



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
4TH PLENARY MEETING

Held on 21 June 2005
in Brussels
MINUTES

1. WELCOME AND APOLOGIES

Dr. I.R. White welcomed all the 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 3RD PLENARY MEETING

Minutes of the 3rd plenary meeting were approved.

5. INFORMATION FROM CHAIRMAN/MEMBERS

Dr. White mentioned that as the next meetings of the Chairmen of the three non-food committees (SCCP, SCHER and SCENIHR) would take place on 22 June 2005 and on 14 September 2005, a report would be given during the next SCCP plenary meeting of 20 September 2005.

6. EMERGING ISSUES

Prof. Sanner informed members about a recent article on phthalates, including those used in cosmetic products, and their effects on the endocrine system.

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

In her report, Prof. Rogiers reminded the members about the revision of the Notes of Guidance. All members were invited to submit their proposals for changes either to Prof. Rogiers or to the secretariat.

Regarding dermal absorption, she said that a meeting was scheduled for 5 July with COLIPA and industry experts as well as with some external scientists in order to solve the frequent problems appearing in the dossiers submitted for evaluation. Participants of the meeting would be:

From the SCCP: Prof. C. Galli
Prof. J.-P. Marty
Prof. T. Platzek
Dr. S. Rastogi
Prof. V. Rogiers (Chair)
Prof. J. Revuz
Dr. I.R. White

External experts: Dr. W. Steiling (Henkel)
Dr. H. van der Sandt (TNO, NL)
Dr. G. Nohynek (L'Oreal)
Prof. Michael Roberts (recommended by Australian Tea tree industry)
Dr. Christopher Rousselle (AFSSAPS)
Dr. André Rougier (L'Oreal)
Dr. G. Renner (COLIPA)

Finally, she said that the meeting of the WG on genotoxicity was postponed to September 2005.

7.2. HAIR DYES AND COLORANTS

Report of the Co-ordinator

In his report, Prof. T. Platzek said that 2 meetings of the WG had taken place since the last plenary of 21 June 2005. Draft opinions on C67, C178 and on the colorant CI 26100 were addressed to the plenary for adoption.

He also said that Prof. E. Lynge had been invited to a meeting to present an overview on epidemiological studies on cancers related to the use of hair dyes. On the basis of currently available data, studies on bladder cancer and leukaemia in the USA and Japan indicate a relationship between the use of permanent hair dyes and cancer risk. The preparations used in both countries differ from the European ones. An on-going study in Spain may shed light on the situation in one part of Europe.

The meeting considered it reasonable, for safety reasons, to apply results obtained elsewhere and assess the situation after receiving further results from the Spanish study. Secretariat will keep abreast of the situation and will provide the respective data for the group as soon as results become available. Prof. Lynge will check whether the European cohort study on Health and Diet includes questions on hair dyes too.

Prof. Sanner and Prof. Lynge will draft the conclusions for the next WG Meeting in the autumn.

The secretariat announced a further 90 submissions to be evaluated this year. It was agreed to call on external experts to evaluate these safety dossiers.

C67, Acid Blue 62, doc. n° SCCP/0878/05

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 Acid Blue 62, when used in hair dye formulations.*
- 2. Does the SCCP recommend any further restrictions with regard to the use of Acid Blue 62 in hair dye formulations?*

As a result, the SCCP concluded that the use of Acid Blue 62 as a hair colouring agent ('direct' dye) in semi-permanent and temporary hair dye formulations at a maximum concentration of 0.5% in the finished cosmetic product did not pose a risk to the health of the consumer. However, its nitrosamine content should not exceed 50 ppb.

Aa Acid Blue 62 is also permitted for the use as a colorant (CI 62045) in other cosmetic products, which have short contact with the skin (Product category 4, according to Annex 4 of the Cosmetics Directive 76/768/EEC), the SCCP stated that its assessment pertained only to the use of Acid Blue 62 as a direct hair dye and that there had been no assessment of the safety of the substance as a colorant for other purposes.

The opinion was adopted.

C178, Acid Green 25, doc. n° SCCP/0879/05

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 Acid Green 25, when used in hair dye formulations.*
- 2. Does the SCCP recommend any further restrictions with regard to the use of Acid Green 25 in hair dye formulations?*

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

- complete information on the >10% impurity;
- Data on exposure from other cosmetic products;
- a percutaneous absorption study according to the Notes of Guidance;
- Data on teratogenicity;
- An additional *in vitro* test specifically detecting chromosomal aberrations (preferably an *in vitro* micronucleus test which detects clastogenic and aneugenic effects) should be performed.

