

Scientific Committee on Cosmetic and Non-Food Products

Minutes of the 16th Plenary Meeting

Brussels, 13 March 2001

Dr. Ian R. White, the chairman of the SCCNFP, welcomed all participants and introduced Dr. Leigh Henderson, a toxicologist who has particular expertise and interest in the use, side effects and beneficial properties of enzymes in personal care and household products.

1. Review on the safety and potential adverse effects of enzymes in personal care and household products. Dr. L. Henderson

Enzymes were introduced into laundry detergents in the mid-1960s. Hence, most of the safety data comes from the detergents industry : exposure to initially high enzyme air levels induced occupational asthma as they are potent respiratory sensitisers. They are uncommon as primary cutaneous allergens.

Dr. Henderson highlighted the available data and the research in progress to develop low allergenic enzymes.

The lecture was followed by a discussion. Questions on the low purity of enzymes (mixture rather than single enzymes) and the lack of an international unit standardisation were raised.

2. Adoption of the Agenda (doc. n° SCCNFP/0439/00) (in annex)

The agenda was adopted.

During this point of the agenda, Dr. Giovanni Fracchia and Mr. Abraao Carvalho, recently nominated respectively as acting Head of Unit SANCO/C-2 and Head of Unit ENTR/F-3 briefly addressed the committee and presented themselves.

3. 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.

Further, no Member declared any particular interest with regard to the substances listed under point 8 - New Dossiers - of the agenda which could be regarded as prejudicial to their independence in the light of a possible authorisation to act as rapporteur for one of these substances.

4. Approval of the minutes of the 15th plenary meeting of 6 December 2000,

doc. n° SCCNFP/0438/00

The minutes were adopted.

5. Rules of Procedure, doc. n° SCCNFP/0042/98

Commission Decision 97/579/EC of 23 July 1997 setting up the scientific committees, requires the renewed SCCNFP to adopt its Rules of Procedure.

The Chairman recalled that these rules ensure that the SCCNFP performs its task in the best possible way, in compliance with the principles of excellence, independence and transparency, while respecting the legitimate requirements of commercial confidentiality. The Rules of Procedure also ensure close co-operation with the other scientific committees and with the Scientific Steering Committee.

The SCCNFP adopted its Rules of Procedure.

6. SCCNFP - Specific Working Parties**6.1 Alternatives***Report of the Co-ordinator*

In his report, Prof. Loprieno said that since the renewal of the committee, the WP has discussed its work programme for the coming months: a complete revision of the Notes of Guidance.

He mentioned that this work will be undertaken in close co-operation with the newly established WP on Exposure and Risk Assessment, and especially for those Annexes to the Notes of Guidance which deal with the determination/calculation of a Margin of Safety (UV Filters, Hair Dyes and Preservatives). Particular attention will be made to the fact that these calculations must be based on reliable and precise data.

In the margin of the discussion, Dr Norgaard mentioned that the SCCNFP's Notes of Guidance were increasingly used as reference material in the discussion on regulatory matters with e.g. Japan and the USA.

As ECVAM is the Commission service responsible for the validation of methods alternative to animal tests, a meeting was proposed with ECVAM to discuss studies in progress on the development and validation of alternative methods of relevance for cosmetics.

Within the framework of the on-going discussion on the draft 7th Amendment of the cosmetics directive and on the draft report of the European Parliament on this draft 7th Amendment, Prof. Loprieno discussed the committee's deep concern that if there is a total ban of all animal tests, including those for which no alternative/non-animal test method has been validated, the SCCNFP will not longer be in a position to execute its responsible advisory function because of the lack of scientifically based safety data.

6.2 Detergents & Similar Household Products

Report of the Co-ordinator

In his report, Prof. Vives Rego said that the first meeting of the renewed WP will take place on 14 March, during which the work programme will be discussed.

In comparison to the Cosmetics Directive where there are appropriate provisions for consumer information and consumer health protection, the legislation in the field of detergents and similar household products appears devoid these kind of measures.

Assessments of risk is the overall objective of the WP and the work programme will be drafted along these lines.

6.3 Exposure & Risk Assessment

Report of the Co-ordinator

In his report, Prof. Schaefer said that the Working Party, during its very first meeting of 12 March 2000 had elaborated its mandate. In the context of cosmetics, it is fundamental to properly define terms such as 'damage', 'exposure', 'risk' and 'harm'.

Industry will be requested to submit accurate and current epidemiological based data on exposure to cosmetic products under various conditions. Specific questions will be asked on how the studies were conducted.

At a later stage, the current risk assessment procedures will be revised and adapted, based on the SSC First Report on the Harmonisation of Risk Assessment Procedures.

