Scientific Committee on Cosmetic and Non-Food Products

Minutes of the 24th Plenary Meeting

Brussels, 24 – 25 June 2003

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

1. Adoption of the Agenda, doc. n° SCCNFP/0716/03

The agenda was adopted.

2. Declaration of interests and confidentiality

No 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 23rd plenary meeting of 18.3.03, doc. n° SCCNFP/0664/03

The minutes were approved.

5. SCCNFP - Working Groups

5.1 Alternatives

Report of the Co-ordinator

Prof. Loprieno said that, since the previous plenary meeting one meeting of the WG had taken place during which a first draft of the revised Notes of Guidance were presented and discussed. The revision should be finalised before the end of the current mandate (end November 2003).

5.2 Detergents, Household & similar Products

Report of the Co-ordinator

Prof. Vives Rego said that two meetings had taken place since the last plenary meeting of 18 March 2003 during which the following papers have been prepared :

Final report of the WG 'Detergents, Household and similar Products', doc. n° SCCNFP/0701/03

The paper gives an overview of the work done by the Working Group and is annexed to these minutes (annex 1).

Azole antimycotic resistance, doc. n° SCCNFP/0706/03

In addition to its opinions on the use of ketoconazole in cosmetics (doc. n° SCCNFP/0164/99 and SCCNFP/0601/02), the SCCNFP was asked to give its opinion on the safe use of azoles in cosmetic products and to answer the following questions :

- *Does SCCNFP see any possibility for the development of resistance or cross-resistance by fungi to azole fungicides (including ketoconazole and clotrimazole), if these substances are used in cosmetic products?*

- *Does SCCNFP propose any recommendations on concentration at which azole fungicides (including ketoconazole and clotrimazole) can be used in cosmetic anti-dandruff shampoos?*

The SCCNFP confirmed its earlier opinions, namely that there is at present no scientific evidence of development of resistance or cross-resistance of fungi to azole fungicides (including ketoconazole and clotrimazole) used in cosmetics.

The opinion was adopted.

5.3 Exposure & Risk Assessment

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

5.4 Hair Dyes & Colorants

Report of the Co-ordinator

In his report, Prof. Andersen said that several Task Force and WG meetings had taken place since the previous plenary meeting of 18 March 2003 during which the following opinions had been prepared.

He also mentioned that industry representatives were invited on 27 May 2003 to present and illustrate their comments on the SCCNFP proposal for a "Strategy for Testing Hair Dye Cosmetic Ingredients for their Potential Genotoxicity / Mutagenicity", doc. n° SCCNFP/0566/02.
Although the industry endorsed the SCCNFP proposal, the main difference between the approach from industry and the SCCNFP proposal was that industry would only evaluate the precursors and reaction products (as they considered that the intermediates are too short living be

to of toxicological concern), whereas the SCCNFP proposes to evaluate the precursors and the mixture (precursors, intermediates and reaction products) to which the consumer is exposed.

Updated recommended strategy for testing hair dyes for their potential genotoxicity/ mutagenicity/carcinogenicity, doc. n° SCCNFP/0720/03

On 13 March 2003, COLIPA submitted to DG ENTR industry response to the SCCNFP proposal for a Strategy for Testing Hair Dye Cosmetic Ingredients for their Potential Genotoxicity / Mutagenicity", doc. n° SCCNFP/0566/02. Further to this submission, DG ENTR issued a mandate to the SCCNFP asking whether :

- *industry's proposal is in line with the SCCNFP proposal and with the SCCNFP assessment strategy for hair dyes (doc. n° SCCNFP/0553/02).*

- *the data generated according to the industry proposal are sufficient to perform a risk assessment of the material to which the consumer is exposed.*

In response to this mandate and further to the discussion with industry expert on 27 May 2003 (see above), an updated recommended strategy was drafted.

