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
8TH PLENARY MEETING

Held on 20 June 2006 in Brussels
MINUTES

1. WELCOME AND APOLOGIES

Dr. I.R. White welcomed all the participants. Apologies were received from Prof. R. Dubakiene, Prof. J. Krutmann, Dr. R. Grimalt and Prof. J.-P. Marty.

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 draft agenda was approved.

4. APPROVAL OF THE MINUTES OF THE 7TH PLENARY MEETING

Minutes of the 7th plenary meeting were approved.

5. INFORMATION FROM CHAIRMAN/MEMBERS

Dr. White had participated in the SCENIHR WG-meeting on the "Chinese report on possible residual BSE risks in products derived from ruminant materials and used as cosmetic ingredients".
The SCENIHR adopted an opinion on the issue during its 12th plenary meeting of 20 June 2006. The committee concluded that no new scientific data or risk assessment approaches were provided in the Chinese report which were not considered in the European/Chinese report of 2003.

The Secretariat had attended the COLIPA Annual Conference and Science Forum on 1 and 2 June 2006. Presentations are available on the following website: http://www.colipa.com/site/index.cfm?SID=15588&OBJ=20352&back=1

6. EMERGING ISSUES

No issues 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. Rogiers said that the 6th revision of the Notes of Guidance was nearly completed and that it would be presented during the next plenary meeting of 10 October 2006 for formal adoption.

In the framework of this revision, Prof. Kapoulas gave a presentation on methods to calculate the Margin of Safety. It was agreed that the issue would be further discussed during the WG "Alternatives" on 18 September 2006.

7.2. HAIR DYES AND COLORANTS

Report of the Co-ordinator

Prof. T. Platzek reported on the work done during the meetings of the WG that had taken place since the last plenary of 20 June 2006.

Draft opinions were prepared on:

A25, Hydroxybenzomorpholine, doc. n° SCCP/0965/06

The SCCP was asked to answer the following questions:

1. *Does the Scientific Committee on Consumer Products (SCCP) consider Hydroxybenzomorpholine safe for use as an oxidative hair dye with an on-head concentration of maximum 1.0 % taking into account the scientific data provided?*

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

The SCCP concluded that the use of hydroxybenzomorpholine itself as an oxidative hair dye substance at a maximum concentration of 1.0% in the finished cosmetic product (after mixing with hydrogen peroxide) does not pose a risk to the health of the consumer, assuming that the nitrosamine content is less than 50 ppb as required by Directive 76/768/EEC on cosmetic products.

However, hydroxybenzomorpholine is a secondary amine and thus is prone to nitrosation. It should not be used in combination with nitrosating substances. The nitrosamine content should be < 50 ppb.
Based on the data provided, the nitrosamine content is 10-50 times higher than permitted in Directive 76/768/EEC on cosmetic products. The nitrosamine content in ten different batches of hydroxybenzomorpholine is reported to be 492-2616 ppb. More recent data about nitrosamine content should be provided.

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

The opinion was adopted.

A50, N,N-bis(2-Hydroxyethyl)-p-phenylenediamine sulfate, doc. n° SCCP/0983/06

The SCCP was asked to answer the following questions:

1. *Does the Scientific Committee on Consumer Products (SCCP) consider N,N-bis(2-hydroxyethyl)-p-phenylenediamine sulphate safe for use as an oxidative hair dye with a concentration on scalp of maximum 2.5 % taking into account the scientific data provided?*

2. *Does the SCCP recommend any restrictions with regard to the use of N,N-bis(2-hydroxyethyl)-p-phenylenediamine sulphate in oxidative hair dye formulations?*

The SCCP concluded that the use of N,N-bis(2-hydroxyethyl)-p-phenylenediamine sulfate itself as an oxidative hair dye substance at a maximum concentration of 2.0% 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, N,N-bis(2-hydroxyethyl)-p-phenylenediamine sulfate is a tertiary amine, and thus it is prone to nitrosation. It should not be used in combination with nitrosating substances. The nitrosamine content should be < 50 ppb.

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

The opinion was adopted.

