

Scientific Committee on Cosmetic and Non-Food Products

Minutes of the 25th Plenary Meeting

Brussels, 20 October 2003

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

1. Adoption of the Agenda, doc. n° SCCNFP/0749/03

The agenda was adopted.

2. Declaration of interests and confidentiality

Prof. Rogiers had previously declared an interest on three hair dyes on the agenda and would not participate in discussion of these. No other Member declared any interest that could prevent her/him from participating in the discussion of any of the items on the agenda. The members signed the annual declaration of confidentiality.

3. Approval of the minutes of the 24th plenary meeting of 24 – 25 June 2003, doc. n° SCCNFP/0723/03

The minutes were approved.

4. SCCNFP - Working Parties

4.1. Alternatives & Dossier

Report of the Co-ordinator

A detailed overview was given of the meetings and activities that have taken place since the process was started on 03.10.2002. Members of SCCNFP have also participated in the work of the Inter-committee Working Group on non-animal testing, where several comments on the document were made.

Prof. Loprieno said that the Alternatives WG meeting will take place on 12.11.03 and that part of the Notes of Guidance concerning mutagenicity will be discussed. It will be automatically incorporated into the Notes of Guidance when approved by SCCNFP.

Two draft opinions were prepared in the working group meetings :

- * Basic criteria for the in vitro assessment of percutaneous absorption of cosmetic ingredients, updated October 2003, doc. n° SCCNFP/0750/03
- * Notes of Guidance for the testing of cosmetic ingredients and their safety evaluation, doc. n° SCCNFP/0690/03

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 three Task Force and WG meetings had taken place since the previous plenary meeting of 24–25 June 2003, during which the following opinions had been prepared.

Opinions on :

* A 53, 2,4,5,6-Tetraaminopyrimidine	doc. n° SCCNFP/0695/03
* A 94, 2-Chloro-6—3-aminophenol HCl	doc. n° SCCNFP/0697/03
* A 138, 2,6-Dihydroxyethylaminotoluene	doc. n° SCCNFP/0678/03
* A 146, PEG-3,2',2'-di-p-phenylenediamine	doc. n° SCCNFP/0733/03
* B 60, 2-Nitro-5-glyceryl methylaniline	doc. n° SCCNFP/0688/03
* C 172, HC Blue n°14	doc. n° SCCNFP/0734/03
* Basic Orange 31	doc. n° SCCNFP/0736/03
* Basic Red 51	doc. n° SCCNFP/0735/03
* Basic Yellow 81	doc. n° SCCNFP/0735/03

The SCCNFP concluded that the information submitted on these substances was insufficient to allow a risk assessment to be carried out. Therefore, and before any further consideration, full safety data were requested.

The opinions were adopted.

4.5. Inventory

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

4.6. Preservatives & Fragrances

Report of the Co-ordinator

In his report, Prof. Kemper said that three WG meetings had taken place since the plenary meeting of 24–25 June 2003, during which the following opinions had been prepared:

Bergamottin, doc n° SCCNFP/0740/03

The SCCNFP is requested to answer the following questions :

* *Does the data provided justify an update of the “Initial List of fragrance” for n° 6 and n° 21 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 No 6 reads: *May be used in cosmetic products, provided that the total concentration of furocoumarin-like substances in the finished cosmetic product does not exceed 1 ppm.*

No 21 concerns Methyl N-methylantranilate and is not to be addressed in this Opinion.

The present Opinion will primarily deal with questions concerning photomutagenicity of bergamottin.

The SCCNFP concludes that it has insufficient information regarding the photo-toxic potential of bergamottin to perform an adequate safety evaluation. Consequently, the SCCNFP is unable to provide an update of entry n° 6 of Table 1 - List of perfumery materials which must not form part of cosmetic products except subject to the restrictions and conditions laid down – of the opinion concerning 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/0392/00 of 25.09.01).

Also data on its mutagenic/genotoxic potential are needed.

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 24–25 June 2003, during which the following opinion had been prepared :

Benzoic acid, 2-[4-(diethylamino)-2-hydroxybenzoyl]-, hexylester, doc. n° SCCNFP/0650/03

The SCCNFP is requested to answer the following questions :

* *Is benzoic acid, 2-[4-(diethylamino)-2-hydroxybenzoyl]-, hexylester safe for use in cosmetic products as a UV filter up to 10 %?*

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

The SCCNFP is of the opinion that the use of benzoic acid, 2-[4-(diethylamino)-2-hydroxybenzoyl]-, hexylester up to 10% in sunscreen products, alone or in combination with other UV absorbers, is safe.

The opinion was adopted.

Consultation paper on Risks and Health Effects from Tattoos, Body Piercing and Related Practices, doc. n° SCCNFP/0751/03

The SCCNFP was asked :

1. *To assess the overall scientific quality of the report titled “Risks and Health Effects from Tattoos, Body Piercing and Related Practices”. In considering this, The Committee is asked to comment as to whether the report has identified and reviewed to a satisfactory degree the types of risks and health effects that are associated with tattoos and body piercing.*
2. *To identify additional risks and adverse health effects that the report should include in order for it to be complete and comprehensive.*
3. *To advise the Commission on the types of activities (studies, research, epidemiology, prevalence, etc) that need to be undertaken in order to establish a solid data base on the size and severity of the risks and health effect associated with tattoos and body piercing.*

An Opinion of The Scientific Committee on Cosmetic Products and Non-Food Products intended for Consumers concerning the Safety of Tattoos was adopted by the SCCNFP during the 11th Plenary meeting of 17 February 2000.

