Scientific Committee on Cosmetic and Non-Food Products

Minutes of the 26th Plenary Meeting

Brussels, 9 December 2003

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

1. Adoption of the Agenda, doc. n° SCCNFP/0769/03

The agenda was adopted.

2. Declaration of interests and confidentiality

Prof. Andersen declared an interest on Lyral™ submission evaluated and would not participate in any discussion of it. No other 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 25th plenary meeting of 20.10.03, doc. n° SCCNFP/0759/03

The minutes were approved.

4. SCCNFP - Working Parties

4.1. Alternatives & Dossier

Report of the Co-ordinator

DG Enterprise gave an overview of plans of work with alternative methods by DG ENTR in co-operation with JRC, ECVAM and DG ENV. It was mentioned that the outcome of the stakeholders' working group will be sent to SCCNFP before the summer 2004.
Members of the ECVAM working group presented the results from the last meeting.

Discussion on Proposal for Mutagenicity/Genotoxicity tests recommended for the safety testing of cosmetic ingredients doc n° SCCNFP/0755/03**.**

It was agreed that as the main task of SCCNFP is to assess potential risks to the consumer it is essential to recommend tests that provide the necessary data for risk assessment.
As the paper is a proposal, it was agreed to call for the comments within a limited timeframe until the 29 February 2004.

There was general consensus on the draft. The paper was adopted.

4.2. Detergents, Household & similar Products

Report of the Co-ordinator

Prof. Vives Rego reported that no activities had taken place in this area.

4.3. Exposure & Risk Assessment

No activities have taken place in this area. A new co-ordinator will be nominated in due course.

4.4. Hair Dyes & Colorants

Report of the Co-ordinator

In his report, Prof. Andersen said that no meeting had taken place since the last Plenary meeting, but issues had been discussed during the other WG meetings. The following had been postponed from the last Plenary Meeting and was now presented:

* Opinion on A 128, 6-Hydroxyindole, doc. n° SCCNFP/0667/03

The opinion was adopted.

4.5 Inventory

No activities have taken place in this area.

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 20th October 2003, during which the following opinions had been prepared:

P 70, Benzethonium chloride, doc n° SCCNFP/0762/03

The SCCNFP was requested to answer the following questions :

* *Is Benzethonium Chloride safe for use in leave-on cosmetic products (except for products for oral use) at 0.1%?*

* *Does the SCCNFP propose any additional restrictions or conditions for its use in cosmetic products?*

The SCCNFP concluded that the data provided in the submitted dossier supports the requested use of benzethonium chloride as a preservative in leave-on products, except products for oral use, up to a maximum concentration of 0.1%.

The opinion was adopted.

Isopimpinellin, doc. n° SCCNFP/0761/03

The SCCNFP was requested to answer the following question :

- *Does the data provided justify an update of the "Initial List of fragrance" for No 6 of the table attached to this opinion (An Initial List of Perfumery Materials which must not form part of Cosmetic Products except subject to the restrictions and conditions laid down [SCCNFP/0392, Adopted 25.09.01]) and how should the restrictions and conditions laid down be changed accordingly?*

The restriction in n° 6 reads: *May be used in cosmetic products, provided that the total concentration of furocoumarin-like substances in the finished cosmetic product do not exceed 1 ppm.*

The present opinion deals primarily with questions concerning photomutagenicity of isopimpinellin. The submitted data demonstrated that isopimpinellin is photomutagenic in *Salmonella typhimurium* TA102.

SCCNFP concluded that there is incomplete information on photomutagenicity and on photoclastogenicity of isopimpinellin to enable a safety evaluation in order to provide an update of the "Initial List of fragrance" for No 6 of the table attached to this opinion (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, 25.09.01]).

The opinion was adopted.

Linalool, doc. n° SCCNFP/0760/03

The SCCNFP adopted two opinions on fragrance allergy in consumers with an analysis of the need for appropriate consumer information and identification of consumer allergens (SCCNFP/0017/98, adopted during the 10th plenary meeting of 8 December 1999 and SCCNFP/0421/00, adopted during the 14th plenary meeting of 24 October 2000).

The SCCNFP identified 26 substances, used as fragrance ingredients, on which information should be provided to consumers about the known presence in cosmetic products. Because of the lack of dose/elicitation data for these substances, the SCCNFP had been unable to provide recommendations on levels above which the information to the consumers would be necessary. For practical risk management reasons, there is a need for threshold levels for the provision of information. For leave-on products, a level of 10 ppm in the finished cosmetic product had been endorsed and for rinse-off products, the SCCNFP 100 ppm (Memorandum on the SCCNFP

opinion concerning fragrance allergy in consumers, adopted during the 16th plenary meeting of 13 March 2001, doc. n° SCCNFP/0450/01).