A154, 1-Hydroxyethyl-4,5-diaminopyrazole sulfate, doc. n° SCCP/0990/06

The SCCP was asked to answer the following questions:

1. *Does the Scientific Committee on Consumer Products (SCCP) consider 1-Hydroxyethyl-4,5-diamino pyrazole sulfate safe for use as an oxidative hair dye with a concentration on-head of maximum 3.0 % taking into account the scientific data provided?*

2. Does the SCCP recommend any further restrictions with regard to the use of 1-Hydroxyethyl-4,5-diamino pyrazole sulfate in oxidative hair dye formulations?

The SCCP concluded that the information submitted was inadequate to assess the safe use of the substance.

Before any further consideration, the following information was required:

* an *in vitro* percutaneous absorption study under oxidative conditions and conforming to the current Notes of Guidance for Safety Evaluation
* an appropriate mammalian cell gene mutation test in vitro
* Studies on genotoxicity/mutagenicity in finished hair dye formulations should be undertaken following the relevant SCCNFP/SCCP opinions and in accordance with the Notes of Guidance

The opinion was adopted.

B66, HC Violet n° 1, doc. n° SCCP/1025/06

The SCCP was asked to answer the following questions:

1. Is 1-Amino-3-methyl-4(2-hydroxyethyl)-amino-6-nitrobenzene safe for use in hair dye formulations taking into account the data provided?

2. Does the SCCP recommend any further restrictions with regard to the use of 1-Amino-3-methyl-4(2-hydroxyethyl)-amino-6-nitrobenzene in hair dye formulations?

The SCCP concluded that the use of HC Violet n° 1 itself as a semi-permanent hair dye at a maximum concentration of 0.28 % and as an oxidative hair dye at a maximum concentration of 0.25% 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, HC Violet n° 1 is a secondary amine, and thus is prone to nitrosation. It should not be used in combination with nitrosating substances. The nitrosamine content should be < 50 ppb.

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

The opinion was adopted.

Skin penetration of oxidative hair dyes formed by the coupling of precursors and couplers under simulated conditions of hair dyeing. Update of the Annex to the Opinion SCCP/0941/05 on Exposure to reactants and reaction products of oxidative hair dye formulations, doc. ° SCCP/1004/06

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.*

The SCCP understands that about a hundred different precursors and couplers are used in the oxidative hair dye formulations in the EU. The data presented indicates that in some cases significant amounts of oxidative hair dye reaction products become systemically available to the consumer.
Studies, similar to those presented here, should be extended to include additional indicative combinations of precursors and couplers. According to the updated strategy of hair dyes (genotoxicity, doc n° SCCP/0971/06) further testing may be required.

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

Review of the SCCNFP opinion on Hair Dye Strategy in the light of additional information, doc. n° SCCP/0959/05

The SCCP was asked to review, and if appropriate, to amend its overall assessment of the use of hair dyes and cancer risk as stated in the opinions SCCNFP/0484/01, SCCNFP/0797/04 and SCCNFP/0807/04 on the basis of currently available scientific information and taking into account the opinion of the Bundesinstitut für Risikobewertung 'Hair dyes on the Test Bench: Their Regulation at European level' of 14 September 2004, in particular with regard to non-permanent hair dyes.
BfR concluded that a differentiated handling of oxidative and non-oxidative hair dyes is justifiable. It recommended granting an extension of the deadline for submitting dossiers which are still outstanding for non-oxidative hair dyes.

Due to differences in technology of hair dye formulations, as well as in view of the epidemiological findings concerning various cancers, the SCCP supports differentiated approaches for the different types of hair dye substances involved and that priority should be given to the evaluation and regulation of oxidative hair dye substances.

The issue of sensitisation was not addressed.

The document was adopted.

7.3. PRESERVATIVES AND FRAGRANCES

Report of the Co-ordinator

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

P77, Methyldibromo glutaronitrile, doc. n° SCCP/1013/06

The SCCP was asked to answer the following questions:

In the light of the submission received by the European Commission in response to opinion SCCP/863/05, does the SCCP alter its opinion set out therein?

The SCCP concluded that no safe use-level for methyldibromo glutaronitrile in cosmetic rinse-off products has been established.