There was a general consensus on this draft. The paper was adopted

Opinions on :

* A143, 2,5,6-Triamino-4-pyrimidinol sulfate, doc. n° SCCNFP/0710/03
* B5, Disperse Red 17, doc. n° SCCNFP/0677/03
* B36, HC Red n° 7, doc. n° SCCNFP/0678/03
* B 56, 6-Nitro-o-toluidine, doc. n° SCCNFP/0682/03
* B60, 2-Nitro-5-glyceryl methylaniline, SCCNFP/0688/03
* B63, HC Yellow n° 11, SCCNFP/0660/03
* B68, HC Orange n° 3, SCCNFP/0676/03
* B69, HC Yellow n° 9, SCCNFP/0680/03
* B80, HC Yellow n° 7, SCCNFP/0675/03
* B102, HC Yellow n° 13, SCCNFP/0689/03
* C10, Basic Yellow 57, doc. n° SCCNFP/0679/03

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, appropriate safety data were requested.

The opinions were adopted.

5.5 Inventory

No activities have been taken place in this area.

5.6 Preservatives & Fragrances

Report of the Co-ordinator

In his report, Prof. Kemper said that one WG meeting had taken place since the plenary meeting of 18 March 2003, during which the following opinions had been prepared :

P56, update of entry n° 39 of Annex VI to Directive 76/768/EEC, doc n° SCCNFP/0670/03

P56, the mixture of 5-Chloro-2-methyl-isothiazolin-3(2H)-one and 2-Methylisothiazolin-3(2H)-one with magnesium chloride and magnesium nitrate is currently listed in Annex VI, part 1 and consequently allowed for use in cosmetic products under the conditions and restriction laid down in the Annex. According to Annex VI, only magnesium chloride and magnesium nitrate may be used as stabilisers.

Since modern manufacturing processes and formulation techniques have made it possible to reduce the amount of magnesium nitrate and chloride stabiliser needed, or even replace it entirely with other alternative stabilisers, e.g. copper sulfate, the European Commission was asked to allow the use of copper sulfate as stabilising system, or to delete from the entry n° 39 of Annex VI any reference to stabilisers.

The SCCNFP concluded that, taking into account that the active ingredients and their ratio remain unchanged and that the concentration of the stabiliser system in the finished cosmetic products is negligible, the replacement of magnesium chloride and magnesium nitrate by copper sulfate or any other authorised cosmetic ingredient as a stabiliser system in the mixture of 5-Chloro-2-methyl-isothiazolin-3(2H)-one and 2-Methylisothiazolin-3(2H)-one does not alter the toxicological profile of this mixture.

The opinion was adopted.

Essential oils, doc. n° SCCNFP/0673/03

Directive 2003/15/EC of the European Parliament and of the Council of 27 February 2003 amending Council Directive 76/768/EEC on cosmetic products (7th amendment) states that :

- Certain substances have been identified as an important cause of contact-allergy reactions in fragrance-sensitive consumers. In order to ensure that such consumers are adequately informed, it is therefore necessary to amend the provisions of Directive 76/768/EEC to require that the presence of these substances be mentioned in the list of ingredients. This information will improve the diagnosis of contact allergies among such consumers and will enable them to avoid the use of cosmetic products which they do not tolerate ("Whereas" n° 15).

- A number of substances have been identified by the SCCNFP as likely to cause allergenic reactions and it will be necessary to restrict their use and/or impose certain conditions concerning them ("Whereas" n° 16).

- Perfume and aromatic compositions and their raw materials shall be referred to by the word “perfume” or “aroma”. However, the presence of substances, the mention of which is required under the column “other limitations and requirements” in Annex III, shall be indicated in the list irrespective of their function in the product (Article 1.4.).

The European Commission received from federations representing part of the essential oil industry data to justify that such a regulation should not apply for natural ingredients and asked the SCCNFP to answer the following question :

* *Does the data provided justify that the opinions given by the SCCNFP on fragrance allergy in consumers do not apply to essential oils?*

During the 10th plenary meeting of 8 December 1999, the Scientific Committee on Cosmetic Products and Non-Food Products intended for consumers (SCCNFP) adopted an opinion concerning fragrance allergy in consumers (doc. n° SCCNFP/0017/98). The paper is an analysis of the need for appropriate consumer information and identifies fragrance allergens. Additionally, the SCCNFP adopted during the 14th plenary meeting of 24 October 2000 an opinion concerning oakmoss/treemoss extracts and appropriate consumer information.

