

Scientific Committee on Cosmetic and Non-Food Products

Minutes of the 18th Plenary Meeting

Brussels, 25 September 2001

Dr. Ian R. White, the chairman of the SCCNFP, welcomed all participants and said that he had asked Prof. Hans Schaefer, member of the committee, to give a lecture on the skin and its barrier function. The topic was pertinent, Committee will initiate a revision of the calculation of percutaneous absorption and the calculation of the Margin of Safety.

1. The skin and its barrier function.

Prof. Schaefer illustrated the various key aspects of the skin barrier including the composition, the structure and the properties governing the diffusion of substances through the skin.

The lecture was followed by a discussion, which focussed mainly on questions in relation with the physiology and function of the stratum corneum.

2. Adoption of the Agenda (doc. n° SCCNFP/0513/01) (in annex)

The agenda was adopted, subject to the insertion under point 6 – Report of the Chairman - of the adoption of the opinion concerning the amendment of entry n° 419 of Annex II to Directive 76/768/EEC concerning cosmetic products.

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.

4. Approval of the minutes of the 17th plenary meeting of 12 June 2001, doc. n° SCCNFP/0501/01

The minutes were approved.

5. SCCNFP - Specific Working Parties

5.1 Alternatives

Report of the Co-ordinator

Prof. Loprieno said that no meetings of WP had taken place since the previous plenary meeting of 12 June 2001. Also, there had been no progress in the validation of methods alternative to animal tests that required an action/opinion of the SCCNP.

5.2 Detergents & Similar Household Products

Report of the Co-ordinator

In his report, Prof. Vives Rego said that the material AISE had been asked to submit concerning the chemicals used in their products had been received. Based on these data, a preliminary discussion paper on an inventory of detergent ingredients was drafted. This paper will be sent to AISE for comments. Additionally, AISE will be asked to submit information required to complete the inventory.

The document (SCCNFP/0519/01) was adopted.

Within the contexts of the work on biocides, a review (doc. n° SCCNFP/0520/01) had been drafted providing details of terminology, legal aspects and progress in procedures regarding biocides. Although it is not the task of the SCCNFP to prepare papers of this type, it was considered a very useful document and the Commission was invited to distribute the paper to its relevant services for comments.

5.3 Exposure & Risk Assessment

Report of the Co-ordinator

Prof. Schaefer reported on the following items :

- Exposure data : reliable exposure data is a prerequisite for a proper risk assessment. A meeting with industry experts (epidemiologists, statisticians) is planned to address the questions/requests of the committee in this respect. Based on these questions, industry should design, and subsequently perform, the studies required, i.e. investigations utilising modern epidemiological methods on representative consumer panels.
- Margin of Safety : the WP has initiated the revision of the calculation of the Margin of Safety (MoS). At a first stage, the WP will consider the way these calculations were made in the past. Based on their findings, a proposal for an amendment will be prepared.
- Harmonisation of risk assessment : Prof. Schaefer proposed to modify the format of the opinions according to the standardised format for the presentation of risk assessment findings presented in the Scientific Steering Committee's first report on the harmonisation of risk assessment procedures.

5.4 Hair Dyes & Colorants

Report of the Co-ordinator

In his report, Prof. Andersen said that :

- a meeting planned for 17 October 2001 with industry experts will discuss responses to the opinion of 12 June 2001 concerning the use of permanent hair dyes and bladder cancer;
- Lawsone was banned as a hair dye because of its genotoxic properties (opinion of 13 March 2001). However, lawsone is present in the vegetable dye Henna and the committee will review the use of this substance.

5.5 Inventory

Report of the Co-ordinator

Prof. Parra said that the WP had finalised the draft opinion on the presence of substances classified as carcinogenic, mutagenic and toxic to reproduction, category 1, 2 and 3 according to the Chemicals Directive 67/548/EEC in cosmetic products

Opinion concerning chemical ingredients in cosmetic products classified as carcinogenic, mutagenic or toxic to reproduction according to the chemicals directive 67/548/EEC, doc. n° SCCNFP/0474/01

Directive 76/769/EEC concerning the marketing and use of certain dangerous substances and preparations states that substances classified carcinogenic, mutagenic or toxic for reproduction categories 1 and 2 according to Annex I of the dangerous substances Directive 67/548/EEC may not be used in substances and preparations placed on the market for use by the general public at concentration equal or higher than those specified in the directive.

Cosmetic products are excluded from these regulations.

However, as the general public uses cosmetic products, the SCCNFP was asked (i) whether such substances pose a significant threat to the health of the consumer when used in cosmetic products and (ii) whether the SCCNFP proposes any restrictions or conditions for the use of these substances in cosmetic products.

The SCCNFP concluded that :

- * substances classified category 1 or 2 (except substances only carcinogenic by inhalation) and substances with similar potential must not be intentionally added to cosmetic products;
- * substances classified category 3 and substances with similar potential must not be intentionally added to cosmetic products unless it can be demonstrated that their levels do not pose a threat to the health of the consumer.
- * if a carcinogen, mutagen, or a substance toxic to reproduction is present in a cosmetic product from its presence in a natural ingredient, as an impurity or because it is formed during

manufacture, it must be demonstrated that the product does not pose a threat to the health of the consumer.

The opinion was adopted by the SCCNFP.

5.6 Preservatives & Fragrances

Report of the Co-ordinator

Prof. Kemper reported on the following :

- *Alpha-Hydroxy Acids* : a protocol on the skin penetration study was accepted. Timeframe : 6 months.
- *iodopropynyl butylcarbamate (P91)* : a further request from industry for an additional meeting on IPBC had been received. However, the committee did not consider a further meeting necessary, as the questions asked were quite clear. An appropriate response should be received as a matter of urgency.
- *draft opinion on Zinc pyrithione (P81) and on Hexamidine and its salts (P8)* : further to the opinion on +-marked preservatives, additional safety data has been received to substantiate the safety of the 'other uses' of the substances listed in Annex VI, part 1, e.g. Zinc pyrithione and Hexamidine and its salts.