In light of the submission, the SCCP did not alter its previous opinion stating that no safe use-level for methyldibromo glutaronitrile in rinse-off products has been established.

The opinion was adopted.

Coumarin, doc. n° SCCP/0935/05

The SCCP was asked to answer the following questions:

1. *Does the SCCP consider that Coumarin with the specified purity (> 99.99%) has no sensitizing properties when used in cosmetic products?*

2. *If yes, does the SCCP propose any restrictions or conditions for its use in cosmetic products?*

3. *Do the data provided change the opinion of the SCCP concerning Fragrance Allergy in Consumers (SCCNFP/0017/98)?*

The SCCP concluded that coumarin with the purity of 99.9% has been shown to be able to elicit allergic contact reactions in individuals patch tested to a 2% dilution.

The test substance has not been identified by batch number with an associated chemical analysis.

The data submitted did not cause the SCCP to change the Opinion “Fragrance allergy in consumers doc n°SCCNFP/0017/98.

The opinion was adopted.

Clarifications to SCCNFP/0392/00 'An initial List of Perfumery Materials which must not form part of Cosmetic Products except subject to the Restrictions and Conditions laid down', doc. n° SCCP/1023/06

The SCCP was asked to answer the following questions:

1. *Does the SCCP foresee the same restrictions for all the allyl esters mentioned in either SCCNFP/0392/00 or SCCNFP/0389/00? If yes, what restriction should be applied to these substances in cosmetic products?*

2. *Does the SCCP consider that the use of allyl heptine carbonate, methyl octine carbonate and methyl heptine carbonate as fragrance ingredients is safe for the consumer?*

The SCCP concluded that the same restrictions are applicable to all allyl esters listed in section II of the inventory, despite the confused and inappropriate terminology used in the above mentioned opinions. Attention was drawn to the possibility that allyl esters may be hydrolysed in the skin to allyl alcohol although it was not considered because of the absence of relevant data.

As a consequence, six esters of allyl alcohols (see opinion SCCP/1023/06) should be added to the initial list of allyl esters that may be used as ingredients in cosmetic products only under the conditions and restrictions previously specified for allyl esters.

The terms "heptine carbonate" and "octine carbonate" are used in INCI names as synonyms of "2-octynoate" and "2-nonynoate" respectively, i.e. to organic acid derivatives having a triple bond located in the position 2 of their 'acyl' moiety (apparently, the location of triple bond is omitted in the INCI name for reasons of simplicity).

Entry 16 of annex II to the Cosmetic Directive refers to "alkyne alcohols" and to "esters or ethers or salts of alkyne alcohols". According to the IUPAC and CAS rules of chemical nomenclature, these alcohols are named 'alkynols' or 'alkynyl (alkinyl) alcohols', and their esters or ethers are named 'alkynyl esters' and 'alkynyl ethers' respectively.

The triple bond (denoted by the "yn") occurs in a hydrocarbon chain not containing a carboxy-group, as in the previous case of alkynoic acids and their esters. Therefore, the group of alkynyl esters is quite distinct from the group of esters of alkynoic acids, and allyl heptine carbonate, methyl octine carbonate and methyl heptine carbonate do not belong to the alkynyl esters regulated by the entry 16 of annex II of the Cosmetic Directive.

The SCCP concluded that the current regulations regarding allyl heptine carbonate, methyl octine carbonate and methyl heptine carbonate are not contradictory to the regulations related to allyl alcohol and allyl esters.

The opinion was adopted.

7.4. UV FILTERS AND AD HOC SUBSTANCES

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

S1, 4-Aminobenzoic acid, doc. n° SCCP/1008/06

The SCCP was asked to answer the following questions:

1. *Is 4-Aminobenzoic acid (PABA) safe for continued use as a UV filter in cosmetic products under the current restriction of 5.0 % as a maximum concentration?*

2. *Does the SCCP consider that the use of 4-Aminobenzoic acid (PABA) is safe for the consumer in a concentration up to 5 % when used in other cosmetic products than sunscreen products?*

3. *Does the SCCP propose any further restrictions or conditions for its continued use in cosmetic products?*

The SCCP concluded that, although 4-aminobenzoic acid is presently permitted and used as a sunscreen, much of the information did not conform to current standards and guidelines.