The opinion was adopted.

CI 26100 (CI Solvent Red 23) as a colorant in cosmetic products, doc. n° SCCP/0902/05

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 CI 26100 is used as a colorant in cosmetic products.*
2. *Does the SCCP recommend any further restrictions or conditions for its use as a colorant in cosmetic products?*

The SCCP concluded that it could not assess, on the basis of provided data, the risk to consumers when CI 26100 is used as a colorant in cosmetic products.

For a sound risk assessment further studies are needed a) on percutaneous absorption of CI 26100 and 4-aminoazobenzene as well as b) on the rate of azo cleavage under experimental conditions mimicking the use conditions. The results should allow an estimation of exposure of the consumers to both substances. Depending on these data the need of further studies on subchronic toxicity and teratogenicity would be a matter of discussion.

Studies are required to assess the local mutagenic/carcinogenic potential of CI 26100 after topical application.

The information is required by 1 March 2006.

The opinion was adopted.

7.3. PRESERVATIVES AND FRAGRANCES

Report of the Co-ordinator

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

Benzoic acid and sodium benzoate, doc. n° SCCP/0891/05
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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 Benzoic acid, its salts and esters are used for non-preservative purposes in cosmetic rinse-off products at a maximum concentration of 2.5 % and in cosmetic oral-care products at a maximum concentration of 1.7 %, and in leave-on products up to 0.5%.*
2. *Does the SCCP recommend any further restrictions with regard to the use of Benzoic acid, its salts and esters safe when used for non-preservative purposes in cosmetic products?*

Adequate data was provided only for benzoic acid and sodium benzoate, but not the other salts or esters.

As a result, the SCCP concluded that, on the basis of provided data, benzoic acid and sodium benzoate are safe for use for preservative and non-preservative purposes in cosmetic rinse-off products at a maximum concentration of 2.5 % and in cosmetic oral-care products at a maximum concentration of 1.7 %, and in leave-on products up to 0.5%. The possible non-preservative functions have not been stated.

However, in the interest of consumer safety, generation of data on irritation and sensitisation of the other salts and esters is required if they are to be used in cosmetic products.

Moreover, the SCCP stated that inclusion of all relevant data should have been made available, particularly if from the grey literature as required by the SCCNFP Notes of Guidance (SCCNFP/0690/03). In the IUCLID database, more modern percutaneous absorption studies were summarised. The study for eye irritation was not provided with the Submission I. These should all have been provided with Submission I.

The opinion was adopted.

Tagetes erecta, T. minuta and T. patula Extracts and Oils (phototoxicity only), doc. n° SCCP/0869/05

The SCCP was asked to answer the following questions:

- *On the basis of currently available information, the SCCP is asked to assess the risk to consumers when Methylhydrocinnamic aldehyde, Tagetes absolute, Tagetes minuta absolute, Tagetes oil, Opoponax or Storax are present in cosmetic products, and if necessary, to revise the maximum concentration in fragrances used in cosmetic products considering the concentration limits or other restrictions suggested by industry.*
- *Does the SCCP recommend any further restrictions with regard to the presence of Methylhydrocinnamic aldehyde, Tagetes absolute, Tagetes minuta absolute, Tagetes oil, Opoponax or Storax as an ingredient of fragrances used in cosmetic products?*

As a result, the SCCP concluded that *Tagetes* extracts and oils are phototoxic. As no safe limit of use in cosmetic products has been demonstrated, it is recommended that *Tagetes erecta, Tagetes minuta and Tagetes. patula* extracts and oils should not form part of cosmetic products.

The opinion was adopted.

7.4. UV FILTERS AND AD HOC SUBSTANCES

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

Amino acids obtained by hydrolysis of human hair, doc. n° SCCP/0894/05

The SCCP was asked to answer the following questions:

1. *Does the method to hydrolyse human hair with HCl (> 20% throughout the whole process) for at least 6 hours at 100°C guarantee the absence of a possible risk to transmit adventitious agents which could have contaminated the raw material?*
2. *Is the safety of amino acids obtained from human hair comparable to the safety of amino acids obtained from other non-human origin (e.g. chicken feathers)?*

As a result, the SCCP concluded that the resulting risk, based on current scientific data, of the use in cosmetic products for topical application of amino acids obtained by hydrolysis of human hair or chicken feathers under the conditions described under point 3, is negligible.