Council Directive 2003/15/EEC amended Directive 76/768/EEC by adding a list of the 26 fragrances mentioned by the SCCNFP in Annex III with the following limitation : "*The presence of the substances must be indicated in the list of ingredients referred to in Article 6.1.(g) when its concentration exceeds : 0.001% in leave-on products, 0.01% in rinse-off products*". Linalool (CAS n° 78-70-6) is one of these 26 fragrances (Annex III, n° 84).

The European Commission received a letter from an association with a new technological and dermatological assessment of linalool and related esters when used as fragrance ingredients. This assessment was published in Food and Chemical Toxicology 41 (2003), authored by the Research Institute for Fragrance Materials (RIFM). In this assessment the RIFM Panel has determined that there are no safety concerns regarding linalool and related esters under the declared levels of use and exposure.

The SCCNFP was asked to answer the following question :

Do the data provided justify that the opinions given by the SCCNFP on fragrance allergy in consumers do not apply to linalool?

The SCCNFP concluded that the submitted data, as well as other recent clinical data, do not support the request for linalool to be excluded from the opinion of the SCCNFP on fragrance allergens (doc. n° SCCNFP/0017/98 of 8 December 1999).

The opinion was adopted.

Lyral™, doc. n° SCCNFP/0760/03

4-(4-hydroxy-4-methylpentyl)-3-cyclohexene-1 carboxaldehyde is used as a fragrance ingredient in cosmetic products. It is not regulated in an Annex to the Cosmetics Directive but is one of the 26 fragrance ingredients identified by the SCC NFP *(Fragrance allergy in consumers: a review of the problem, analysis of the need for appropriate consumer information and identification of consumer allergens (adopted by the SCCNFP during the plenary session of 8 December 1999)* as being a recognized allergen in fragrance compounds.

The European Commission had received a letter from the University Louis Pasteur, Strasbourg, France with data demonstrating that current consumer exposure to 4-(4-hydroxy-4-methylpentyl)-3-cyclohexene-1 carboxaldehyde in cosmetic products exceeds the threshold for elicitation in sensitized individuals and that exposure is likely to induce a significant level of sensitization in the population. The data was generated through a 5th Framework programme: *Fragrance chemical allergy: a major environmental and consumer health problem in Europe (QLK4-CT-1999-01558*).

The letter was also sent to COLIPA who replied that results of additional studies were to be expected by mid-November 2003 and appended two documents (1. Fine fragrance: understanding usage patterns and exposure ; 2. Perfume allergens: why contact allergy risk management should not be based on eliciting concentrations of the allergens).

The SCCNFP was asked to answer the following question:

* *Is 4-(4-hydroxy-4-methylpentyl)-3-cyclohexene-1 carboxaldehyde safe for use in cosmetic products taking into account the data provided?*
If not, does the SCCNFP consider 4-(4-hydroxy-4-methylpentyl)-3-cyclohexene-1 carboxaldehyde is safe if used up to a maximum concentration in cosmetic products and do the data provided indicate such a concentration?

* *And/or does the SCCNFP recommend any further restrictions with regard to the use of 4-(4-hydroxy-4-methylpentyl)-3-cyclohexene-1 carboxaldehyde as a fragrance in cosmetic products?*

The available data clearly demonstrate that 4-(4-hydroxy-4-methylpentyl)-3-cyclohexene-1 carboxaldehyde is an important contact allergen. In recent large European surveys, it has been shown that in patients with eczema 1.9 – 2.7% react to 4-(4-hydroxy-4-methylpentyl)-3-cyclohexene-1 carboxaldehyde 5% in petrolatum on routine testing. The allergy is often relevant. The frequency of contact allergy in the general population is unknown. The proportion of individuals with eczema who are evaluated by diagnostic patch testing will depend on the accessibility of appropriate facilities within their geographical location in Europe.

Therefore, the current use levels of 4-(4-hydroxy-4-methylpentyl)-3-cyclohexene-1 carboxaldehyde are unsafe as current use levels have both caused the induction and elicitation of contact allergy to it.

Additionally, although the presence of it in a finished cosmetic product will be identified on ingredient labels if present at 10ppm (0.001%) in leave on products or 100ppm (0.01%) in rinse off cosmetic products, only that unknown proportion of individuals who have been clinically tested will be able to avoid cosmetics that are potentially harmful to them.

Industry has recommended that 4-(4-hydroxy-4-methylpentyl)-3-cyclohexene-1 carboxaldehyde should not be used at a level greater than 1.5% in a finished cosmetic product. This recommended level far exceeds levels known to be a risk to the consumer.