So far, the SCCNFP has identified 26 fragrance ingredients for which there is a need to provide the consumer with information when they are present in cosmetic products.

Because of the lack of dose/elicitation data for these substances, the SCCNFP has been unable to provide recommendations on levels above which the information to the consumer would be necessary. However, for practical risk management reasons, it was proposed that for leave-on products this level should be 10 ppm in the finished cosmetic product and for rinse-off products, a working level ten times higher than that recommended for leave-on products (doc. n° SCCNFP/0450/01, adopted on 13 March 2001).

The above-mentioned opinions of the Scientific Committee on Cosmetic Products and Non-Food Products intended for consumers (SCCNFP) concerning fragrance allergy in consumers are based on and supported by an extensive number of studies, published in leading scientific journals. None of these studies indicates a difference in allergenicity between a fragrance ingredient synthetically produced or extracted from a natural product. An important problem with fragrance substances of ‘natural origin’ is the difficulty of quality control. There may be considerable variation in the content of toxic/sensitising chemicals; oakmoss is an example. There is no demonstration in the peer reviewed scientific literature that fragrances compounds of natural origin are ‘safer’ than synthetics.

On review of the information submitted, the SCCNFP concluded that the data provided did not justify that the opinions adopted by the SCCNFP concerning fragrance allergy in consumers do not apply to essential oils.

The opinion was adopted.

5.7. UV Filters & Absorbers

In his report, Dr. Lina said that 4 Task Force and Working Group meetings had taken place since the plenary meeting of 18 March 2003, during which the following opinions had been prepared :

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

Further to a request for inclusion of Benzoic acid, 2-[4-(diethylamino)-2-hydroxybenzoyl]-, hexylester in Annex VII, part 1 – List of permitted UV Filters which Cosmetic Products may contain – to Council Directive 76/768/EEC, the SCCNFP was asked 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?*

As a result, the SCCNFP concluded that the information submitted was in part inadequate to allow a risk assessment of this substance to be carried out. Consequently, and before any further consideration, an adequate *in vitro* percutaneous absorption study is required.

As to a safety assessment of an use of UV-filters by children over the age of 1 year, the SCCNFP issued a position statement (SCCNFP/0557/02).

The opinion was adopted.

Zinc oxide, doc. n° SCCNFP/0649/03

Further to a request for inclusion of Zinc oxide in Annex VII, part 1 – List of permitted UV Filters which Cosmetic Products may contain – to Council Directive 76/768/EEC, the SCCNFP was asked to answer the following questions :

- *Is Zinc oxide safe for use in cosmetic products as a UV filter up to 25 %?*

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

The main concern of the present evaluation was related to the risk assessment of micronised (approximately 0.2 μm) ZnO, which may be coated by other compounds, and which is used as an ingredient in sunscreen formulations.

As a result, the SCCNFP concluded that :

* a considerable part of the investigations and their results submitted have been performed 15 or more years ago and consequently cannot fulfil modern requirements. However, there is a broad basic knowledge on Zn^{2+} and its compounds, e.g. ZnO.

* The physico-chemical specifications of ZnO used in many of the studies are incomplete, the purity/impurities not specified. On the other hand, ZnO is practically insoluble in water. Thus, in general, ZnO may be considered as a non-toxic substance, including when used in cosmetic products.

* Micronised ZnO has been demonstrated to be photoclastogenic, possibly photo-aneugenic, and a photo-DNA damaging agent in mammalian cells cultured *in vitro*. The relevance of these findings needs to be clarified by appropriate investigations *in vivo*.

* There is a lack of reliable data on the percutaneous absorption of micronised ZnO and the potential for absorption by inhalation has not been considered.

Based on the above, the SCCNFP concluded that there more information is needed to enable a appropriate safety evaluation of micronised Zinc oxide for use as a UV filter in cosmetic products. Consequently, an appropriate safety dossier on micronised ZnO itself, including possible pathways of cutaneous penetration and systemic exposure, is required.

As to a safety assessment of an use of UV-filters by children over the age of 1 year, the SCCNFP issued a position statement (SCCNFP/0557/02).