Before any further evaluation of the use of 4-aminobenzoic acid, both as a UV-filter and for purposes other than a UV filter, the SCCP required a new dossier, in which data on all relevant toxicological endpoints and conforming to modern standards and SCCNFP/SCCP guidelines, to be submitted before 1 July 2007.

The applicant should also specify for what other purposes the substance should be used.

The opinion was adopted.

S83, Benzoic acid, 2-[4-(diethylamino)-2-hydroxybenzoyl]-, hexylester doc. n° SCCP/0996/06

The SCCP was asked to answer the following questions:

1. *Does the SCCP consider that the use of the Benzoic acid, 2-[4-(diethylamino)-2-hydroxybenzoyl]-, hexylester is safe for the consumer in a concentration up to 10 % when used in other cosmetic products than sunscreen products?*

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

The SCCP concluded that, although the substance is presently permitted and used as a sunscreen, the information submitted does not conform to current standards and guidelines for the safety evaluation of cosmetic ingredients.

Before any further consideration, the following information was required:

- an absorbance spectrum of the substance

- a mammalian gene mutation test.

The applicant should specify for what other purposes the substance should be used.

The opinion was adopted.

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

The scientific committee was requested to answer the following questions in relation to the sunbeds for cosmetic purposes:

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 phototype, intensity of exposure, duration of exposure and associated uncertainties.*

The SCCP concluded that the use of UVR tanning devices to achieve and maintain cosmetic tanning, whether by UVB and/or UVA, is likely to increase the risk of malignant melanoma of the skin and possibly ocular melanoma.
People with known risk factors for skin cancer, especially malignant melanoma, should be advised not to use UVR tanning devices. Specifically, these are (i) skin phototypes I and II and

[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 presence of freckles, (ii) atypical and/or multiple moles and (iii) a family history of melanoma. Eye protection from UVB and UVA should be worn if sunbeds are used.

Risk of melanoma seems to be particularly high when using sunbeds at a young age. Thus UVR tanning devices should not be used by individuals under the age of 18 years.

The opinion was adopted.

8. NEXT PLENARY MEETING

The 9th plenary meeting of the SCCP will take place on 10 October 2006.

9. ANY OTHER BUSINESS

- **Exposure data: t**he following text was prepared for inclusion in the minutes of the meeting:
  "*In the absence of comprehensive information from industry on cosmetic use by the European citizen, it was agreed that the Commission should be recommended to generate data to provide appropriate information on the use and exposure to the array of cosmetic products which the European consumer currently uses. This information is essential for proper risk assessment processes to take place. "*

- **New mandate:** the presence and release of nitrosamines from children's balloons

- **Submission of a safety dossier:** the secretariat was asked to inform the applicants about the following requests regarding submissions:

  * the summary of the dossier must be in Word format and should comply with the standard format used in the SCCP opinions.
  * In case the submitted studies are not available in Word, they should be in a searchable pdf-format;
  * Deviations from the Notes of Guidance must be justified.

- **Dates of WG meetings:**

28 June	Nanosubstances in Cosmetics
11 July	Hair Dyes
29 August	Hair Dyes
6 September	ad hoc substances & UV Filters + Fragrances & Preservatives
18 September	Alternatives
26 September	Hair Dyes
3 October	ad hoc substances & UV Filters+ Fragrances & Preservatives
10 October	Plenary Meeting

Annex I: List of Participants.

Annex I

Scientific Committee on Consumer products
8th Plenary Meeting

Held on 20 June 2006
in Brussels

List of Participants

Members of the SCCP
Dr. C. CHAMBERS, Prof. G. DEGEN, Dr. B. JAZWIEC-KANYION, Prof. V. KAPOULAS, Prof. C. LIDEN, Prof. T. PLATZEK, Dr. S. RASTOGI, Prof. J. REVUZ, Prof. V. ROGIERS (Vice chair), Prof. T. SANNER (Vice chair), Prof. G. SPEIT, 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 ENTR F3: Mrs. A. ORLOFF