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
3RD PLENARY MEETING

Held on 15 March 2005
in Brussels
MINUTES

1. WELCOME AND APOLOGIES

Chairman welcomed participants.

Apologies were received from Prof C. Galli.

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 2ND PLENARY MEETING

Minutes of the 2nd plenary meeting were approved.

5. 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 27 April 2005. Amongst others, the need for clarification of terms, such as ‘damage to human health’ or ‘acceptable risk’ was discussed.

He also mentioned that a new item on ‘Emerging issues’ was inserted in the agenda. Members are invited to share recent scientific information that may be of interest to the Commission and the other Members.

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

Report of the Co-ordinator

Prof. Rogiers said that one WG meeting had taken place since the previous plenary meeting of 7 December 2004.

During that meeting, the discrepancies between the timetables for phasing out animal testing as proposed by DG ENTR and the timetable proposed by the SCCNFP in its opinion on the issue of 1 July 2004 (doc. n° SCCNFP/0834/04) were discussed.
The SCCP expressed its disappointment that DG ENTR did not follow its advice in this matter and had chosen a more political point of view.

She also mentioned that work has started on a further revision of the SCCP Notes of Guidance. The members were invited to submit proposals for changes.
In the frame of this task, meetings will be organised with industry/external experts on e.g. dermal absorption and genotoxicity.
Regarding genotoxicity, Prof. Rogiers said that this work will be closely related with the inter-committee (SCHER (leading), SCCP and SCENIHR) discussions on the EFSA preliminary opinion on genotoxicity.

6.2. HAIR DYES AND COLORANTS

Report of the Co-ordinator

In his report, Prof. T. Platzek illustrated the draft opinions which have been prepared since the previous plenary meeting.

A16, para-Aminophenol, doc. n° SCCP/0867/05

The SCCP was asked to answer the following questions:

- Is para-Aminophenol safe for use in cosmetic products?
- Does the SCCP propose any restrictions or conditions for its use in cosmetic products?

As a result, 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:

- adequate analytical characterisation as well as the physico-chemical profile, including information on solubility, purity and impurities;

- data on the genotoxicity/mutagenicity following the relevant SCCNFP opinions and in accordance with the Notes of Guidance.

The opinion was adopted.

A129, Isatin, doc. n° SCCP/0876/05

The SCCP was asked to assess the risk to the consumer when Isatin used in hair dye formulations.

Regarding the use of Isatin 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 is required:

- Data on its stability in cosmetic hair dye formulations;
- data on genotoxicity/mutagenicity following the relevant SCCNFP-opinions and in accordance with the Notes of Guidance.

Regarding its use in direct hair dye formulations, the SCCP concluded that the use of Isatin as hair colouring agent ('direct' dye) in semi-permanent hair dye formulations at a maximum concentration of 1.6% in the finished cosmetic product does not pose a risk to the health of the consumer.

This hair dye, like many other hair dyes, is a skin sensitiser.

The opinion was adopted.

C117, Hydroxyanthraquinone aminopropyl methyl morpholinium methosulfate doc. n° SCCP/0875/05

The SCCP is asked to assess the risk to the consumers when Hydroxyanthraquinone aminopropyl methyl morpholinium methosulfate is used in hair dye formulations.

As a result, the SCCP concluded that the information submitted is inadequate to assess the safe use of the substance. Before any further consideration, the following information is required by July 2005:

- nature/characterisation of the impurities;
- nitrosamine content.

This hair dye, like many other hair dyes, is a skin sensitiser.

The opinion was adopted.

6.3. PRESERVATIVES AND FRAGRANCES

Report of the Co-ordinator

Dr. White said that two Working Group meetings had taken place during which the following opinions had been prepared:

P29, Triclocarban, doc. n° SCCP/0851/05

The adoption of the opinion was postponed.

The secretariat was asked to recalculate the Margin of Safety based on the information on absorption after oral administration. The SCCP agreed to adopt the opinion by written procedure.

P77, Methyl dibromoglutaronitrile, doc. n° SCCP/0863/05

The SCCP was asked to answer the following questions:

- On the basis of currently available information and taken into account the data provided, the SCCP is asked to assess the risk to consumer of methyldibromo glutaronitrile when used at the recently recommended maximum concentration in rinse-off products.
- Does the SCCP recommend any further restrictions than already recommended in its opinion adopted on 4 June 2002 and updated by opinion SCCNFP/0806/04 adopted on 23 April 2004 with regard to the use of methyldibromo glutaronitrile as a preservative in cosmetic products?

