

## Scientific Committee on Cosmetic and Non-Food Products

### Minutes of the 23<sup>rd</sup> Plenary Meeting (Brussels, 18 March 2003)

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

#### **1. Adoption of the Agenda, doc. n° SCCNFP/0651/03**

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. Current status on Alternatives to Animal Testing, Dr. T. Hartung, Head of ECVAM**

Dr. T. Hartung illustrated the current and future work of ECVAM in the frame of the 7<sup>th</sup> Amendment.

#### **4. Approval of the minutes of the 22<sup>nd</sup> plenary meeting of 17.12.02, doc. n° SCCNFP/0632/02.**

The minutes were approved.

#### **5. SCCNFP - Working Groups**

##### **5.1 Alternatives**

###### *Report of the Co-ordinator*

Prof. Loprieno said that no meetings of the WG had taken place since the previous plenary meeting. However, meetings are planned to discuss the complete revision of the SCCNFP Notes of Guidance, which should be adopted before the end of the current mandate (November 2003).

##### **5.2 Detergents, Household & similar Products**

###### *Report of the Co-ordinator*

Prof. Vives Rego said that no meetings had taken place since the last plenary meeting of 17 December 2002.

### 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 7 Task Force and WG meetings had taken place since the previous plenary meeting of 17 December 2002 during which 13 opinions had been prepared.

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| Opinion on a request for re-evaluation of hair dyes listed in Annex III, doc. n° SCCNFP/0635/03 |
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In the framework of the 26<sup>th</sup> Adaptation to technical progress of Directive 76/768/EEC on cosmetic products, 60 hair dyes have been listed in Annex III, part 2. Their listing in part 2 of Annex III implies that these substances are provisionally allowed until 30 September 2004 and that a re-evaluation has to be done before that date.

An ad-hoc Working Group of the Standing Committee on Cosmetic Products was set up which established a list of 46 hair dyes to be re-evaluated and formulated the questions to the SCCNFP on each of these substances. Furthermore the European Commission has received a letter from a Member State with data demonstrating the possible risk of mutagenicity/carcinogenicity of m-Phenylenediamine, COLIPA A3 (classified mutagen category 3, according to Directive 67/548/EEC).

The SCCNFP concluded that the previously submitted data for these 46 substances as well as for other existing substances listed in Annex III of Directive 76/768/EEC, like A3, no longer comply to present standards. Therefore, and before any further consideration, adequate safety data were requested on these substances.

The opinion was adopted.

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| Opinions on A111, Dihydroxyindole, doc. n° SCCNFP/0657/03 |
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Dihydroxyindole is clastogenic *in vitro* with and without metabolic activation but is not a bacterial mutagen. Comparing the NOEL (3 mg/kg/day, rat 13-week study) with the maximum systemic exposure dose in humans indicated a margin of safety of 10, which is not adequate.

The SCCNFP concluded that Dihydroxyindole is not suitable for use in hair dyes.

The opinion was adopted.

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| Opinion on A147, Dihydroxyindoline HBr, doc. n° SCCNFP/0669/03 |
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The SCCNFP concluded that, based on the present available information, Dihydroxyindoline HBr does not pose a health risk when used as a semi-permanent hair dye at concentrations not exceeding 2.0 %.

The opinion was adopted.

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| Opinion on C129, HC Green n° 1, doc. n° SCCNFP/384/00 |
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HC Green n° 1 was considered to be a mutagen, clastogen and aneugen *in vitro*. It produced equivocal results *in vivo*. The SCCNFP concluded that it was not possible to assess the safe use of the substance. Therefore, and before any further consideration, adequate safety data were requested.

The opinion was adopted.

\* Opinion on :

- A117, 5-Amino-4-chloro-2-methylphenol, hydrochloride, doc. n° SCCNFP/0659/03
- A130, HC Blue n° 7, doc. n° SCCNFP/0643/03
- B87, 4-Amino-2-nitrodiphenylamine-2'-carboxylic acid, doc. n° SCCNFP/0658/03
- C8, Basic Red 76, doc. n° SCCNFP/238/99
- C9, Basic Brown 16, doc. n° SCCNFP/668/06
- C119, HC Red n° 8; doc. n° SCCNFP/0660/03

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

The opinions were adopted.

\* The SCCNFP decided to postpone the adoption of an opinion on :

- A80, Hydroxyethyl-p-phenylenediamine sulphate, doc. n° SCCNFP/0666/03
- A128, 6-Hydroxyindole, doc. n° SCCNFP/0667/03
- B56, 6-Nitro-o-toluidine, doc. n° SCCNFP/0682/03

## 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 December 2002, during which the following opinions had been prepared :

P51, Inorganic sulfites and bi-sulfites, doc. n° SCCNFP/0648/03

Cosmetic products marketed in the EU may only contain those preservatives which are listed in Annex VI of the Cosmetics Directive 76/768/EEC, "List of preservatives which cosmetic products may contain". The preamble of the Annex states that preservatives marked with the symbol (+) may also be added to cosmetic products in concentrations other than those laid down in the Annex for other specific purposes apparent from the presentation of the products. Inorganic sulfites and bi-sulfites bear the symbol (+) and can therefore be used in cosmetics at higher concentrations, as long as they are not employed as preservatives.

In its opinion of 17 February 1999 concerning the restrictions on materials listed in Annex VI of Directive 76/768/EEC on cosmetic products, the SCCNFP stated that those substances indicated by (+) in Annex VI, when incorporated into cosmetic formulations for non-preservative functions, should be subjected to the same restrictions in usage levels and warnings as when used for preservative effects. If a preservative marked with the symbol (+) is added for non-preservative purpose to a cosmetic product in a concentration higher than that laid down in the Annex VI, data to substantiate its safety should be submitted to the SCCNFP.