The opinion was adopted.

CMR: Request for Confirmation of the SCCNFP Opinion 0474/01 on Chemical Ingredients in Cosmetic Products Classified as Carcinogenic, Mutagenic or Toxic to Reproduction according to Council Directive 67/548/EEC, doc. n° SCCP/0913/05

In relation to the substances annexed, the SCCP was asked whether there are new elements that would lead it to amend its opinions 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.

Fluorine compounds in oral hygiene products for children under the age of 6 years

A general view is that good epidemiological data on water fluoridation efficacy is missing and for caries prevention there is no data on efficacy of fluoride below 1000 ppm in toothpastes.

J. Cortvriend (DG ENV) gave an overview of the drinking water directive. Currently there is a proposal to reduce fluoride concentration to 1 mg/l, what still may be high for children.

Several comments were introduced to the draft opinion, which will be sent to three external experts - Prof. J. Ekstrand (Sweden) Dr. A. Petersen (Norway) and Prof. E. Treasure (UK) + a copy to DG ENV and Mr. Daskaleros.

Glyoxal, doc. n° SCCP/0881/05

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 Glyoxal is present up to 100 ppm in cosmetic products.*
2. *Does the SCCP recommend any further restrictions with regard to its presence in cosmetic products?*

The SCCP concluded that:

- * On the basis of provided data any risk to consumers when glyoxal is present up to 100 ppm in cosmetic products is considered to be negligible.
- * The SCCP does not recommend any further restrictions with regard to its presence in cosmetic products.

The opinion was adopted.

2-Mercaptobenzothiazole (MBT) (sensitisation only), doc. n° SCCP/0883/05

The SCCP was asked to:

- Assess the potential skin sensitisation risks to infants and adults from exposure to 2-mercaptobenzothiazole (MBT) released from natural rubber products (soothers and teats, gloves, rubber bands etc). In doing so the Committee should, if possible, also identify a level or exposure below which the risk of skin sensitisation would not be expected to be manifested in real life use situations.
- In light of its response to question 1, comment on the appropriateness of the CEN standard limit for MBT of 8 mg/kg rubber for rubber soothers and teats as a means to minimise the skin sensitisation risk.
- Comment on any other possible health risks that may emerge from the findings of the submitted studies concerning the antioxidants BHT, A2246, A 245, and volatile compounds in particular where the levels released exceed the CEN standard values.
- Identify any additional investigative work that need to be done concerning the above chemicals or the others (e.g. certain phthalates) that were detected in the products tested in order to better assess their release and dimension the risks.

In response to the questions asked, the SCCP concluded that:

- The risk of sensitisation from exposure to MBT released from natural rubber soothers and teats is negligible.
- The CEN standard limit of 8 mg/kg rubber for soothers and teats is appropriate to minimise sensitisation risks.
- No data on health hazards emerging from the release of BHT, A2246, A245 and volatile compounds were available.
- There may be a considerable greater migration from gloves and elastic bandages.

The SCCP would like to draw the Commission's attention to the need to investigate the release of MBT and similar allergic substances from other consumer products (e.g. foot wear) which have the potential to cause sensitisation (producing allergic contact dermatitis) in the consumer.

The opinion was adopted.

8. NEXT PLENARY MEETING

The 5th plenary meeting of the SCCP will take place on 20 September 2005.

9. ANY OTHER BUSINESS

* The SCCP was very concerned that the dossier on micronised ZnO has not yet submitted for evaluation. It recommended the Commission services to demand the information required by the 1 December 2005

* During the 1st Plenary Meeting of the SCCP on 7-8 September 2004, the co-ordinators of the various WGs were elected for 6 months. Dr. White asked for new candidates for these positions. As no new candidates were proposed, current co-ordinators will continue.

* Dates for WG Meetings:

5 July – Percutaneous absorption (Alternatives and Dossier)

26 July - UVR

31 August – Preservatives and fragrances

1 September – Ad hoc substances

6 September – Hair Dyes

30 September - Genotoxicity

Annex I: List of Participants.

Annex I

Scientific Committee on Consumer products

4th Plenary Meeting

*Held on 21 June 2005
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

DG ENV D2: Mr. J. CORTVRIND