

## **Scientific Committee on Cosmetic and Non-Food Products**

### **Minutes of the 17<sup>th</sup> Plenary Meeting**

Brussels, 12 June 2001

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Dr. Ian R. White, the chairman of the SCCNFP, welcomed all participants and introduced Dr. Gerhard Nohynek, a senior toxicologist with a particular interest in risk perception (intuitive toxicology).

#### **1. Risk perception and safety of sunscreens. Dr. G. Nohynek**

Dr. Nohynek elucidated how for real risks, objective and quantitative data are perceived. Risk perception, however, is often subjective and qualitative : media and the general public do not readily discriminate between degrees of toxic hazard and toxic risk.

There may be trust and distrust in the information source and misleading risk perception may result in false regulatory principles.

He illustrated the risk perception of the estrogenicity of organic UV filters as a textbook example of misguided risk perception and misinterpretation of toxicological data.

The lecture was followed by a discussion, which focussed mainly on questions in relation to the SCCNFP opinion on the evaluation of potential estrogenic effects of UV filters (point 5.7 of the agenda).

#### **2. Adoption of the Agenda (doc. n° SCCNFP/0480/01) (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 16<sup>th</sup> plenary meeting of 13 March 2001, doc. n° SCCNFP/0455/01**

The minutes were approved.

#### **5. SCCNFP - Specific Working Parties**

## 5.1 Alternatives

### *Report of the Co-ordinator*

In the absence of Prof. Loprieno, Dr. White reported on what had happened since the previous plenary meeting.

The Working Party had met with Prof. Balls, the director of ECVAM, the Commission service responsible for the validation of methods alternative to animal tests. Prof. Balls had given an overview of what has been achieved from the point of view of the science and technology of finding alternatives. What may be achievable in a relatively short term from the point of view of validation procedures and what is not going to be achievable into the foreseeable future.

Memorandum on Scientific Evaluations and Opinions, doc. n° SCCNFP/0461/01
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The issue of the quality of the safety files submitted by industry has often been raised and the view expressed that not all existing information was being submitted to the committee. Important information may be unpublished or 'hidden' in other fields of science or be in confidential dossiers of industry.

In the interest of consumer's health protection, the present memorandum is a requests to submit, besides the results procured by the applicants themselves, all relevant published literature and other findings to the applicant's best ability as well as "grey material" available elsewhere.

The memorandum was adopted and will be inserted in the SCCNFP's Notes of Guidance.

## 5.2 Detergents & Similar Household Products

### *Report of the Co-ordinator*

In his report, Prof. Vives Rego said that the WP met representatives from the Association Internationale de la Savonnerie, de la Détergence et des Produits d'Entretien (AISE).

The discussion focussed on (i) the types of the products manufactured by the detergents industry - their definitions and functions in order to establish a glossary - , (ii) on the methodologies used for risk assessment and (iii) on the committee's request to have robust data on consumer exposure.

Moreover, he said that AISE has been asked to submit data on the chemicals used in their products in order to establish an inventory, in analogy with the 'cosmetics'-inventory.

## 5.3 Exposure & Risk Assessment

*Report of the Co-ordinator*

Prof. Schaefer reported on the following items :

- harmonisation of the protocols on percutaneous absorption : although the OECD guidelines fully apply, it appeared that they are not specific enough to address the particularities of cosmetic products. The OECD guidelines address cases where exposure is not defined or uncertain. Cosmetics are applied voluntarily.
- calculation of percutaneous absorption : in future, the margin of safety (MoS) will be calculated by relating penetration data to the human body surface intended to be exposed. The systemic body load will be calculated without passing through the percentage of absorption.
- in-use conditions : the calculation of the MoS was initially based on an application of 2mg/cm<sup>2</sup> in *in vitro* studies and does not correspond to in-use values which would rather fall between 0.5 to 1 mg/cm<sup>2</sup>.
- MoS and children : in general, skin penetration is similar in children as in adults. However, more information is required on the physiology of children skin and on body weight versus skin area.
- specific recommendations in case the MoS is close to 100 : studies on penetration kinetics will requested on a case-by-case basis. Two approaches appear scientifically sound and feasible : (i) the assessment of compounds bound irreversibly to epidermal protein at the end of 24h *in vitro* essays, and which would be rejected *in vivo* by proliferation/desquamation of the epidermis, and (ii) the determination of the AUC in blood and excreta of human volunteers.