Results from the experimental data above, and a risk assessment model, suggest that a safe level of exposure for the consumer would be in the range of 0.9 μg /cm^2 to 10 μg /cm^2.

Based on the information presently available, a concentration of up to 0.02% in a finished cosmetic product will have a low potential to *induce* sensitisation, or *elicit* allergic contact reactions in those consumers already sensitised to this fragrance chemical.

Although strictly a risk management matter, because of the importance of 4-(4-hydroxy-4-methylpentyl)-3-cyclohexene-1 carboxaldehyde as an allergen for the consumer, a more easily recognised INCI name than hydroxyisohexyl 3-cyclohexene carboxaldehyde may be of assistance to the consumer.

The opinion was adopted.

Update initial list of prohibited fragrance compounds, doc. n° SCCNFP/0771/03

The SCCNFP was asked to respond to the following questions :

1. Does the SCCNFP agree to the inclusion of all IFRA restricted materials in the Annex III (List of substances which cosmetic products must not contain except subject to restrictions and conditions laid down)? Are the permitted levels recommended by IFRA suitable for use in the Cosmetics Directive 76/768/EEC ?

2. Does the SCCNFP agree that all materials that IFRA recommend should not be used as fragrance compounds are included in Annex II (List of substances which must not form part of the composition of cosmetic products)?

3. It is proposed that all known fragrance allergens are labelled on cosmetics if used in the products. Does the SCCNFP agree to this proposal? If so :

- *Which chemicals fall under this classification?*
- *Is there a maximum concentration of each chemical permissible without the requirement for labelling?*

4. Restrictions are proposed for the 3 most common fragrance allergens (cinnamic aldehyde, isoeugenol, hydroxycitronellal). Does the SCCNFP agree to restriction on the use of common fragrance allergens (Annex III listing)? If so :

- *Which fragrance materials should be subject to restrictions?*
- *What are the conditions for restrictions (maximum concentration, fields of applications, etc) ?*

Obviously, in response to each of the questions listed above, a scientific justification will be necessary.

During its 12th plenary meeting of 3 May 2000, the SCCNFP adopted an opinion on an initial list of perfumery materials which must not form part of fragrance compounds used in cosmetic products (doc. n° SCCNFP/0320/00 final).

The current opinion consists of an update of this list.

On the basis of the assessment of the cutaneous toxicities of the substances tabulated, the Scientific Committee on Cosmetic Products and Non-Food Products intended for Consumers (SCCNFP) is of the opinion that these substances should not be used as fragrance ingredients in cosmetic products.

Other substances will be discussed for possible inclusion at a later date.

The opinion was adopted.

Update initial list of restricted fragrance compounds, doc n° SCCNFP/0770/03

The SCCNFP has been asked to respond to the following questions :

1. Does the SCCNFP agree to the inclusion of all IFRA restricted materials in the Annex III (List of substances which cosmetic products must not contain except subject to restrictions and conditions laid down)? Are the permitted levels recommended by IFRA suitable for use in the Cosmetics Directive 76/768/EEC ?

2. Does the SCCNFP agree that all materials that IFRA recommend should not be used as fragrance compounds are included in Annex II (List of substances which must not form part of the composition of cosmetic products)?

3. It is proposed that all known fragrance allergens are labelled on cosmetics if used in the products. Does the SCCNFP agree to this proposal? If so :

- *Which chemicals fall under this classification ?*
- *Is there a maximum concentration of each chemical permissible without the requirement for labelling ?*

4. Restrictions are proposed for the 3 most common fragrance allergens (cinnamic aldehyde, isoeugenol, hydroxycitronellal). Does the SCCNFP agree to restriction on the use of common fragrance allergens (Annex III listing)? If so :

- *Which fragrance materials should be subject to restrictions?*
- *What are the conditions for restrictions (maximum concentration, fields of applications, etc) ?*

Obviously, in response to each of the questions listed above, a scientific justification will be necessary.

During the 18th Plenary meeting of 25 September 2001, the SCCNFP adopted an opinion on an initial list of perfumery materials to be included in Annex III - List of substances which cosmetic products must not contain except subject to restrictions and conditions laid down - to Directive 76/768/EEC (doc. n° SCCNFP/0392/00 final).

The current opinion consists of an update of this list.

On the basis of the available information and assessment of the cutaneous toxicity of the substances tabulated, it is the recommendation of the Scientific Committee on Cosmetic Products and Non-Food Products intended for Consumers (SCCNFP) that these substances may be used as ingredients in cosmetic products only under the conditions and restrictions specified in the attached table.

Additional substances will be discussed for possible inclusion at a later date.

The opinion was adopted.