6.4 Hair Dyes & Colorants

Report of the Co-ordinator

In his report, Prof. Andersen said that 2 draft opinions on hair dyes and a position paper on skin stains (temporary tattoos) were approved.

The attention of the WP had been drawn to a population based control study which showed a significantly increased risk of bladder cancer among regular users of hair dyes. The WP was very concerned about the outcome of the study and will, as a matter of urgency, review all available/relevant data.

The committee adopted the opinion on Lawsone with a classification 2A : the available data support the conclusion that the substance constitutes a health hazard. Lawsone is clearly mutagenic and clastogenic (genotoxic substance).

Draft opinion on A17 : 1-Naphthol, doc. n° SCCNFP/0130/00

In its opinion of 23.6.1999, the SCCNFP considered A17 to be safe for use in oxidative hair dye formulations at a maximum concentration of 1.0%, which, after mixing with hydrogen peroxide, corresponds to 0.5% upon application (doc. n° SCCNFP/0130/99).

By letter of 16 May 2000, COLIPA requested the committee to evaluate the safety of A17 at a concentration of 2.0% (1.0% upon application).

As a result, the WP concluded that also at a maximum concentration of 2.0% (1.0% upon application) A17 is safe for use in oxidative hair dye formulations.

The SCCNFP adopted the revised opinion on 1-Naphthol. Classification 1 at 2.0 % (1.0 % upon application).

Draft position paper concerning PPD and similar substances and their use in skin stains (temporary tattoos), doc. n° SCCNFP/0442/01

It is known that p-Phenylenediamine (PPD) and similar substances are used in skin stains (temporary tattoos). Reported cases of severe allergic contact dermatitis from the use of hair dye chemicals in these skin staining products (temporary tattoos) have recently been discussed by the WP.

As a consequence, the WP approved a draft position paper stating that PPD and similar substances should not be used in skin stains (temporary tattoos).

The SCCNFP adopted the position paper.

6.5 Inventory

Report of the Co-ordinator

In his report, Prof. Parra recalled that during 2000 opinions on Section I – cosmetic ingredients other than perfume and aromatic raw materials - and on Section II – perfume and aromatic raw materials – of the inventory and common nomenclature have been adopted. These 2 opinions concluded the committee's work concerning the 1st update of the inventory of ingredients employed in cosmetic products.

On 3 April 2001, a WP meeting is planned during which the work on the second update of the inventory will be initiated. All the improvements, which could not have been included in the 1st update, e.g. restrictions or prohibition of specific botanicals (in Section I and II), nomenclature for hair dyes and colouring agents, as well as the issue of chemicals classified carcinogens,

mutagens or toxic to reproduction category 1 and 2, according to Directive 67/548/EEC on chemicals, will be addressed.

6.6 Preservatives & Fragrances

Report of the Co-ordinator

In his report, Prof. Kemper mentioned the issues discussed since the last plenary meeting :

- *Alpha-Hydroxy Acids* : during a previous meeting, industry agreed to do a number of additional experiments (evaluations of the percutaneous absorption, skin barrier integrity and photo-sensitivity) with particular emphasis on the worst case situations and to present the draft protocols of these tests to the WP for approval before the work is undertaken.

Further evaluation of *Alpha-Hydroxy Acids* will resume upon receipt of the results.

Draft memorandum on the SCCNFP opinion concerning Fragrance Allergy in Consumers, doc. n° SCCNFP/0450/01

During the 10th plenary meeting of 8 December 1999, the SCCNFP adopted an opinion on fragrance allergens for which there is a need for consumer information. Because of the lack of data, the SCCNFP was unable to provide recommendations on levels above which the information to the consumer would be necessary.

However, for practical risk management reasons, there is a need for such threshold levels. In response to this need, a memorandum was drafted saying that it was noted that there is a proposal that for leave-on products this threshold should be 10 ppm in the finished cosmetic product. For rinse-off products, a working level ten times higher than that recommended for leave-on products could be considered reasonable.

The SCCNFP adopted the memorandum.

Draft reply to the letters from industry concerning the SCCNFP opinion on Acrylamide residues in cosmetics, doc. n° SCCNFP/0448/01

Industry had expressed concern about the SCCNFP opinion saying that the opinion was not based on sound scientific evidence for the following reasons :

- * the T25 calculation of cancer potency. The value used differs from the value accepted by the EU Working Group for the classification and labelling of dangerous substances;
- * the T25-value was calculated using an old and no longer used model;
- * the dermal exposure was overestimated.

After consideration of these arguments, the WP decided that there is no reason to change the opinion and addressed a draft reply to the plenary meeting for formal adoption.

The SCCNFP adopted the reply to these letters.

Draft memorandum on Scientific Evaluations and Opinions, doc. n° SCCNFP/0461/01

The opinions adopted by the SCCNFP are based on the safety data submitted/available at the time of evaluation.

