCCNFP pointed out that the physico-chemical specifications of ZnO used in many

of the submitted studies were incomplete. The main concern related to the risk assessment of microfine (approximately 0.2 µm) ZnO, which may be coated by other compounds, and which is used as an ingredient in sunscreen formulations.
Microfine ZnO has been demonstrated to be photoclastogenic, possibly photo-aneugenic, and a photo-DNA damaging agent in mammalian cells cultured in vitro. Clarification of the relevance of these findings is required by appropriate investigations *in vivo*.

The SCCNFP was of the opinion that more information is required to enable a proper safety evaluation of microfine Zinc oxide for use as a UV filter in cosmetic products. Consequently, an appropriate safety dossier on microfine ZnO itself, including possible pathways of cutaneous penetration and systemic exposure, was required.

Hitherto, the requested safety dossier has not been provided. It is understood that microfine and ultra-fine zinc oxide is widely used in sunscreen products on the European market. The safety to the consumer of this use remains to be assessed. The attention of the Commission and the Member States is drawn to this.

The statement was adopted.

Fluorine compounds in oral hygiene products for children under the age of 6 years, doc. n° SCCP/0882/05

The SCCP was requested to answer the following questions:

* *Does the data provided change the opinion of the SCCP on the safety of fluorine compounds in oral hygiene products for children under the age of 6 years, as stated in its opinion SCCNFP/0653/03?*

* *If yes, does the SCCP propose any further restrictions or conditions for the use of fluorine compounds in oral hygiene products for children under the age of 6 years?*

The SCCP reiterates the opinion that the maximum permitted concentration of 0.15% (1500 F^- ppm) fluoride does not pose a safety concern when used by children under the age of 6 years, based on the available scientific evidence.

It must be emphasised that the data used were generated from studies primarily on sodium fluoride. Extrapolation of this to the other fluoride compounds presently listed in Annex III of the Cosmetics Directive 76/768/EEC can only be made with respect to fluorosis.

There is strong evidence that toothpaste containing 0.15 % (1500 ppm) fluoride is effective at preventing dental caries in all age groups, including children under the age of 6. This cariostatic effect decreases as the fluoride concentration is reduced. Below 1000 ppm, the cariostatic effect of fluoride is not established. Further research is recommended in order to assess the effect under 1000 ppm fluoride.

If the sole source of fluoride exposure is toothpaste containing fluoride between 1000-1500 F^- ppm, used as recommended, there is a minimal concern that children under the age of 6 will develop fluorosis since the amount absorbed would be less than half the accepted adequate

intake of 0.7 mg/day fluoride intake for children between the ages of 1 and 3, that maximally reduces dental caries without causing unwanted side effects.

In this document, the only oral health product considered is toothpaste. No data for other products were considered. It is known that mouthwashes specifically for children have been developed and are available in some EU members.
Although it is beyond the scope of the mandate, there is exposure to fluoride from other sources. This is not addressed in detail here by the SCCP. The present opinion clearly has implications for the efficacy and safety of systemic fluoride supplementation for caries prevention.

The opinion was adopted.

Risk of ingredients deriving from category 1-material and category 2-material as defined in Regulation 1774/2002 in cosmetic products, doc. n° SCCP/0883/05

The SCCP was asked to answer the following question:

Does the SCCP agree that the use of ingredients deriving from category 1 and 2 material (as defined in Regulation 1774/02) in cosmetic products raises concerns in terms of biological risk for human health?

Based on the opinions adopted by the Scientific Steering Committee concerning:

- the risks of non conventional transmissible agents, conventional infectious agents or other hazards such as toxic substances entering the human food or animal feed chains via raw material from fallen stock and dead animals (including also: ruminants, pigs, poultry, fish, wild/exotic/zoo animals, fur animals, cats, laboratory animals and fish) or via condemned materials" (adopted during the meeting of 24-25 June 1999 and re-edited at the meeting of 22-23 July 1999).[1]

- the safety of tallow obtained from ruminant slaughter by-products (revised opinion and report adopted during the meeting of 28-29 June 2001 and editorial clarifications introduced during the meeting of 6-7 September 2001).[2]

and referring to the opinions adopted by the SCCNFP on:

- the use of specified risk material in cosmetics, clarification for tallow derivatives, adopted on 30 July 2003;
- the amendments to entry 419 of Annex II to Directive 76/768/EEC on Cosmetic Products, adopted on 12 June 2001, 25 September 2001, 27 February 2002 and on 17 December 2002,

the SCCP concluded that ingredients derived from category 1 and 2 material (as defined in Regulation 1774/02) raise concern in terms of biological risk for human health and therefore must not be present in cosmetic products.

[1] http://www.europa.eu.int/comm/food/fs/sc/ssc/out53_en.pdf

[2] http://europa.eu.int/comm/food/fs/sc/ssc/out228_en.pdf

The opinion was adopted.

8. NEXT PLENARY MEETING

The 6th plenary meeting of the SCCP will take place on 13 December 2005.

9. ANY OTHER BUSINESS

* Nanotechnology: the public consultation on a mandate on "nanotechnology in cosmetic products" ended on 31 August 2005. 4 comments were received. Two of them asked to be informed when an opinion is adopted. The two others submitted scientific information. The opinion on nanotechnology, which the SCENIHR is drafting at present, will be used as a basic document for further scientific discussions on the used of nanotechnology in cosmetics. Members are invited to propose (external) experts for this Task Force.

* Cyclomethicone: Prof. Degen informed the meeting on the on-going discussion on cyclomethicone in the WG.

* Dates for WG Meetings:

30 September	-	Genotoxicity
25 October	-	Preservatives & Fragrances
26 October	-	Hair Dyes
8 November	-	ad hoc Substances
15 November	-	Task Force UVR (sunbeds)
30 November	-	Hair Dyes
13 December	-	PLENARY
14 December	-	Alternatives

Annex I: List of Participants.

Annex I

Scientific Committee on Consumer products
5th Plenary Meeting

Held on 20 September 2005
in Brussels

List of Participants

MEMBERS OF THE SCCP:
Prof. G. DEGEN, Prof. R. DUBAKIENE, Dr. R. GRIMALT, Dr. B. JAZWIEC-KANYION, Prof. V. KAPOULAS, Prof. J. KRUTMANN, Prof. C. LIDEN, Prof. J.-P. MARTY, Prof. T. PLATZEK, Dr. S. 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. C. DEKINDT, Mrs. T. PEETSO, Mrs M. PUOLAMAA, Mr. A. VAN ELST

DG SANCO B3: Mr. P. DASKALEROS

DG ENTR F3: Mr. S. FUEHRING, Mrs. A. ORLOFF