4.7. UV Filters & *ad hoc* substances

In his report, Dr. Lina said that one Working Group meeting had taken place since the plenary meeting of 20 October 2003, during which the following opinion had been prepared :

Choline Chloride, doc. n° SCCNFP/0672/03

The SCCNFP was requested to answer the following questions :

* *Does the safety profile documented in the attached submission support the use of choline chloride in cosmetic products?*

* *Does the SCCNFP propose any restrictions or conditions for the use of choline chloride in cosmetic products?*

In view of the extensive oral exposure from food, the SCCNFP concluded that dermal exposure to choline chloride, in rinse off products at 5%, is not anticipated to pose any serious risk.

Since it is a quaternary ammonium derivative, it may be a potential irritant. Before any further consideration, additional data on irritation (skin and mucous membrane) at the intended use concentrations and in accordance with the Notes of Guidance are required.

The opinion was adopted.

Diethyl phthalate, doc n° SCCNFP/0767/03

The Scientific Committee on Cosmetics and Non Food Products indented for Consumer adopted an opinion on Diethyl Phthalate, doc. n° SCCNFP/0411/01, during its 20th plenary meeting of 4 June 2002. In its opinion, the SCCNFP stated that the safety profile of diethyl phthalate supports its use in cosmetic products at current levels.

Recently, the European Commission received two publications on phthalates :

* Duty SM et al. (2003) "The Relationship between Environmental Exposures to Phthalates and DNA Damage in Human Sperm Using the Neutral Comet Assay", *Environm. Health Persp.* 111, 1164-1169.
* Barr DB et al. (2003) "Assessing Human Exposure to Phthalates using Monoesters and their Oxidised Metabolites as Biomarkers", *Environm. Health Persp.* 111, 1148-1151.

The SCCNFP has been requested to review the publications cited above and to answer the following questions :

* *Does the data provided in the attached publications change the overall assessment of diethyl phthalate as stated in the opinion of SCCNFP SCCNFP/0411/01 ?*

* *If yes, what does the SCCNFP recommend on the basis of the new data provided ?*

The SCCNFP concluded that the data provided in the above-mentioned publications do not change the overall assessment of diethyl phthalate as stated in its opinion on diethyl phthalate of 4 June 2002 (doc. n° SCCNFP/0411/01).

The opinion was adopted.

Furocoumarins in sun protection and bronzing products, doc n° SCCNFP/0765/03

The adaptation to technical progress of the Annexes to Council Directive 76/768/EEC of 27 July 1976 on the approximation of the laws of the Member States relating to cosmetic products. Commission Directive 95/34/DC of 10 July 1995 amended Annex II, reference number 358 as follows: "Furocoumarines (e.g. trioxysalan, 8-methoxypsoralen, 5-methoxypsoralen) except for normal content in natural essences used. In sun protection and in bronzing products, furocoumarines shall be below 1 mg/kg." The technical adaptation was based on an opinion adopted by the Scientific Committee on Cosmetology (SCC) in 1990. Furocoumarines are recognized to photomutagenic and photocarcinogenic. The SCC had not been able to conclude from the available scientific, technical and epidemiological data at that time that the association of protective filters with furocoumarines would guarantee the safety of sun protection and bronzing products containing furocoumarines above a minimum level. Therefore, in order to protect public health, furocoumarines were limited to less than 1 mg/kg (1 ppm) in these products.

The European Commission received in July 2003 a letter from Jean-Jacques Goupil indicating that new documents on the safety and efficacy of sun protection and bronzing products with an efficient dose of 15 to 60 ppm 5-methoxypsoralen had been transmitted to Health and Consumer Protection DG. Dr. Patricia Martin-Lamanthe supported the request by another letter in July 2003.

The SCCNFP is requested to answer the following question :

- *Does the data provided justify a higher limit for furocoumarins in sun protection and bronzing products?*
- *If yes, which limit for furocoumarines is scientifically justified in sun protection and bronzing products in association with UV-filters?*

SCCNFP concluded that the data available from *in vitro* short-term studies, experimental studies in animals, and epidemiological studies on humans on the effect of furocoumarines in sun protection and sun bronzing product do not justify a higher limit than 1 ppm (not to be intentionally added) for furocoumarines in cosmetics. This Opinion should be interpreted in conjunction with the Opinion on CMR substances (SCCNFP/0474/01, final, Adopted 25 September 2001)

The opinion was adopted.

5. Any Other Business

The next Plenary Meeting will be on 16 March 2004.

Attendance List

Present:	Mr	K.E. Andersen	Mr	J.-P. Marty	
	Mrs	C. Chambers	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	I.R. White	(Chairman)
	Mr	N. Loprieno			

Apologies:	Mr	R. Anton	
	Mr	J. Vives-Rego	

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