In order to be assured that all relevant information has been made available, the WP drafted a memorandum on this topic requesting that future safety files submitted to the SCCNFP for evaluation include, besides the toxicological studies performed by the applicant, a relevant literature search.

The SCCNFP addressed the draft paper to the WP 'Alternatives & Dossier' for further consideration.

6.7. UV Filters & Absorbers

Report of the Co-ordinator

In his report, Dr. Lina said that there are at present no files under consideration.

- *Annex 6 – General Scheme for Determining the Margin of Safety of UV Filters* : two clerical errors were found under point (a) in Annex 6 to the Notes of Guidance and corrected.

On page 63 of the Notes of Guidance, the correct text should read :

(a) The amount of formulation typically applied in use is 1.0 mg (formulation)/cm² over the entire body surface, taken to be 1.8 m² (18 g/person/day).

7. Report of the Chairman

Report of the Chairman

In his report, Dr. White thanked all members who contributed to the opinion the SSC is preparing on the safety of genetically modified cotton. The issue was raised because there was concern about residues which might be present on the cotton fibres.

Draft opinion on Mepyramine, doc. n° SCCNFP/0452/01

The committee was requested to adopt an opinion on the use of mepyramine in cosmetic products.

Mepyramine is an antihistamine and the committee was asked to review the safety of use of mepyramine in cosmetic products considering that more than 16 different antihistamines are forbidden in cosmetics through Annex II of the cosmetics directive.

Therefore, and in analogy with other substances which exert pharmacological action, it was decided to request a safety file to base the opinion on.

Table of Pending Issues, doc. n° SCCNFP/0032/98

This document is an internal working document and distributed for information only. It lists the various files under consideration and their present state.

8. New Dossiers

Safety files were received concerning the following substances :

- Salicylic acid;
- Benzoic acid, its salts and esters;
- Hexamidine and its salts (including isethionate and p-hydroxy-benzoate);
- 1-Hydroxy-4-methyl-6-(2,4,4-trimethylpentyl)-2-pyridon and its monoethanolamine salt (Piroctone olamine);
- alpha-Tocophenol acetate;
- Amendment of entry n° 419 of Annex II to the cosmetics SCCNFP/0451/01 Directive 76/768/EEC following Commission Decision 2000/418/EC on Specified Risk Materials (SRM) related to BSE;
- Methoxy-, Ethoxyethanol, Ethoxyethanol acetate.

None of the members declared to have an interest, which could be regarded as prejudicial to their independence. The respective rapporteurs will be assigned by Dr. White, the Chairman, in agreement with the vice-Chairmen, Prof. Kemper and Prof. Loprieno.

9. Any Other Business

No particular item was raised.

Attendance List

Present	:	Mr K.E. Andersen	Mr J.-P. Marty
		Mr R. Anton	Mr J. Parra

Mrs C. Chambers	Mr T. Platzek	
Mr A. Di Domenico	Mr S. Rastogi	
Mr V. Kapoulas	Mrs V. Rogiers	
Mr F. Kemper	Mr T. Sanner	
Mr C. Laurent	Mr H. Schaefer	
Mr B. Lina	Mr J. Vives Rego	
Mr N. Loprieno	Mr I. R. White	(Chairman)

External Expert : Mrs L. Henderson Unilever

Commission :	Mrs L. Benali	DG SANCO
	Mrs C. Brochot	DG SANCO
	Mr A. Carvalho	DG ENTR
	Mrs S. Clarke	DG SANCO
	Mr T. Daskaleros	DG SANCO
	Mrs C. De Geeter	DG ENTR
	Mrs F. Drion	DG SANCO
	Mr G. Fracchia	DG SANCO
	Mr L. Norgaard	DG ENTR
	Mr A. Van Elst	DG SANCO

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(Brussels, 13 March 2001)

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2. Adoption of the Agenda
3. Declaration of interest
4. Approval of the minutes of the 15th plenary meeting of 6 December 2000
5. Rules of Procedure
6. SCCNFP - Specific Working Parties
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Report of the Co-ordinator
 - 6.2 Detergents & Similar Household Products
Report of the Co-ordinator
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 - 6.4 Hair Dyes & Colorants
Report of the Co-ordinator

Draft opinion on C146 : Lawsone

Draft opinion on A17 : 1-Naphthol

Draft position paper concerning PPD and similar substances and their use in skin stains (temporary tattoos)
 - 6.5 Inventory
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6.6 Preservatives & Fragrances

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Draft reply to the letters from industry concerning the SCCNFP opinion on Acrylamide residues in cosmetics

Draft memorandum on Scientific Evaluations and Opinions

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7. Report of the Chairman

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Draft opinion on Mepyramine

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