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
6TH PLENARY MEETING

Held on 13 December 2005
in Brussels
MINUTES

1. WELCOME AND APOLOGIES

Dr. I.R. White welcomed all the participants. Apologies were received from Prof C. Galli and Dr. J. van Engelen.

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. APPROVAL OF THE MINUTES OF THE 5TH PLENARY MEETING

Minutes of the 5th plenary meeting were approved.

5. INFORMATION FROM CHAIRMAN/MEMBERS

Dr. White informed the members about the meeting of the Chairmen of the Scientific Committees / Panels involved in risk assessment. The meeting took place in Brussels on 7 and 8 December 2005 and was organised by DG SANCO.
The objective of the meeting was to increase mutual awareness and cooperation between the Scientific Committees/Panels.

6. EMERGING ISSUES

Use of silver in consumer products, such as socks, pyjamas or dishwashing machines, and in medical devices such as wound dressings, is a growing concern in Sweden.

The matter was raised in the Swedish Toxicological Council whether the use of silver could be involved in the development of bacterial resistance. This issue will be followed-up.

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. Rogiers reported on the conference "Europe goes Alternative", hosted by DG Enterprise, DG Research and the Joint Research Centre in Brussels on 7 November.

The conference was the starting point for a European Partnership between the Commission and industry to promote alternative approaches to animal testing. The partners agreed to the "Three Rs Declaration" aiming at refining, reducing or replacing (3 Rs) of animal use. A task force will set up an action programme with concrete activities during the first quarter 2006. It will be designed in the perspective of identifying barriers to progress and propose appropriate solutions in order to promote the development, validation and regulatory acceptance of alternative approaches.

Finally, it was mentioned that the WG is currently updating the recommended strategy for testing hair dyes for their potential genotoxicity/mutagenicity and the Notes of Guidance.

7.2. HAIR DYES AND COLORANTS

Report of the Co-ordinator

In his report, Prof. Platzek said that 2 meetings of the WG had taken place since the last plenary of 20 September 2005.

Draft opinions were prepared on:

A157, Quinolinium, 4-formyl-1-methyl-, salt with 4-methylbenzenesulfonic acid (1:1), doc. n° SCCP/0923/05

The SCCP was asked to answer the following questions:

1. *On the basis of provided data the Scientific Committee of Consumer Products (SCCP) is asked to assess the risk to consumer when Quinolinium, 4-formyl-1-methyl-, salt with 4-methylbenzenesulfonic acid (1:1) is used in cosmetic products.*

2. *Does the SCCP recommend any restrictions with regard to its use in cosmetic products?*

The SCCP concluded that the information submitted was insufficient to assess the safe use of the substance. Before any further consideration, the SCCP required the following information:

- data on the stability of Quinolinium, 4-formyl-1-methyl-, salt with 4-methylbenzenesulfonic acid (1:1) 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.

B75, Hydroxyethyl-2-nitro-p-toluidine, doc. n° SCCP/0924/05

The SCCP was asked to answer the following questions:

1. *On the basis of provided data the Scientific Committee on Consumer Products (SCCP) is asked to assess the risk to consumer when Hydroxyethyl-2-nitro-p-toluidine is used in cosmetic products.*

2. *Does the SCCP recommend any further restrictions with regard to its use in cosmetic products?*

The SCCP concluded that the information submitted was inadequate to assess the safe use of the substance. Before any further consideration, the following information is required:

- the stability of Hydroxyethyl-2-nitro-p-toluidine in the various solvents used (e.g. percutaneous absorption study) has to be clarified.

- an *in vitro* percutaneous absorption study according to the SCCNFP Notes of Guidance

However, the final text will be revised and distributed through the secretariat for adoption following the written procedure.

C169, *Lawsonia inermis*, doc. n° SCCP/0943/05

The SCCP was asked to answer the following questions:

1. *Does the Scientific Committee on Consumer Products (SCCP) consider Lawsonia inermis safe for use as a hair dye taken into account the scientific data provided?*

2. *Does the SCCP recommend any restrictions with regard to the use of Lawsonia inermis in any hair dye formulations?*

The SCCP concluded that the information submitted was insufficient to assess the safe use of the substance as a hair dye.
To exclude a clastogenic potential of Henna Rot (*Lawsonia inermis*), additional testing with batch 1271 is required. An additional *in vitro* chromosome aberration test or (preferentially) an *in vitro* micronucleus test should be performed. In case of a positive result, appropriate *in vivo* genotoxicity testing has to be considered.