The opinion was adopted.

Methyl acetate, doc. n° SCCNFP/0694/03

The Danish EPA has received a request from a poison information department in a hospital regarding the regulation of methyl acetate in cosmetics. A child had played with a bottle of nail polish remover containing 50 w/w % methyl acetate and there was suspicion that it had ingested some of the product. At a concentration of 50 w/w % methyl acetate, the lethal dose for humans might be 14 g of nail polish remover. The Danish EPA found it not unlikely that children could risk methanol poisoning if nail polish removers are not properly stored/contained.

The SCCNFP was asked to answer the following question :

* *Is the use of methyl acetate in cosmetic products safe?*

* *Is there a need for setting a concentration limit for the use of this substance in cosmetic products?*

* *Is there a need to set restrictions on which products methyl acetate can be used in?*

* *Is there a need for an obligatory warning label regarding the storage conditions, taking into account the risk for children using cosmetic products containing the ingredient ?*

The SCCNFP concluded that the use of methyl acetate, as such, in cosmetic nail polish removers can be considered as safe. However, and in order to assess the risk when used in cosmetic products other than nail polish removers, a complete safety dossier, according to the Notes of Guidance (doc. n° SCCNFP/0321/00) should be submitted although it is unlikely that, considering its toxicity profile, methyl acetate would be used in cosmetic products other than

nail polish removers. Moreover, the imposition of safety measures, such as child-safe bottle, the use of colouring agents that are not easily confused with soft drinks or particular labelling, are considered as 'risk management measures' and therefore fall out of the field of competence of the SCCNFP.

The opinion was adopted.

Fluorine compounds in oral hygiene products for children under the age of 6 years, doc. n° SCCNFP/0653/03

Currently twenty fluorine compounds are approved and may be used in oral hygiene products up to a maximum authorised concentration in the finished products of 0.15 % (1500 ppm), calculated as fluorine Annex III, part 1, entries n° 26 to 42, 47 and 56. When one fluorine compound is mixed with other permitted fluorine compounds, the total F-concentration must not exceed 0.15 %.

The Commission has received a request from a Member State for the restriction of the concentration of fluorine compounds in oral hygiene products used by children under the age of 6 years. Although fluorides give an important aid in preventing dental caries, children might absorb an excessive amount of fluorine by swallowing toothpaste. This may cause fluorosis. Therefore, the Member State requests to limit the maximum authorised concentration in oral hygiene products used by children under the age of 6 years to 0.05 % (500 ppm) and to put the following conditions of use and warnings which must be printed on the label :

* The amount of the toothpaste on the brush must have the size of a pea.

* Children must rinse their mouth well and spit out the toothpaste after brushing.

The SCCNFP was asked to answer the following questions :

- *Is the use of fluorine compounds in oral hygiene products as regulated in 76/768/EEC safe when used by children under the age of 6 years, taking into account the risk of causing fluorosis?*

- *Does the SCCNFP propose any restrictions or conditions for the use of fluorine compounds in oral hygiene products for children under the age of 6 years?*

Based on the available pool of scientific evidence, the SCCNFP concluded that the maximum permitted concentration of 0.15% (1500 ppm) fluorine in oral hygiene products does not pose a safety concern when used by children under the age of 6 years.

The data used in this evaluation were generated from studies primarily on sodium fluoride. Extrapolation of this to the other fluoride compounds presently listed in Annex III can only be made with respect to fluorosis.

There is strong evidence that toothpaste containing 0.15 % (1500 ppm) is effective at preventing dental caries in all age groups, including children under the age of 6. This cariostatic effect decreases as the concentration is reduced. Below 1000 ppm, the cariostatic effect is not established. Further research is recommended in order to assess effects under 1000 ppm.

If the sole source of fluoride exposure is toothpaste containing fluoride between 1000-1500 F^- ppm, used as recommended, there is minimal risk that children under the age of 6 will develop fluorosis. It is recommended that children under the age of 6 use a pea size amount of toothpaste with supervised brushing.

The opinion was adopted.

