Scientific Committee on Cosmetic and Non-Food Products

Minutes of the 19th Plenary Meeting

Brussels, 27 February 2002

Dr. Ian R. White, the chairman of the SCCNFP, welcomed all participants and said that he had asked Dr. Suresh Rastogi, member of the committee, to give a lecture on the presence of fragrance allergens in non-cosmetic consumer products.

1. Fragrance materials in non-cosmetic consumer products

Dr. Rastogi described and commented on the chemical analyses performed to demonstrate the presence – frequency and concentration - of potential fragrance allergens in detergents and household cleaning products.

The lecture was followed by a discussion, which focussed mainly on trends on the use of fragrance materials in these types of consumer products.

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

The agenda was adopted.

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 18th plenary meeting of 25 September 2001, doc. n° SCCNFP/0516/01

The minutes were approved.

5. SCCNFP - Specific Working Parties

5.1 Alternatives

Report of the Co-ordinator

Prof. Loprieno said that no meeting of the Working Party had taken place since the previous plenary meeting of 25 September 2001. However, WP meetings have been planned to revise and update the consumer exposure data as well as the related annexes in the SCCNFP Notes of Guidance.

A complete revision of the Notes of Guidance is envisaged at a later stage.

In this context, the committee invited DG ENTR to keep them informed about the acceptance and status of their document 'Understanding the Principles of Safety Evaluation of Finished Cosmetic Products (considering a ban on animal testing).

5.2 Detergents & Similar Household Products

Report of the Co-ordinator

In his report, Prof. Vives Rego said that the following documents and/or requests for information had recently been sent to industry (AISE) :

- a preliminary discussion paper on an inventory of detergent ingredients;
- a request for data on the use of biocides, including preservatives, in hand-washing and surface cleaning products to analyse and quantify the risk related to the exposure to this type of agents.
- the WP's comments on 3 HERA (Human and Environmental Risk Assessment, an AISE/CEFIC project) documents concerning human and environmental effects of detergents ingredients.

A meeting with AISE has been planned on 22 April to discuss these issues.

Position Statement on Consumer Safety of Detergents, Household and similar Products, doc. n° SCCNFP/0551/02

Prof. Vives Rego reported on the proposed revision of the EU detergents legislation. He said that in August 2001, DG ENTR ran an internet consultation on the subject of a proposed revision of the detergents legislation. Stakeholders' opinions were invited on the text of the draft proposal for a Regulation. In the draft, new provisions were included which made reference to the SCCNFP and in particular to the risk evaluation to be undertaken by the SCCNFP of detergent substances or preparations which are irritant or sensitising for man.

After consideration of the replies received, the reference to the SCCNFP has been withdrawn from the draft proposal because it was believed that the consumer would be sufficiently informed and protected through the labelling provisions provided for by the dangerous substances and/or the dangerous preparations directives.
The committee argued that these labelling provisions are insufficient : the label must allow the consumer to avoid products (detergents or any other household cleaning product) containing specific substances to which they are allergic. This kind of information can only be provided for by complete labelling of the ingredients. Moreover, it was stressed that the committee can play an important role by reviewing the safety of possible 'problem'-substances.

The position statement was adopted.

5.3 Exposure & Risk Assessment

Report of the Co-ordinator

Prof. Schaefer reported on the following items :

- *Position statement on the calculation of the Margin of Safety for ingredients used in cosmetics which may be applied to the skin of children, doc. n° SCCNFP/0557/02* : key issue is whether there is a need for a special Margin of Safety for ingredients used in cosmetics, and in particular sun screen products, especially designed for children.

Taking into account that (i) human skin matures in the first days to weeks after birth, (ii) the ratio of the SA/BW (skin surface area / body weight) of children of one to two year and of adults is about 1.7, and that (iii) the variation in toxico-kinetics (in the case of cosmetics = percutaneous absorption) is covered by the respective factor for inter-individual variation, there is no scientific justification to add an extra uncertainty factor due to a larger exposure surface area in children over the age of one year.

