Scientific Committee on Cosmetic and Non-Food Products

Minutes of the 21st Plenary Meeting

Brussels, 17 September 2002

Dr. Ian R. White, the chairman of the SCCNFP, welcomed all participants.

1. Adoption of the Agenda (doc. n° SCCNFP/0603/02)

The agenda was adopted.

2. Declaration of interest

No Member declared any interest that could prevent her/him from participating in the discussion of any of the items on the agenda.

3. Approval of the minutes of the 20th plenary meeting of 4 June 2002, doc. n° SCCNFP/0589/02

The minutes were approved.

4. SCCNFP - Working Groups

4.1 Alternatives

Report of the Co-ordinator

In his report, Prof. Loprieno said that, since the previous plenary meeting of 4 June 2002, no meetings of the WG had taken place.

However, he informed the committee about a conference that had taken place in Brussels on 9 and 10 July 2002 concerning "Research into Alternatives to Animal Experimentation", jointly organised by DG Research and DG Joint Research Centre.

He thanked Prof. Rogiers for her lecture 'Contribution of the SCCNFP to the three 'Rs' in which she highlighted the role and position of the SCCNFP regarding the implementation of the 3Rs-methodology in the safety assessment of cosmetic ingredients. He also thanked both Prof. Kemper and Prof. Rogiers for their active participation in the round table discussion at the end of the conference.

4.2 Detergents, Household & similar Products

Report of the Co-ordinator

Prof. Vives Rego said that no WG meeting had taken place since the previous plenary meeting of 4 June 2002.
He informed the committee that he received a series of papers prepared by industry in the framework of their HERA-initiative and which will be discussed by the WG in a future meeting.

Proposal for a Regulation of the European Parliament and of the Council on Detergents, doc. n° COM (2002) 485 final of 4.9.2002 : Mr. Daskaleros illustrated the final version of the Commission proposal on detergents. Although the systematic consultation of the SCCNFP on substances or preparations used in detergents that are irritant or sensitising for man had been withdrawn from the initial proposal, the committee was very pleased to learn that labelling provisions for preservatives (as defined in the Biocides Directive) and recognised fragrance allergens had been inserted.

4.3 Exposure & Risk Assessment

Report of the Co-ordinator

In the absence of Prof. Schaefer, Prof. Marty said that only one WG meeting had taken place since the previous plenary of 4 June 2002. During this WG meeting, the modifications to be made in the Notes of Guidance concerning percutaneous absorption were discussed. These proposed modifications will be sent to the WG 'Alternatives & Dossier' for inclusion in the Notes of Guidance.

4.4 Hair Dyes & Colorants

Report of the Co-ordinator

In his report, Prof. Andersen said that :

* a special Task Force on Hair Dyes, set up by the Working Group 'Hair Dyes' to answer a request from DG ENTR for a re-evaluation of certain hair dyes currently listed in Annex III, part 2 of the cosmetics directive (26th adaptation), discussed the essential requirements to answer this request.

In the framework of this task, a paper was drafted stipulating these requirements, namely :

(i) reliable information on the chemical-physical properties, and especially on the purity and on impurities;
(ii) data on the genotoxicity and carcinogenicity following the SCCNFP-paper "Proposal for a Strategy for Testing Hair Dye Cosmetic Ingredients for their Potential Genotoxicity/Mutagenicity", doc. n° SCCNFP/0566/02 of 4 June 2002;
(iii) data on the percutaneous absorption following the methodologies described in the 'Notes of Guidance', published by the SCCNFP.

* the concerns expressed during the previous plenary meeting of 4 June 2002 regarding the conclusions on the genotoxicity of lawsone had been reconsidered and that a revised draft opinion was tabled for discussion.

Opinion on C146 : Lawsone, doc. n° SCCNFP/0583/02

Further to the discussion on the draft opinion during the previous plenary meeting, an overview of all the available genotoxicity data was presented and discussed.

