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

2ND PLENARY MEETING

Held on 7 December 2004
in Brussels
MINUTES

1. WELCOME AND APOLOGIES

Chairman welcomed participants.
Apologies were received from Prof Galli, Dr. Grimalt, Prof Speit and Dr. van Engelen.

2. ADOPTION OF THE DRAFT AGENDA

The draft agenda was approved.

3. DECLARATIONS OF INTEREST ON MATTERS ON THE AGENDA

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

4. APPROVAL OF THE MINUTES OF THE 1ST PLENARY MEETING

Minutes of the previous plenary meeting were approved with minor editorial changes.

5. INFORMATION FROM CHAIRMAN/MEMBERS

The chairman presented briefly the items discussed at the Inter-Committee Coordination Group on 13th October 2004 in particular mentioning the priorities on harmonisation within the Scientific Committees and with other Risk Assessment Bodies.

The members were informed that two members of the Scientific Committees were invited as external experts to the EFSA working group on Genotoxicity, which is working towards producing a document on a harmonised approach for risk assessment of Genotoxic and Carcinogenic Substances.

6. 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

6.1. Alternatives

Prof. V. Rogiers reported that no activities had taken place in this area.
Members expressed their concern that an opinion of the SCCNFP concerning "Report for Establishing the Timetable for Phasing out Animal Testing for the purpose of the Cosmetics Directive" issued by ECVAM (30/04/2004), adopted by written procedure on 1 July 2004, had not been taken into account by Enterprise Directorate-General in the final timetable for replacing animal testing in cosmetics.

6.2. Hair Dyes and Colorants

Prof. T. Platzek gave an overview of the meetings and activities that had taken place since the 1st Plenary Meeting of the SCCP, during which the following opinions had been prepared:

A 80, Hydroxyethyl-p-phenylenediamine sulphate, doc. n° SCCP/0666/03

The SCCP is requested to answer the following questions:

1. Is Hydroxyethyl-p-phenylenediamine sulfate safe for use in cosmetic products?

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

The SCCP is of the opinion that the information submitted is inadequate to assess the safe use of the substance.

Before any further consideration, the following information is required:

* complete physico-chemical characterisation of the test substances used, including data on stability.
* data on percutaneous absorption following the SCCNFP Notes of Guidance
* data on the genotoxicity/mutagenicity following the relevant SCCNFP-opinions and in accordance with the Notes of Guidance.

The opinion was adopted.

B 7, Basic Brown 17, doc. n° SCCP/0666/03

The SCCP is requested to answer the following questions:

1. On the basis of currently available information, the SCCP is asked to assess the risk to consumers of Basic Brown 17 when used in hair dye formulations.

2. Does the SCCP recommend any further restrictions with regard to the use of Basic Brown 17 in hair dye formulations?

The SCCP is of the opinion that the information submitted is inadequate to assess the safe use of the substance.

Before any further consideration, the following information is required:

- *complete physico-chemical characterisation of the test substances used, including data on stability.*
- *data on the genotoxicity/mutagenicity following the relevant SCCNFP-opinions and in accordance with the Notes of Guidance.*

The opinion was adopted.

6.3. Preservatives and Fragrances

Dr. I.R. White reported that two Working Group meetings had been held during which the following opinions had been prepared:

Atranol and Chloroatranol present in natural extracts (e.g. oak moss and tree moss extract), doc. n° SCCP/0847/04

The SCCP is requested to answer the following questions:

1. On the basis of currently available information, the SCCP is asked to assess the risk to the consumer when atranol and chloroatranol are present in cosmetic products, and if necessary to revise atranol and chloroatranol maximum concentration in fragrances used in cosmetic products.

2. Does the SCCP recommend any further restrictions with regard to the presence of chloroatranol and atranol as an ingredient of fragrances used in cosmetic products?

The SCCP is of the opinion that:

Because chloroatranol and atranol are components of a botanical extract, oak moss absolute, it has been impossible to trace exposure.
Chloroatranol was shown to cause elicitation of reactions by repeated open exposure at the ppm level (0.0005%) and at the ppb level on patch testing (50% elicit at 0.000015%).
As chloroatranol and atranol are such potent allergens (and chloroatranol particularly so), they should not be present in cosmetic products.

Although the mandate requested an opinion on cosmetic use only, the risks to consumer health from presence of chloroatranol/atranol in other types of consumer products should be assessed.

The opinion was adopted.

Hydroxyisohexyl 3-cyclohexene carboxaldehyde (Lyral), doc. n° SCCP/0838/04

On the basis of currently available information, the SCCP is asked to review and if necessary to revise the opinion of the SCCNFP of 9 December 2003, as concerns:

- induction of sensitisation in consumers;
- elicitation of contact allergic reactions in previously sensitised consumers.

Does the SCCP recommend any further restrictions with regard to the use of 4-(4-hydroxy-4-metylpentyl)-3-cyclohexene-1-carboxaldehyde as a fragrance in cosmetic products?

The SCCP is of the opinion that:

Current epidemiological data demonstrates that contact allergy to Hydroxyisohexyl 3-cyclohexene carboxaldehyde is a problem in Europe. The provided experimental data does not demonstrate the highest level for the safe use of Hydroxyisohexyl 3-cyclohexene carboxaldehyde in cosmetics.

Because of the widespread use and potential exposure to Hydroxyisohexyl 3-cyclohexene carboxaldehyde, data for all toxicological end-points should be provided to enable a full risk assessment.

The opinion was adopted.