#### 5.4 Hair Dyes & Colorants

*Report of the Co-ordinator*

In his report, Prof. Andersen said that the WP had reviewed, as a matter of urgency, all available/relevant data related to a population based control study which showed a significantly increased risk of bladder cancer among long term regular users of hair dyes. An opinion on the use of permanent hair dyes and bladder cancer risk had been prepared and tabled for adoption.

Opinion on the use of permanent hair dyes and bladder cancer risk, doc. n° SCCNFP/0484/01

The attention of the Committee was recently drawn to a population-based case-control study. Although the causative agent could not be definitively established, the study implicates long-term use of permanent hair dyes as a risk factor in bladder-cancer development. Based on these findings, the Committee concluded that the potential risk for the development of bladder cancer in users of permanent hair dyes is of concern and requested a full quantitative list of all dyes currently used in permanent hair dye formulations in the EU. Moreover, the committee recommended that the European Commission provides the resources for the urgent review of the information and performs further epidemiological studies to evaluate the possible association between bladder cancer and the use of permanent hair dyes in the EU.

The opinion was adopted.

It was pointed out that the safety evaluations of hair dyes should follow the current Guidelines and that the data assessed should conform to currently accepted standards.

## 5.5 Inventory

### *Report of the Co-ordinator*

Prof. Parra said that the WP :

- reviewed the tasks to be carried out regarding the 2<sup>nd</sup> update of the inventory.
- initiated the work to identify - and subsequently consider - the substances classified as carcinogenic, mutagenic and toxic to reproduction, category 1 and 2 according to the Chemicals Directive 67/548/EEC in the EU Inventory of cosmetic ingredients and in the International Cosmetic Ingredient Dictionary (published by the Cosmetic, Toiletry and Fragrance Association).
- initiated the work to review the safety profile of botanicals which pose a significant threat to the health of the consumer and which use should be prohibited.

Opinion on dialkyl- and dialkanolamines and their salts in cosmetic products, doc. n° SCCNFP/0462/01

Presently the use of secondary dialkanolamines in cosmetic products is prohibited (entry n° 411 of Annex II). However, the SCCNFP has been asked whether their salts should also be banned.

Since the salts of dialkanolamines have similar properties regarding nitrosamine formation, the Committee concluded that these salts should also be banned. Moreover, the Committee proposed the same for dialkylamines and their salts because of similar properties.

In addition, the Committee :

- proposed to insert fatty acid dialkylamides, monoalkylamines and their salts and trialkylamines and their salts respectively in entries 60, 61 and 62 of Annex III.
- said that, in principle, secondary amines and alkyldimethyl –N-oxides are potential precursors of nitrosamines.

The opinion was adopted by the SCCNFP.

## 5.6 Preservatives & Fragrances

### *Report of the Co-ordinator*

In his report, Prof. Kemper said that concerning :

- Alpha-Hydroxy Acids, an agreement had been found on the additional experiments (evaluations of the percutaneous absorption, skin barrier integrity and photo-sensitivity) to be performed. The results are expected by late 2001.
- the safety of children : this work will be carried out in close co-operation with the WP 'Exposure and Risk Assessment'.

- the safety evaluations of IPBC (P91), fragrances ingredients 'to be restricted' and a series of '+'-marked preservatives (e.g. salicylic acid, benzoic acid, zinc pyrithione, hexamidine and its salts, 2-phenoxyethanol and Piroctone olamine) were on-going.

## 5.7. UV Filters & Absorbers

### *Report of the Co-ordinator*

In his report, Dr. Lina said that the work of the WP focussed mainly on the evaluation of potentially estrogenic effects of UV-filters.

Opinion on the evaluation of potentially estrogenic effects of UV-filters, doc. n° SCCNFP/0483/01

A recent study, suggesting that a number of UV filters show estrogenic activity, had alerted national health authorities, the popular press and the public.