Based on the present available information, the committee concluded that :

- lawsone is mutagenic and clastogenic in some experiments;
- the available negative studies do not override the positive results.

As a consequence, the committee considered lawsone not suitable for use as a non-oxidising colouring agent for hair dyeing and, by extension, not suitable for any other cosmetic use(s).

The opinion was adopted.

Opinion on C169 – Lawsonia inermis (Henna), doc. n° SCCNFP/0505/01

The SCCNFP was requested to evaluate the submitted safety data and to inform the Commission whether Lawsonia inermis (Henna), derived from the dried leaves of the mentioned plant, can be safely used in cosmetic hair dye formulations and whether the SCCNFP propose any restrictions or conditions for its intended use.

Lawsonia inermis (Henna) contains normally 1 to 2 % of 2-Hydroxy-1,4-naphthoquinone. This chemical has been evaluated separately by the SCCNFP (doc. n° SCCNFP/0583/02, final).

On the basis of the information submitted, the SCCNFP concluded that the data on Lawsonia inermis (Henna) are inadequate, and that before any further consideration, a full and adequate dossier would be required, including :

* specifications of the substance tested and marketed, and
* adequate *in vivo* genotoxicity data on natural henna containing the maximum amount of 2-Hydroxy-1,4-naphthoquinone.

The opinion was adopted.

4.5 Inventory

Report of the Co-ordinator

In his report, Prof. Parra said that, since the previous plenary meeting of 4 June 2002, no meetings of the WG had taken place.

4.6 Preservatives & Fragrances

Report of the Co-ordinator

In his report, Prof. Kemper said that two WG meetings had taken place since the plenary meeting of 4 June 2002. The following opinions had been prepared :

Opinion on ATHN, doc. n° SCCNFP/0609/02

In its opinion of 24 October 2000 on the use of AHTN in cosmetic products, the committee stated that no final conclusion could be made on the basis of the information submitted and requested :

- data on the purity of the substance;
- a new *in vitro* penetration study in accordance with the SCCNFP Notes of Guidance;
- an *in vitro* 3T3 Neutral Red Uptake Phototoxicity Test to confirm the absence of phototoxicity;
- the results of the investigation and characterisation of pigmentation of internal organs in rats.

The additional information had been evaluated and a further opinion prepared.

On review of the information currently available, the SCCNFP concluded that AHTN could be safely used as a fragrance ingredient in cosmetic products up to a maximum concentration of 12 % in the fragrance compound.

The SCCNFP repeated its concern that the opinion was formulated only as a review of the cosmetic use of AHTN. For a full safety assessment of AHTN, it is necessary to consider other sources of consumer exposure from non-food products e.g., laundry products.

The opinion was adopted.

Opinion on HHCB, doc. n° SCCNFP/0610/02

In its opinion of 24 October 2000 on the use of HHCB in cosmetic products, the committee stated that no final conclusion could be made on the basis of the information submitted and requested :

- data on the purity of the substance and its possible isomers;
- a new in vitro penetration study in accordance with the SCCNFP Notes of Guidance;
- an *in vitro* 3T3 Neutral Red Uptake Phototoxicity Test to confirm the absence of phototoxicity;

The additional information has been evaluated and a further opinion prepared.

On review of the information currently available, the SCCNFP concluded that HHCB could be safely used as a fragrance ingredient in cosmetic products without any restriction for its use.

The SCCNFP repeated its concern that the opinion was formulated only as a review of the cosmetic use of HHCB. For a full safety assessment of HHCB, it is necessary to consider other sources of consumer exposure from non-food products e.g., laundry products.

The opinion was adopted.

Opinion on Triclosan, doc. n° SCCNFP/0600/02

The SCCNFP was asked to review the use of triclosan as a preservative in cosmetic products taking into account the risk of resistance development by certain micro-organism and taking into account the fact that triclosan is also used in other consumer products.