However, it appeared that a proper risk assessment on the 'other uses' could not be made without taking the previous submissions into account. As these submissions might contain studies performed years ago and no longer acceptable by modern standards, it was agreed to devote a WP meeting to look into all the old submissions to see whether new safety dossiers containing studies conforming with modern standards may be required.

Draft opinion on an initial list of perfumery materials which must not form part of cosmetic products except subject to the restrictions and conditions laid down, doc. n° SCCNFP/0392/01

Analogous to the opinion adopted during the 12th plenary meeting of 3 May 2000 concerning an initial list of perfumery materials which must not form part of fragrance compounds used in cosmetic products, the SCCNFP had now considered the IFRA restricted fragrance ingredients in view of a possible inclusion in Annex III, Part 1 - List of substances which cosmetic products must not contain except subject to the restrictions and conditions laid down - to Directive 76/768/EEC on cosmetic products.

The opinion contains only those perfumery materials for which safety data were available and was therefore called an '*initial list of perfumery materials which must not form part of cosmetic products except subject to the restrictions and conditions laid down*'. Other ingredients will be added as soon as safety data become available.

The document was adopted.

As a complement to this opinion, a paper was presented which tabulates the substances listed in the opinion with their respective entries in the 1st update of section II of the inventory. The committee adopted this internal working document.

5.7. UV Filters & Absorbers

Report of the Co-ordinator

In his report, Dr. Lina said that no WP meetings had taken place since the previous plenary meeting of 12 June 2001.

Since a final draft opinion on the use of alpha-Tocopherol acetate in cosmetic products was not available at the time of the previous plenary meeting of 12 June 2001, Dr. Lina said that a final version was now tabled for adoption.

Opinion on the use of alpha-Tocopherol acetate, doc. n° SCCNFP/0494/01

Alpha-Tocopherol and its derivatives are not subject to a particular regulation in any of the annexes to Directive 76/768/EEC concerning cosmetic products. Their use falls under Article 2 of the Directive, which says that ‘A cosmetic product put on the market within the Community must not cause damage to human health when applied under normal or reasonable foreseeable conditions of use’.

As a result, and regarding the safety profile of vitamin E, it was concluded that the use of alpha-Tocopherol and its derivatives in cosmetic products does not give reason for concern.

The opinion was adopted by the SCCNFP.

6. Report of the Chairman

Report of the Chairman

In his report, Dr. White said that the committee had again been asked to express its view on the update of entry n° 419 of Annex II to the cosmetics Directive concerning specified risk material (SRM) regarding transmissible spongiform encephalopathies (TSEs).

Opinion on the amendment to entry n° 419 of Annex II to Directive 76/768/EEC on cosmetic products, doc. n° SCCNFP/0521/01

During the meeting of the Standing Committee on Cosmetic Products of 26 July 2001, it was said that there was a need for a further update of the opinion of the SCCNFP of 12 June 2001 on Entry n° 419 because of new scientific evidence regarding the use of specified risk material presenting a risk as regards TSE.

The reason for this question was Commission Decision 2001/233/EC of 14 March 2001 amending Decision 2000/418/EC as regards mechanically recovered meat and bovine vertebral column.

Based on Commission Decision 2001/233/EC, the SCCNFP proposed to amend entry n° 419 of Annex II so that it includes “the vertebral column excluding the vertebrae of the tail, but including dorsal root ganglia”.

In addition, also the following tissues shall be designated as specified risk material in the United Kingdom and in Portugal with the exception of the Autonomous Region of the Azores : “the entire head excluding the tongue, including the brains, eyes, trigeminal ganglia and tonsils; the thymus; the spleen and spinal cord of bovine animals aged over six months”.

The opinion was adopted.

7. Any Other Business

No items were raised under this point.

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	Mr T. Sanner
		Mr F. Kemper	Mr H. Schaefer
		Mr C. Laurent	Mr J. Vives Rego
		Mr B. Lina	Mr I. R. White (Chairman)
		Mr N. Loprieno	
Apologies	:	Mrs V. Rogiers	
Commission	:	Mrs S. Clarke	DG SANCO
		Mr L. Norgaard	DG ENTR
		Mr A. Van Elst	DG SANCO

Annex

Scientific Committee on Cosmetic and Non-Food Products

Agenda for the 18th plenary meeting

(Brussels, 25 September 2001)

1. The skin and its barrier function.
2. Adoption of the Agenda
3. Declaration of interest
4. Approval of the minutes of the 17th plenary meeting of 12 June 2001
5. SCCNFP - Specific Working Parties
 - 5.1 Alternatives
 - 5.2 Detergents & Similar Household Products
 - 5.3 Exposure & Risk Assessment
 - 5.4 Hair Dyes & Colorants
 - 5.5 Inventory

Draft opinion concerning chemical ingredients in cosmetic products classified as carcinogenic, mutagenic or toxic to reproduction according to the chemicals directive 67/548/EEC

- 5.6 Preservatives & Fragrances

Draft opinion on an initial list of perfumery materials which must not form part of cosmetic products except subject to the restrictions and conditions laid down

- 5.7. UV Filters & Absorbers

Draft opinion on the use of alpha-Tocopherol acetate

6. Report of the Chairman

Draft opinion on the amendment to entry n° 419 of Annex II to Directive 76/768/EEC on cosmetic products

7. Any Other Business