On 27/4/2001, an ad hoc Working Group discussed the issue and published a preliminary report on the scientific review of these investigations. Serious concerns were expressed as to the validity of the results published.

In its opinion on the evaluation of potentially estrogenic effects of UV-filters, the SCCNFP concluded that a number of important technical and scientific shortcomings were present in the study. Moreover, and based on currently established information, the SCCNFP concluded that organic UV-filters used in cosmetic sunscreen products, allowed in the EU market today, have no estrogenic effects that could potentially affect human health.

The opinion was adopted.

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

Alpha-Tocopherol and its derivatives are not subject to 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.

Since a draft final text was not available at the time of the meeting, the Committee asked the secretariat to circulate the final draft opinion amongst the members so that it could be adopted by written procedure.

## 6. Report of the Chairman

*Report of the Chairman*

In his report, Dr. White said that he had nothing to mention in particular. However, he said that the committee was 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/0451/01

Entry n° 419 stipulates that “Bovine, ovine and caprine tissues and fluids from the encephalon, the spinal cord and the eyes, and ingredients derived therefrom” must not form part of the composition of cosmetic products. Entry n° 419 has been further amended in order to be in line with the Commission Decisions defining specified risk material (SRM) regarding transmissible spongiform encephalopathies (TSEs).

Recently, Commission Decision 2001/2/EC has updated the list of tissues defined as specified risk material on the basis of the opinion of the Scientific Steering Committee of 27-28 November 2000.

Based on the opinion of the SSC and on Commission Decision 2001/2/EC, the SCCNFP proposed to amend entry n° 419 of Annex II so that it includes “the intestines from the duodenum to the rectum of bovine animals of all ages, and ingredients derived therefrom”.

The opinion was adopted.

## **7. Any Other Business**

Recently, Directorate C of DG SANCO had been re-organised with the merging of units SANCO/C2 and SANCO/C3. Mr. Peter Wagstaffe, former Head of Unit SANCO/C3 had been nominated acting Head of the new unit SANCO/C2.

He briefly presented himself and informed the Committee about the foreseeable future of the SCCNFP especially in relation to the setting up of the European Food Authority.

### Attendance List

Present	:	Mr K.E. Andersen	Mr J. Parra
		Mr R. Anton	Mr T. Platzek
		Mrs C. Chambers	Mr S. Rastogi
		Mr A. Di Domenico	Mrs V. Rogiers

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	J.-P. Marty			

Apologises : Mr N. Loprieno

External Expert : Mr G. Nohynek L'Oréal

Commission	:	Mrs	L. Benali	DG SANCO
		Mrs	S. Clarke	DG SANCO
		Mrs	F. Drion	DG SANCO
		Mr	L. Norgaard	DG ENTR
		Mr	A. Van Elst	DG SANCO
		Mr	P. Wagstaffe	DG SANCO

**Annex**

**Scientific Committee on Cosmetic and Non-Food Products**  
**Agenda for the 17<sup>th</sup> plenary meeting**  
(Brussels, 12 June 2001)

1. Risk perception and safety of sunscreens. Dr. G. Nohynek
2. Adoption of the Agenda
3. Declaration of interest
4. Approval of the minutes of the 16<sup>th</sup> plenary meeting of 13 March 2001,
5. SCCNFP - Specific Working Parties

5.1 Alternatives

*Report of the Co-ordinator*

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

5.2 Detergents & Similar Household Products

*Report of the Co-ordinator*

5.3 Exposure & Risk Assessment

*Report of the Co-ordinator*

5.4 Hair Dyes & Colorants

*Report of the Co-ordinator*

Opinion on the use of permanent hair dyes and bladder cancer risk, doc. n° SCCNFP/0484/01

5.5 Inventory

*Report of the Co-ordinator*

Opinion on dialkyl- and dialkanolamines and their salts in cosmetic products

5.6 Preservatives & Fragrances

*Report of the Co-ordinator*

5.7. UV Filters & Absorbers



*Report of the Co-ordinator*

Opinion on the evaluation of potentially estrogenic effects of UV-filters

Opinion on the use of alpha-Tocopherol acetate

6. Report of the Chairman

*Report of the Chairman*

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

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