As triclosan is used in a wide range of consumer products, e.g. household detergents, textiles, or plastics intended for contact with food or feed, the Commission services decided to request the Scientific Steering Committee (SSC) for its opinion prior to address the issue to the SCCNFP.

Based on the SSC opinion concerning triclosan of 27-28 June 2002, and on the basis of the information provided by the Swedish Medical Products Agency, the SCCNFP concluded that :

- under its current conditions of use as a preservative in cosmetic products, triclosan is safe taking into account the risk of resistance by certain micro-organism, and that

- there is no need for setting a new concentration limit for the use of triclosan in cosmetic products.

Taken into account the fact that triclosan is used in other consumer products, the SCCNFP endorsed the recommendations expressed by the SSC in its above-mentioned opinion and in its opinion on microbial resistance of 28 May 1999.

The opinion was adopted.

Opinion on Ketoconazole - antimycotic resistance, doc. n° SCCNFP/0610/02

The SCCNFP was asked to review the use of ketoconazole in cosmetic dandruff shampoo at concentrations of either 1 % or 2 % taking into account any possibility for the development of resistance or cross-resistance by the fungi to ketoconazole.

Also this opinion was predominately based on the SSC opinion on azole antimycotic resistance of 27-28 June 2002, although a possible resistance of fungi from the cosmetic use of antimycotic substances, and ketoconazole in particular, was not expressively discussed by the SSC.

As a result, the SCCNFP concluded that :

- there is at present no scientific evidence of development of resistance or cross-resistance of fungi to ketoconazole, if ketoconazole is used in cosmetic dandruff shampoo at concentrations up to 2 %.
- there is no scientific reason to modify the SCCNFP opinion on ketoconazole adopted at the 8th plenary meeting of 23 June 1999 (doc. n° SCCNFP/0164/99).

Also, the SCCNFP endorsed the options to manage the resistance proposed by the SSC in its above mentioned opinion, and in particular the option that there might be a need for "an assessment of the extent to which cosmetic (e.g. shampoos) and medical uses (dermatological applications) are contributing to the development of azole resistance to fungi.

The opinion was adopted.

Opinion on P74 – 2,4-Dichlorobenzyl alcohol, doc. n° SCCNFP/0604/02

The committee decided to postpone the adoption of the opinion on 2,4-Dichlorobenzyl alcohol to the plenary meeting of 17 December 2002 in order to allow the WG to rephrase the text of the opinion.

Opinion on Hydrogen (carbamide, zinc) peroxide in tooth bleaching, doc. n° SCCNFP/0602/02

The SCCNFP was asked to review the use of hydrogen (carbamide, zinc) peroxide in tooth bleaching/whitening products at concentrations up to 6.0% (present or released) with a limitation of a maximum of 50 mg per day.

In its previous opinions on the use of hydrogen (carbamide) peroxide in tooth whitening (doc. n° SCCNFP/0058/98, SCCNFP/0200/99), the SCCNFP stated that hydrogen peroxide (and equivalent) could only be safely used at a maximum concentration of 0.1%. Products containing higher concentrations should exclusively be administered under supervision of a dentist, should contain a warning against overuse and should not be used by habitable tobacco and alcohol users.

The previous safety dossiers described a technique where hydrogen peroxide (and equivalent) was used in a custom made or prefabricated tray that covered the teeth. The present dossier is primarily based on the use of textured strips containing 6% hydrogen peroxide and designed to fit the front teeth.

As a result, the SCCNFP concluded that these tooth bleaching agents containing 0.1 to 6.0 % hydrogen peroxide (or equivalent for hydrogen peroxide releasing substances) could only be safely used under the supervision of a dentist. Moreover, the SCCNFP stressed that :

- these tooth whitening products should not be used prior to or immediately after dental restoration;
- conditions such as pre-existing tissue injury or concurrent use of tobacco and/or alcohol may exacerbate the toxic effects of hydrogen peroxide

The opinion was adopted.