Clarification concerning the SCCNFP opinion on the update of entry N39 of Annex VI to Directive 76/768/EEC on Cosmetic Products: Mixture of 5-chloro-2-methyl-isothiazolin-3(2H)-one and 2-methylisothiazolin-3(2H)-one, doc. n° SCCP/0849/04

The SCCP is requested to answer the following question:

- Clarify if the expression "authorised" was used according to the above mentioned interpretation. And if it is not the case, which ingredients such expression refers to.

In response to the questions asked, the SCCP is of the opinion that the expression "authorised cosmetic ingredient" should be interpreted as "any ingredient which, in the light of the Cosmetics Directive, is allowed or not prohibited and may be used in cosmetic products, provided that any substance belonging to the classes of ingredients listed in the Annexes III-VII of the Directive may be used only if it is included in the respective annex."

The opinion was adopted.

6.4. UV Filters and ad hoc substances

Prof. Sanner reported that two Working Group meetings had taken place since the plenary meeting of 7.-8 September 2004, during which the following opinions had been prepared:

Hydrogen peroxide in tooth whitening products, doc. n° SCCP/0844/04

The SCCP is requested to answer the following questions:

1. Does the SCCP agree that the new additional data provide the necessary reassurance to support the safety of up to 6% hydrogen peroxide in tooth whitening products freely and directly available to consumers in various application forms (strips, trays, etc.)?
2. Considering the new additional data provided, does the SCCP recommend that any specific information should be provided to consumers related to the safe use of these tooth whitening products?

3. If the answer to the question on free and direct availability to consumer is negative, would the SCCP identify and quantify any remaining risks that need to be addressed taking into account in particular the overall data on pharmacokinetics and exposure?

The SCCP has decided to undertake a public consultation on the basis of the preliminary opinion.

Interested parties were invited to submit comments or pertinent scientific information by email (Sanco-sc6-secretariat@cec.eu.int) by 31 January 2005.

The preliminary opinion is available at:
http://europa.eu.int/comm/health/ph_risk/committees/04_sccp/sccp_cons_01_en.htm

Tea Tree Oil, doc. n° SCCP/0843/04

On the basis of data provided, the SCCP is asked to assess the risk to consumers when Tea Tree Oil is used in cosmetic products.

1. Does the SCCP propose any restrictions or conditions for the use of Tea Tree Oil as an undiluted product?
2. Does the SCCP propose any restrictions or conditions in terms of concentrations for the use of Tea Tree Oil in cosmetic products?
3. Does the SCCP find it important, for safety reasons, to have a date of minimum durability on the Tea Tree Oil products?

The SCCP is of the opinion that:

The sparse data available suggest that the use of undiluted Tea Tree Oil as a commercial product is not safe. The safety dossier of Tea Tree Oil is incomplete.
The stability of Tea Tree Oil in cosmetic formulations is questionable. A standardized method for the specification of Tea Tree Oil is needed. Industry should develop an analytical testing method based on typical degradation products to ensure and control the stability of the material.

Skin and eye irritation were not assessed by adequate methods. There are relevant data gaps with regard to subchronic toxicity, percutaneous absorption, genotoxicity/carcinogenicity and reproductive toxicity. The safe use of Tea Tree Oil as a cosmetic ingredient cannot be assessed.

A complete dossier of a representative standardized material to all relevant toxicological endpoints is required by the end of 2005; an opinion based on the information available at that time will be given.

The opinion was adopted.

Bishydroxyethyl biscetyl malonamide (Questamide H), doc. n° SCCP/0852/04

The SCCP is requested to answer the following questions:

1. On the basis of data provided SCCP is asked to assess the risk to the consumer when Bishydroxyethyl biscetyl malonamide is used in cosmetic products.

2. And/or does the SCCP recommend any further restriction for its use as an ingredient in cosmetic products?

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

* *a sub-chronic (90-day) oral toxicity study;*
* *a full developmental toxicity study;*
* *a two-generation reproduction toxicity study, with emphasis on hormonal effects in addition to the usual end-points;*
* *data on the genotoxicity/mutagenicity following the relevant SCCNFP-opinions and in accordance with the Notes of Guidance.*

The requested information must be submitted by 31 July 2006.

The opinion was adopted.

Draft opinion on safety evaluation of parabens

Members agreed that some changes should be introduced to the draft opinion. The Rapporteur will prepare the corrected draft opinion.
The Opinion is expected to be adopted by written procedure in the first quarter 2005.

7. ANY OTHER BUSINESS

None

Annex I: List of Participants.

Annex I

Scientific Committee on Consumer products

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List of Participants

MEMBERS OF THE SCCP:
Prof. C CHAMBERS, Prof. G. DEGEN, Prof. R. DUBAKIENE, Dr. B. JAZWIEC-KANYION, Prof. V. KAPOULAS, Prof. J. KRUTMANN, Prof. C. LIDEN, Prof. N. LOPRIENO, Prof. J.-P. MARTY, Prof. T. PLATZEK, Dr. S. RASTOGI, Prof. J. REVUZ, Prof. V. ROGIERS (Vice chair), Prof. T. SANNER (Vice chair), Dr. I. WHITE (Chair)

SCCP Secretariat (DG SANCO):
Mrs. T. PEETSO, Mrs. M. PHILIPPÉ, Mr. A. VAN ELST

DG SANCO C7: Mrs. P. AGUAR FERNANDEZ

DG SANCO B3: Mr. P. DASKALEROS

DG ENTR F3: Ms. R. SCHUMANN