The traditional and current expanding use of Henna Rot (*Lawsonia inermis*) as a body-paint has not been assessed.

The opinion was adopted.

Exposure to reactants and reaction products of oxidative hair dye formulations, doc. n° SCCP/0941/05

The SCCP was asked to answer the following questions:

1. *Does the Scientific Committee on Consumer Products (SCCP) share the view presented in the "Technical Report" that oxidative hair dye reaction products pose no or negligible risk to human health?*

2. *If not, the SCCP is invited to identify any additional information necessary to evaluate the overall risk to reaction products of hair dyes.*

An analytical methodology based essentially on HPLC was developed, which allowed to follow oxidative hair dye coupling chemistry under conditions, reflecting consumer usage. The methodology was applied on 11 different combinations of hair dye precursors and couplers.

Although transient quinonediimine intermediates, essential for the formation of oxidative coupling of precursor and coupler in hair dye formulations, were not found in the present investigation, exposure of consumers to these molecules cannot be ruled out.

The cream base used for the formulation of precursors and couplers contained only basic ingredients but that was not similar to marketed products, which may contain various other ingredients such as colorants. Thus, the influence of these other ingredients on oxidative coupling of precursors and couplers, as well as formation of new molecules is not envisaged in this study.

The SCCP understands that over one hundred different precursors and couplers are used in oxidative hair dye formulations in the EU. Studies, similar to those presented here, with all the most relevant combinations of precursors and couplers should be performed to obtain necessary information on consumer exposure.

As the reaction products (hair dyes) of oxidative coupling of different precursor-coupler combinations (available to consumer) can be predicted, these should be synthesised. Their percutaneous absorption characteristics should be evaluated and in case of significant systemic exposure, further relevant toxicity studies are required.

The aspect of allergenicity (skin sensitisation from intermediates as well as from newly formed compounds) has not been addressed in this opinion.

The opinion was adopted.

7.3. PRESERVATIVES AND FRAGRANCES

Report of the Co-ordinator

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

P72, Alkyl (C16, C18, C22) trimethylammonium chloride, doc. n° SCCP/0917/05

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 Alkyl (C16, C18, C22) trimethylammonium chloride is used in cosmetic products for non-preservative purposes as specified above.*

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

The SCCP concluded that the information submitted was inadequate to assess the safe use of the substance. Before any further consideration, the following information is required:

- a percutaneous absorption study on steartrimonium chloride and behentrimonium chloride according to the SCCNFP Notes of Guidance;
- skin sensitisation studies according to the SCCNFP Notes of Guidance;
- data on the genotoxicity/mutagenicity following the relevant SCCNFP opinions and in accordance with the Notes of Guidance.

However, the final text will be reviewed and distributed through the secretariat for adoption following the written procedure.

Furocoumarins, doc. n° SCCP/0942/05

The SCCP was asked to answer the following questions:

1. *Is the SCCP of the opinion that the limitation to below 1 ppm of furocoumarins should be extended to all finished cosmetic products and not only cover sun protection and bronzing products?*

2. *Does the SCCP recommend any restrictions with regard to the use of the 11 plants extracts, which in the SCCNFP opinion (SCCNFP/0392/00) are known to contain furocoumarins when they are used as ingredients as such in cosmetics and not as ingredients in fragrances?*

The SCCP concluded that the data provided so far has not ruled out the photo-toxicity of any furocoumarin. No new data is provided in Submission III to substantiate consumer safety when using cosmetic products containing furocoumarins.
As the consumer is exposed to sunlight after using various types of cosmetic products, not only bronzing or sun protection products, the SCCP reemphasised that total concentrations of

furocoumarins exceeding 1 ppm in any finished cosmetic product will be of concern with regard to consumer safety.

The Opinion concerns the content of furocoumarins in cosmetic formulations, irrespective of the source of these substances. This Opinion should be interpreted together with the opinion on CMR substances (SCCNFP/0474/01, Final).