However, Prof. Schaefer said that special attention should be given to baby care products, and in particular those used under occlusion and in the napkin zone.
Therefore, industry will be asked to provide data on the specifications of ingredients of concern such as preservatives, perfume, or detergents used in baby care products. Particular attention should be paid to ingredients of small molecular weight such as fragrances, preservatives, colorants, volatile compounds (e.g. alcohol), impurities in pigments or other “active ingredients”.

The Position Statement was adopted.

- *Revision of the calculation of the Margin of Safety* : Prof. Schaefer explained that if the calculation of the MOS is based on a percentage of percutaneous absorption, the result depends on the mass/volume of the material applied on the skin site or skin sample. An application of more than 2 mg/cm² or 5µl/cm² results in a lower percentage of percutaneous absorption and consequently in an unrealistically high MOS.

A draft revision of the calculation of the MOS was tabled, proposing to calculate the Systemic Exposure Dose (SED) by multiplying the percutaneous absorption, expressed in mg/cm², with the surface area of intended use, instead of transforming experimental data into a percentage and subsequently re-transforming it into mg/cm^2. The new approach has the additional advantage that it allows to better differentiate the safety assessment of the various classes of cosmetic products. As a result, the committee invited its WP ‘Alternatives & Dossier’ to take this approach into consideration while updating the Notes of Guidance.

- *Percutaneous absorption* : Prof. Schaefer presented a paper highlighting key statements on the use of data of percutaneous absorption in the safety assessment of cosmetics. Also this paper was addressed to the WP ‘Alternatives & Dossier’ in the framework of the updating of he Notes of Guidance.

- *Harmonisation of risk assessment* : Prof. Schaefer said that the most relevant items of the Scientific Steering Committee’s first report on the harmonisation of risk assessment procedures

had been discussed and that the WP would propose to modify the format of the opinions according to the standardised format for the presentation of risk assessment findings as presented in the SSC's document.

Also, this item has been added to the list of issues to be considered in the framework of the complete revision of the SCCNFP Notes of Guidance.

5.4 Hair Dyes & Colorants

Report of the Co-ordinator

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

- 3 draft opinions on hair dyes, an opinion on certain azo-dyes and a discussion paper on 'assessment strategies for hair dyes' had been finalised and presented for adoption.

- Lawsone : further genotoxicity studies had been received since the adoption of the opinion on Lawsone during the 16th plenary meeting of 13 March 2001.

Discussion paper on "assessment strategies for hair dyes", doc. n° SCCNFP/0553/02

As a follow-up of the SCCNFP opinion on the use of permanent hair dyes and bladder cancer risk, a discussion paper on "Assessment strategies on hair dyes" was drafted.

The main reasons to draft the paper were :

* a robust epidemiological investigation within Europe would take years to complete and there is a need for measures to be introduced to protect the European consumer in the interim;
* a considerable number of permanent hair dyes are used whose safety has not yet been assessed by public authorities.

The paper specifies the safety data to be submitted. Moreover, a dossier must contain a statement saying that the dossier is complete (cf. Memo on evaluations and opinions, SCCNFP/0461/01) as well as a checklist confirming that each of the endpoints of the toxicological profile conforms to modern methods or if not, a statement of why it should be accepted with scientific reasons. Opinions will be based on the safety data submitted. Complementary to its conclusion, the committee will indicate, if applicable, which further data are required before any re-assessment.

The Committee adopted the discussion paper and invited interested parties for their comments.

Opinion on A7 : para-Phenylenediamine (PPD), doc. n° SCCNDP/0129/99

The SCCNFP was requested to evaluate the safety of PPD when used as an oxidising colouring agent for hair dyeing up to a maximum permitted concentration of 4% (free base) in the finished (marketed) cosmetic product.

As a result, no final conclusion could be made on the basis of the submitted dossier regarding the genotoxicity of PPD although there are indications of some genotoxic potential. Therefore, and before any further assessment, additional data would be required on the carcinogenicity of PPD in combination with hydrogen peroxide and couplers (to simulate consumer exposure) upon application to rat's skin, and on the *in vivo* mutagenicity/genotoxicity of the combinations.