4.7. UV Filters & Absorbers

Report of the Co-ordinator

In his report, Dr. Lina said that no WG meetings had taken place since the previous plenary meeting of 4 June 2002.

5. Report of the Chairman

Report of the Chairman

In his report, Dr. White said that a further mandate was received on the use of Specified Risk Materials in cosmetics, and in particular on the derogation for tallow derivatives (entry n° 419 of Annex II to Directive 76/768/EEC on cosmetic products). It appears that the current exceptions made for tallow derivatives in the cosmetics directive are no longer consistent with the opinion of the SSC on the safety of tallow of 28-29 June 2001.

Consultation on the progress in development satisfactory methods to replace animal testing, doc. n° SCCNFP/0599/02

The current text of the directive foresees a marketing ban of cosmetic products containing ingredients or combinations of ingredients tested on animals after 30 June 2002. As the 7th Amendment of the Cosmetics Directive has not yet been adopted, the Commission proposed, for a transitional period, a further postponement (to 31.12.2002) of the entering into force of the marketing ban.

Cosmetics Directive 76/768/EEC Art. 4 n° 1(i), however, stipulates that before submitting such measures, the Commission will consult the Scientific Committee on Cosmetic Products and Non-Food Products intended for the Consumer (SCCNFP).

Hence, and in order to finalise the 7th Amendment in a coherent legal context, the SCCNFP was asked to respond to the following question : "*Can the memorandum on "The actual Status of Alternative Methods to the Use of Animals in the Safety Testing of Cosmetic Ingredients (doc. n° SCCNFP/0546/02, final) adopted at the 20th plenary meeting of 4 June 2002 be considered as the basis for the statement that there has been insufficient progress in developing satisfactory methods to replace animal testing, and in particular in those cases where alternative methods of testing, despite all reasonable endeavours, have not been scientifically validated as offering an equivalent level of protection for the consumer, taking into account OECD toxicity test guidelines?".*

In response to this mandate, the SCCNFP adopted on 27 July 2002 by means of the written procedure an opinion stating that "the memorandum n° SCCNFP/0546/02 should be considered as the basis for the statement that there has been insufficient progress in developing satisfactory methods to replace animal testing, and in particular in those cases where alternative methods of testing, despite all reasonable endeavours, have not been scientifically validated as offering an equivalent level of protection for the consumer, taking into account OECD toxicity test guidelines.

6. Any Other Business

* *7th Amendment of Directive 76/768/EEC on cosmetic products* : Dr. Schumann informed the committee that the conciliation procedure was still on-going. Therefore, the Commission had to propose a further postponement of the entering into force of the marketing ban and, consequently, consult the SCCNFP on the progress in developing alternative methods.

She thanked the committee for their swift response to a mandate concerning the consultation on the progress in development satisfactory methods to replace animal testing, issued on 19 July 2002. (see point 5. Report of the Chairman).

* next meeting : 17 December 2002

Attendance List

Present	:	Mr	K.E. Andersen	Mr	J. Parra
		Mr	A. Di Domenico	Mr	T. Platzek
		Mr	V. Kapoulas	Mr	S. Rastogi
		Mr	F. Kemper	Mrs	V. Rogiers
		Mr	C. Laurent	Mr	T. Sanner
		Mr	B. Lina	Mr	J. Vives Rego
		Mr	N. Loprieno	Mr	I. R. White (Chairman)
		Mr	J.-P. Marty		
Apologies	:	Mr	R. Anton		
		Mrs	C. Chambers		
		Mr	H. Schaefer		

Commission	:	Mrs	S. Clarke	DG SANCO
		Mrs	L. D'Ambrosio	DG SANCO
		Mr	T. Daskaleros	DG SANCO
		Mrs	R. Schumann	DG ENTR
		Mr	A. Van Elst	DG SANCO