6. Report of the Chairman

In his report, Dr. White mentioned and briefly illustrated the following new dossiers :

* the use of Specified Risk Materials in cosmetics – clarification for tallow derivatives;
* Lyral™
* consultation on the progress in developing satisfactory methods to replace animal testing
* P96, benzoisothiazolinone

7. Any Other Business

Next Plenary meeting will be on 20 October 2003.

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	J. Vives Rego
		Mr	N. Loprieno	Mr	I. R. White (Chairman)

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

Apologies Mr R. Anton

Annex 1

Scientific Committee on Cosmetic and Non-Food Products

Final Report of the Working Group "Detergents, Household and Similar Products"

1. Background

The specific WG was established by the directorate, during the Plenary session of SCCNFP on 3rd May 2000.

2. Mandate

In accordance with Commission Decision 97/579/EC, the SCCNFP is competent to answer scientific and technical questions concerning consumer health relating to cosmetic products and non-food products intended for consumers, especially substances used in the preparation of these products, their composition and their use, including packaging and labelling.

In addition, the Commission may request advice from the Committee on any other matters, and the Committee may draw the attention of the Commission to potential or emerging hazards relevant to its competence.

3. Meetings

The WP has met with representatives of the industrial associations including AISE and HERA.

4. Documents produced

- Inventory of Detergents ingredients adopted by the SCCNFP Plenary of 25 September 2001.

- An overview on biocides : Terminology, Legislation, Progress in Procedures. Adopted by the SCCNFP during the 18th Plenary meeting of 25 September 2001.

- Position statement Consumer Safety of Detergents, Household & Similar Products adopted by the SCCNFP during the 19th Plenary meeting of 27 February 2002.

- Position Statement Concerning Fragrance Chemicals in Detergents and other Household Products adopted by the SCCNFP during its 20th plenary meeting of 4 June 2002.

- A specific memorandum on HERA detergent ingredients dossiers and the regulation of European Parliament and of the Council on Detergents (COM(2002), 485 final) adopted in the SCCNFP Plenary of 17 December 2002, Annex 1.

5. Strategy of the Working Group

Detergents and household products consist of diverse products which are used to clean, disinfect, and condition dishes, clothing, textiles and surfaces. In some cases, substances are used to wash laundry (clothing, bedlinen) and become incorporated into the textiles potentially exposing the consumer for long periods e.g. softening agents and brighteners. Many of the ingredients (e.g. fragrances and preservatives) are also used in cosmetics.

The major risk for consumer exposure to this group of products is contact dermatitis (irritant primarily but also allergic). Reducing both irritant and allergic exposure will improve consumer safety.

For the protection of consumer health the WP considered that the priorities are the following :

i) To establish an inventory of ingredients including the following categories : biocides (preservatives, antimicrobials), surfactants, enzymes, bleaching agents and brighteners, solvents and fragrances.

ii) To identify those substances used both in detergents/household products and in cosmetics e.g. fragrances and preservatives.

iii) An important need in the health risk assessment process is the determination of the exposure rate of the ingredients for the consumer. The risk of an adverse health effect cannot be assessed without adequate information on exposure and dose-response data.

iv) To establish a list of the most problematic substances and to gather safety data on these chemicals.

v) Guidelines for the safety evaluation of ingredients and final products need to be established.

6. Risk assessment

The safety evaluation of the ingredients of detergents, household and similar products should be equivalent to the risk assessment process applied for ingredients in cosmetics, drugs, pesticides, food additives etc.

7. The HERA project

HERA regularly provides risk assessment reports on ingredients of household cleaning products. Their reports are available on the Internet (http://www.heraproject.com/RiskAssessment.cfm). The WG considers that these documents may provide important information for all stakeholders,. However, from strictly scientific and consumer health protection aspects , the WG expresses the following :

i) the documents have been drafted by industry without independent peer review;

ii) no ‘worst case’ scenarios are described;

iii) in some cases only classes of substances were considered in the HERA documents;

iv) the effects of impurities are insufficiently described;

v) standardised methodology, including OECD guidelines have not always been followed;

vi) the genotoxic /mutagenic potential of the ingredients have not been adequately investigated by the recommended methods as indicated by OECD and EC guidelines;

vii) complete hazard identification has not been performed in many cases.