The opinion was adopted.

Opinion on B104 : Tetrahydro-6-nitroquinolaxine, doc. n° SCCNFP/0503/01

The SCCNFP was requested to evaluate the safety of tetrahydro-6-nitroquinolaxine when used as a hair dye up to a final concentration of 1.0% on head in the presence or absence of a developer-mix.

As a result, no final conclusions could be made on the basis of the submitted dossier. Further data on *in vivo* mutagenicity/genotoxicity are needed before any re-assessment.

The opinion was adopted.

Opinion on C64&C61 : Disperse Violet 1 impurified with Disperse Red 15, doc. n° SCCNFP/0504/01

The SCCNFP was requested to evaluate the safety of Disperse Violet 1 impurified with Disperse Red 15 when used in colour setting lotions at a maximal concentration of 2 %.

As a result, no final conclusions could be made on the basis of the present dossier. Further data on percutaneous absorption, allergenicity and *in vivo* mutagenicity/genotoxicity are needed before any re-assessment.

The opinion was adopted.

Opinion on C146 : Lawsone, doc. n° SCCNFP/0561/02

During the 16th Plenary meeting of 13 March 2001, the SCCNFP adopted an opinion on lawsone saying that the substance was not suitable for use as a non-oxidising colouring agent for hair dyeing on the basis of its mutagenic and clastogenic potential *in vitro* and *in vivo*.

Additional genotoxicity data had been received and evaluated.

As a result, the SCCNFP concluded there was no scientific basis to modify the opinion on Lawsone adopted on 13 March 2001.

The opinion was adopted.

Opinion on the use of certain Azo-dyes in cosmetic products, doc. n° SCCNFP/0495/01

The SCCNFP was requested to review the safety of 4 azo-dyes : CI 12150, CI 20170, CI 26100 and CI 27290. The concern is that these dyes, currently listed in Annex IV, can be cleaved into carcinogenic amines.

The evaluation made was based on published literature only and focused on the mutagenic and carcinogenic potential of these dyes.

As a result, the SCCNFP concluded that these four azo-dyes may release one or more carcinogenic amines and consequently pose a health risk.

The opinion was adopted.

5.5 Inventory

Report of the Co-ordinator

In the absence of Prof. Parra, Prof. Kapoulas said that, since the previous plenary meeting of 25 September 2001, only one meeting of the WP had taken place during which the use of botanicals in cosmetic products was discussed.

A list of botanicals, taken from section I of the 1st update of the inventory, was sent to industry asking to specify which of these botanicals are actually used in cosmetic products and, for those that are used, which part of the plant is used, the type of extract and the relevant use concentration.

Concerning the 2nd update of the inventory, the Committee expressed its regret that this work had not yet been started and therefore invited the Commission to initiate this important task without delay.

5.6 Preservatives & Fragrances

Report of the Co-ordinator

Prof. Kemper said that a series of draft opinions on '+'-marked preservatives had been finalised and tabled for adoption.

Also, Prof. Kemper said that it became obvious that no proper risk assessment could be performed on the basis of the additional data submitted on the 'other uses' of these preservatives. Thus an internal memorandum had been drafted to clarify the procedure for a proper evaluation of the safety data submitted on these "other uses". The memorandum states that a completely new and up-to-date safety dossier must be submitted when the committee is requested to perform a risk assessment on the 'other uses' of a particular preservative listed in Annex VI of the cosmetics directive.

Opinion on P8 : Hexamidine and its salts, including di-isethionate and di(p-hydroxybenzoate), doc. n° SCCNFP/0514/01

The committee was requested to answer the question whether hexamidine and its salts can be safely used for non-preservative purposes in face care products (leave on and rinse off) at a maximum concentration of 0.2 %.

As a result, the committee concluded that the information submitted was insufficient to allow an adequate risk assessment to be carried out on the 'other uses' of P8. Before any re-assessment, the committee requires a complete and up-to-modern-standards dossier not only on hexamidine but also on its salts (including di-isethionate and di(p-hydroxybenzoate)).