The SCCP concluded that:

- MDBGN was shown to cause elicitation of reactions by repeated open exposures with a rinse-off preparation at the maximum concentration allowed in rinse-off products (0.1%).
- No safe use-level for MDBGN in cosmetic leave-on or rinse-off products has been established.
- As no safe use-level for MDBGN in rinse-off products has been established, it is recommended that MDBGN should not be present in any cosmetic products.

Although the mandate requested an opinion on cosmetic use only, the risks to consumer health from the presence of MDBGN in other types of consumer products with relevant skin contact should be assessed. MDBGN has not yet been classified as a skin sensitizer (R43) in Annex I to Directive 67/548/EEC; the attention of the Commission is drawn to this".

The opinion was adopted.

P95, Ethyl lauroyl arginate, doc. n° SCCP/0837/04

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 Ethyl lauroyl arginate HCl is used as a preservative in cosmetic products up to a maximum authorised concentration of 0.2 %.
2. On the basis of provided data, the SCCP is asked to assess the risk to consumer when Ethyl lauroyl arginate HCl is used up to a maximum authorised concentration of 0.4 % in the following cosmetic products: soap, anti-dandruff shampoos, deodorants and oral hygiene products.
3. Does the SCCP recommend any further restrictions with regard to its use in cosmetic products?

The SCCNFP concluded that the information submitted suggests that ethyl lauroyl arginate causes mucosal irritation. Before any further consideration, the following additional information is required by the end of 2005:

- clarification on purity, composition and impurities;
- an acute inhalation toxicity study.

An opinion based on the information available at that time will be given.

The opinion was adopted.

6.4. UV FILTERS AND AD HOC SUBSTANCES

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

CMR substances, request for Confirmation of the SCCNFP Opinion 0474/01, doc. n° SCCP/0888/05

In relation to the substances annexed to the mandate, the SCCP was asked whether there were new elements that would lead it to amend its opinion on CMR substances of 25 September 2001, and if so, to revise it accordingly.

As a result, the SCCP concluded that there are no new elements that would lead it to amend its opinion on CMR substances of 25 September 2001 (doc. n° SCCNFP/0474/01).

The opinion was adopted.

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

During the 2nd plenary meeting of 7 December 2004, the SCCP decided to undertake a public consultation on its preliminary opinion. Interested parties were invited to submit comments or pertinent scientific information by email by 31 January 2005.

As a result, the SCCP concluded:

1. tooth whitening products containing up to 0.1% hydrogen peroxide

The use of tooth whitening products up to 0.1% hydrogen peroxide is safe.

2. tooth whitening products containing > 0.1% to 6.0 % hydrogen peroxide

- The proper use of tooth whitening products containing > 0.1 to 6.0 % hydrogen peroxide (or equivalent for hydrogen peroxide releasing substances) is considered safe after consultation with and approval of the consumer's dentist.
- The use of tooth whitening products is not recommended prior to or immediately after dental restoration.
- Particular care should be taken in using tooth whitening products by persons with gingivitis and other periodontal diseases or defective restorations. Conditions such as pre-existing oral tissue injury or concurrent use of tobacco and/or alcohol may exacerbate the toxic effects of hydrogen peroxide (see e.g. section 3.3.13.1).
- There is an absence of good clinical data and long-term epidemiological studies that assess the possible adverse effects within the oral cavity.
- The new additional data supplied does not provide the necessary reassurance in terms of risk assessment to support the safety of hydrogen peroxide up to 6 % in tooth whitening products freely and directly available to the consumer in various application forms (strips, trays, etc…). SCCP cannot quantify the risk of potential serious adverse effects in relation to the use of tooth whitening products.

The opinion was adopted.

7. NEXT PLENARY MEETING

The 4th plenary meeting of the SCCP will take place on 21 June 2005.

8. ANY OTHER BUSINESS

None

Annex I: List of Participants.

Annex I

Scientific Committee on Consumer products

3rd Plenary Meeting

Held on 15 March 2004
in Brussels

List of Participants

MEMBERS OF THE SCCP:
Prof. 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. 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: Mrs. A. ORLOFF