It was pointed out that as tattoos are administered by injection of appropriate inks intradermally, they do not fall under the Cosmetics Directive. The recitals of the original Directive 76/768/EEC demonstrate that this is the case. The 5th Whereas of the preamble of the Directive states :

"Whereas this Directive relates only to cosmetic products, whilst products containing substances or preparations intended to be ingested, inhaled, injected or implanted in the human body do not come under the field of cosmetics;"

Tattoos are widely used to adorn the human body. Pigments are applied permanently into the skin. This procedure is also used for cosmetic purposes, the so-called ‘permanent makeup tattooing’ e.g., lip lining, eyebrow lining.

A large number of colours and pigments are used. In part the chemical identity of these agents as well as their toxicological characterisation is incomplete or unknown. Thus their safety evaluation is not possible.

Well-recognised adverse effects of tattoos are known. Examples of these include amongst others granuloma formation, phototoxicity, contact dermatitis, and koebnerisation of skin diseases such as psoriasis and lichen planus.

Important additional health concerns include the transmission of infective agents such as human papilloma viruses, hepatitis and HIV.

For the adequate assessment of the toxicological aspects of tattoos it is necessary for the chemical identity of the colours and pigments to be provided. Therefore, it was recommended that the identity of these substances and materials (e.g., tools and appliances) used in the procedure be obtained so that a formal assessment could take place.

The JRC was requested by DG SANCO to collect and assess all necessary information for establishing a common knowledge basis for the conception of future EU legislation. These organizations are also working with the Council of Europe which is preparing a resolution on 'permanent make-up and tattooing colours'.

The document "Risks and Health Effects from Tattoos, Body Piercing and Related Practices" provides a competent review of the recognised adverse effects of tattoos and body piercings and possible associations with others; it demonstrates the need to establish the characterisation of the substances and materials used in the procedures. The report has identified and reviewed to a satisfactory degree the types of risks and health effects that are associated with tattoos and body piercing and has indicated where there is insufficient knowledge.

There is only a brief discussion of the role of ear piercing and the development of allergic contact sensitivity to nickel. However, the Nickel Directive (94/27/EEC), if properly enforced, should minimise this important association. Piercing may cause hypertrophic scarring, particularly in Afro-Caribbeans.

It is acknowledged that the document does not deal with so-called 'temporary tattoos' as they are skin stains. However, use of these products may pose a risk to health as discussed in document n° SCCNFP/0442/01 of 17 February 2000.

The following are required to be undertaken in order to establish a solid database on the size and severity of the risks and health effect associated with tattoos and body piercing:

Establishing the chemical identity of the substances used as tattoo pigments and products for piercing; quantities used and batch variations. Data on impurities of the products used, the long-term stability of the pigments applied and on the degradation of products related to the removal of them.

Risk assessment of chemicals/products used following Notes of Guidance for Safety Evaluation, i.e. the bioavailability (systemic exposure) of the constituents including their major impurities (possibly aromatic amines) following intradermal application should be analysed.

Formulation of a 'positive list'.

Licensing of premises/individuals undertaking procedures to ensure appropriate standards to reduce microbiological risks, suitability of individuals to receive procedures. 'Clinical standards'.

Comprehensive record keeping to allow prospective studies.

6. Report of the Chairman

* Alpha hydroxy acids: the SCCNFP would refer to its position paper concerning Alpha-hydroxy acids, adopted on 28 June 2000 (doc. n° SCCNFP/0370/00). Subsequently, meetings were held at the Commission to discuss the information required to address the safety issues discussed in the document. At present, no new information has been received to address the concerns. Therefore the recommendations made in document SCCNFP/0370/00 remain unchanged.

* Opinion concerning the use of specified risk material in cosmetics, clarification for tallow derivatives. Opinion adopted by the SCCNFP on 30.07.2003 by means of the written procedure.

* Mandate from DG ENTR requesting clarification by the SCCNFP concerning its opinion on hydrogen peroxide tooth-bleaching agents. The SCCNFP was asked :

i) to clarify the statement “under the supervision of dentist” having in mind this question related to “Take home products” that are freely available to the consumers (i.e. distribution not restricted to healthcare professionals).

ii) to clarify the statement “due to the degradation of hydrogen peroxide in the oral cavity, it is unlikely that the use of tooth whitener will present a cancer risk in persons that do not have an increased risk of oral cancer due to tobacco use, alcohol abuse or genetic predisposition” as it pertains to the risk of cancer to certain populations subgroups that may be associated with the use these products. If such risk exists, the SCCNFP is asked to quantify it if this is possible on the basis of data already submitted to SCCNFP.

It is known that tobacco and alcohol abuse causes an increased risk of oral cancer. Hydrogen peroxide may enhance the risk. The risk cannot be quantified. It is not anticipated that tooth whitening products will represent the risk of oral cancer in people not using tobacco or abusing alcohol. These whitening products should only be used under the surveillance of a dentist. The product should not be freely available to consumers.

7. Any Other Business

The next Plenary meeting will be on 9 December 2003.

Attendance List

Present :	Mr	K.E. Andersen	Mr	J. Parra	
	Mrs	C. Chambers	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 R	
	Mr	N. Loprieno	Mr	I. R. White (Chairman)	
	Mr	J.-P. Marty			
	Commission :	Mr	T. Daskaleros	DG SANCO	
		Mrs	T. Peetso	DG SANCO	
		Mrs	R. Schumann	DG ENTR	
Mr		A. Van Elst	DG SANCO		
Apologies	Mr	A. Di Domenico			