The opinion was adopted.

Opinion on P59 : Piroctone olamine and its monoethanolamine salt, doc. SCCNFP/0525/01

The committee was requested to answer the question whether Piroctone olamine and its monoethanolamine salt can be safely used for non-preservative purposes in face care products (leave on) at a maximum concentration of 1.0 %.

As a result, the committee concluded that the information submitted was insufficient to allow an adequate risk assessment to be carried out on the 'other uses' of P59. Before any re-assessment, the committee requires a complete and up-to-modern-standards dossier not only on piroctone olamine but also on its monoethanolamine salt.

The opinion was adopted.

Opinion on P70 : Benzethonium chloride, doc. n° SCCNFP/0539/01

Benzethonium chloride is presently listed in Annex VI, part 1 – list of preservatives allowed – at a maximum authorised concentration of 0.1 % in rinse-off products only.

The committee was requested to evaluate the safety of benzethonium chloride when used as a preservative in rinse-off and leave-on products except oral care products at a maximum authorised concentration of 0.1%.

As a result, the committee concluded that the data provided in the submitted dossier does not support the safe use of Benzethonium chloride as a preservative in leave-on products at a maximum authorised concentration of 0.1%. However, its present use as a preservative in rinse-off products at a maximum authorised concentration of 0.1 % is considered safe.

The opinion was adopted.

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 25 September 2001.
A meeting is planned on 26 March 2002 to discuss, amongst others, the use of sunscreens by children.

6. Report of the Chairman

Report of the Chairman

In his report, Dr. White said that the committee had 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/0552/02

Recently Commission Decision 2001/2/EC was repealed by Commission Regulation (EC) n° 1326/2001/EC of 29.6.2001 laying down transitional measures to permit the changeover to the Regulation (EC) No 999/2001 of the European Parliament and of the Council of 22 May 2001 laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies.

The current definition for Specified Risk Material is found in Annex V of the latter legislative text and according to Article 3 1(g) does not include products containing or derived from those tissues unless indicated otherwise. There is also no exception made for tallow derivatives that may be used if defined methods have been used to prepare.
Because the designation of specified risk material is dynamic progress and in order to avoid the systematic consultation of the SCCNFP each time the designation of specified risk material is updated, the SCCNFP was asked (i) whether the use in cosmetics of specified risk materials as defined in Regulation No. 999/2001 presents a health risk to consumers, (ii) whether this list should be supplemented regarding ingredients derived from specified risk materials and (iii) whether exceptions should be made for tallow derivatives provided that specific methods have been used to prepare them?

Based on the information presented in the opinion adopted by the Scientific Steering Committee and in the respective EU legislative texts concerning specified risk material (SMR) and concerning certain transmissible spongiform encephalophathies, the SCCNPF concluded that :

* the specified risk materials as defined in Regulation No. 999/2001 represent a health risk to consumers, and that

* this list should be supplemented by the ingredients derived therefrom. However, exceptions may be made regarding tallow derivatives provided that adequate production methods have been used and strictly certified by the producer.

The opinion was adopted.

7. Any Other Business

* The committee was briefed about the status of the 7th Amendment of the cosmetics directive 76/768/EEC. Dr Schumann, DG ENTR, said that the common position, adopted by the Council has been set to the European Parliament (second reading foreseen in June 2002).

* next meeting : 4 June 2002

Attendance List

Present	:	Mr	R. Anton	Mr	J.-P. Marty
		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)
Apologies	:	Mr	K.E. Andersen		
		Mr	J. Parra		
Commission	:	Mrs	V. Barwig	DG SANCO	
		Mrs	S. Clarke	DG SANCO	
		Mr	T. Daskaleros	DG SANCO	
		Mr	A. Sanabria	DG SANCO	
		Mrs	R. Schumann	DG ENTR	
		Mr	A. Van Elst	DG SANCO	
		Mr	M. Walsh	DG SANCO	