The opinion was adopted.

7.4. UV FILTERS AND AD HOC SUBSTANCES

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

Biological effects of ultraviolet radiation relevant to health with particular reference to sun beds for cosmetic purposes, doc. n° SCCP/0949/05

The scientific committee was asked requested to answer the following questions:

1. *What are the general health and safety implications (negative and positive) relating to the exposure of persons to ultraviolet radiation (UVR)[1]?*

2. *What are the differences between risks associated with exposure of persons to natural UVR and those risks from artificial UVR? What are the differences regarding the health and safety risks with respect to exposure of persons to UVA, UVB and UVC radiation respectively?*

3. *Is the total dose value of UVR the only effective health and safety parameter with regard to the risks associated with exposure of persons to both natural and artificial UVR. What is the validity of the Bunsen-Roscoe law[2] over the range of irradiances and wavelengths associated with exposure of persons to both natural and artificial UVR?*

4. *What are the specific health and safety implications (negative and positive) relating to the exposure of persons to UVR from tanning devices for cosmetic purposes?*

5. *Are limit values necessary for the irradiance of UVR from artificial sources, in particular from tanning devices for cosmetic purposes, with respect to health and safety? Is it necessary to give different values for the irradiance of UV-A, UV-B and UV-C radiation respectively? If so, please specify the limit values for the irradiance of artificial UVR above which adverse health effects will occur. What are the uncertainties of these limit values?*

6. *Please specify the limit values of total dose of artificial UV-A, UV-B and UV-C radiation above which adverse health effects will occur, taking into account skin photo-type, intensity of exposure, duration of exposure and associated uncertainties.*

[1] The International Commission on Illumination (CIE) defines ultraviolet radiation (UVR) as optical radiation between 100 and 400 nm. The spectral region is divided into three photo-biological spectral regions: UVC (l00-280 nm), UVB (280-315 nm) and UVA (315-400 nm).

[2] The Bunsen-Roscoe law (law of reciprocity) states that a certain biological effect is directly proportional to the total energy dose irrespective of the administered regime. Dose is the product of intensity and the duration of exposure. (Bunsen R, Roscoe HE, Photochemische Untersuchungen, Poggendorff´s Annalen 1855: 96: 373-394, 1857: 100: 43-88 and 481-516, 1857: 101:235-263, 1859: 108: 193-273.).

The SCCP concluded that the regular use of sunbeds to achieve cosmetic tanning, whether by UVB and/or UVA, is likely to increase the risk of malignant melanoma. People with known risk factors for skin cancer, especially malignant melanoma should be advised not to use sunbeds.

The SCCP decided to put the document on the Commission's web site as a preliminary opinion and to invite interested parties for their comments. A final opinion will be adopted after consideration of the comments received.

The opinion was adopted.

Cyclomethicone D4, doc. n° SCCP/0893/05

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 Octamethylcyclotetrasiloxane is used in cosmetic products.*

2. *Does the SCCP recommend any further restrictions with regard to its use in cosmetic products?*

The SCCP concluded that it was unable to assess the risk to consumers when octamethylcyclotetrasiloxane (D4) is used in cosmetic products. The following information is required before any further consideration:

* Adequate information on the use of D4 in cosmetics in particular in different cosmetic products;
* relevant/appropriate percutaneous absorption studies at different use concentrations;
* Information on the co-use, and hence consumer exposure, of related organosiloxanes, in particular decamethylcyclopentasiloxane (D5).

The opinion was adopted.

8. NEXT PLENARY MEETING

The 7th plenary meeting of the SCCP will take place on 28 March 2006.

9. ANY OTHER BUSINESS

- Tooth Whitening Products – request for a scientific advice: DG ENTR gave an overview on this mandate. Having considered the possible negative impacts of such request and taking into account the need for such advice from the consumer safety point of view, members agreed to accept the mandate. First discussion will be held during the WG Meeting on Alternatives 25. 01.

Annex I: List of Participants.

Annex I

Scientific Committee on Consumer products
6th Plenary Meeting

Held on 13 December 2005
in Brussels

List of Participants

Members of the SCCP
Dr. C. CHAMBERS, 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), Prof. G. SPEIT, 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