The SCCNFP was asked to evaluate a special submission for inorganic sulfites and bisulfites describing appropriate investigations and to answer the following questions :

- \* Are inorganic sulfites and bisulfites, at concentrations up to 0.67 % in oxidative hair dye products, up to 6.7 % in hair waving/straightening products, up to 0.45 % in self-tanning products for the face and up to 0.40 % in self-tanning products for the body safe for use in cosmetic products (all expressed as SO<sub>2</sub>)?
- \* Does the SCCNFP propose any restrictions or condition of the use of inorganic sulfites and bisulfites in cosmetic products?

The SCCNFP concluded that inorganic sulfites and bisulfites do not pose a health risk when used in cosmetic products at concentrations up to 0.67% in oxidative hair dye products, up to 6.7 % in hair waving/straightening products, up to 0.45 % in self-tanning products for the face and up to 0.40 % in self-tanning products for the body (all expressed as SO<sub>2</sub>).

The opinion was adopted.

P56, Kathon CG with copper stabiliser

SCCNFP/0482/01

The adoption of the opinion was postponed to the next plenary meeting as an additional mandate concerning a possible removal of a reference to the stabilising system was received.

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| P94, Methylisothiazolinone, doc. n° SCCNFP/0625/02 |
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The SCCNFP was asked to evaluate the safety data submitted on methylisothiazolinone and to answer the following questions :

- \* Is the use of 2-Methyl-4-isothiazolin-3-one as a preservative in cosmetic products safe?
- \* Is there a need for setting a new concentration limit for the use of this substance in cosmetic products?

The SCCNFP concluded that the information submitted was insufficient to allow an adequate risk assessment to be carried out. The genotoxicity/mutagenicity studies are inadequate in general; the *in vitro* test for clastogenicity has been considered clearly positive in independent studies.

Before any further consideration, the committee requested (i) more detailed information concerning the physico-chemical properties of Methylisothiazolinone (e.g. LCMS analysis, pH, stability and degradation products), (ii) information on the material used in the tests (batch numbers, purity and impurities), (iii) an *in vitro* percutaneous absorption study, and (iv) relevant and adequate genotoxicity/mutagenicity studies.

The opinion was adopted.

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| Wood tar and wood tar preparations, doc. n° SCCNFP/0646/03 |
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Crude and refined coal tars are currently listed in Annex II, n° 420 of Directive 76/768/EEC on cosmetic products. The regulation of coal tars was based on the opinion of the SCC on coal tar, adopted on 3 February 1995 and on the opinions of the SCCNFP concerning refined coal tar, adopted on 20 December 1996 and concerning refined coal tars by bi-distillation, adopted on 28 June 2000.

In its opinions, the SCC/SCCNFP concluded that crude and refined coal tars contain carcinogenic polycyclic hydrocarbons and are therefore not safe for use in cosmetic products.

A member State requested the Commission to include wood tar and wood tar preparations in Annex II of Directive 76/768/EEC on cosmetic products. The SCCNFP was asked to evaluate the submitted safety data and to answer the following questions :

- \* Are wood tar and wood tar preparations safe to be used in cosmetic products?
- \* If yes, does the SCCNFP propose any restrictions or conditions for the use of wood tar and wood tar preparations in cosmetic products?

SCCNFP concluded that wood tar and wood tar preparations do pose a health risk when used in cosmetic products. Wood tar and wood tar preparations contain polycyclic aromatic hydrocarbons which are genotoxic carcinogens. Wood tar preparations have been found to induce both benign and malignant skin tumours in mouse skin and to form DNA adduct in human skin. The products may represent risk of skin cancer.

The opinion was adopted.

## 5.7. UV Filters & Absorbers

As Dr. Lina was not able to attend the meeting, Dr. White said that one WG meetings had taken place since the plenary meeting of 18 December 2002, during which 3 opinions had been prepared.

Ethoxyethanol, ethoxyethanol acetate, 2-methoxyethanol and 2-methoxyethanol acetate (glycol ethers and their acetates), doc. n° SCCNFP/0663/03

The EU Commission has received a notification from the Norwegian Authorities in which they inform that a ban has been introduced in Norway on the use of ethoxyethanol, ethoxyethanol acetate, 2-methoxyethanol and 2-methoxyethanol acetate (glycol ethers and their acetates) in cosmetic products.

Ethoxyethanol, ethoxyethanol acetate, 2-methoxyethanol and 2-methoxyethanol acetate (glycol ethers and their acetates) have been used as solvent and/or viscosity decreasing agents in cosmetic products. The substances are classified as toxic to reproduction, category 2 according to Directive 67/548/EEC.

The SCCNFP was requested to answer following questions :

- \* Do the safety profiles of the compounds ethoxyethanol, ethoxyethanol acetate, 2-methoxyethanol and 2-methoxyethanol acetate (glycol ethers and their acetates) support their use in cosmetic products?
- \* Does SCCNFP propose any restriction in their use in cosmetic products?

The SCCNFP concluded that ethoxyethanol, ethoxyethanol acetate, 2-methoxyethanol and 2-methoxyethanol acetate (glycol ethers and their acetates) do pose a health risk when used in cosmetic products. Ethoxyethanol, ethoxyethanol acetate, 2-methoxyethanol and 2-methoxyethanol acetate (glycol ethers and their acetates) are classified as toxic to reproduction, category 2 according to Directive 67/548/EEC. As a consequence, the Opinion of SCCNFP concerning Chemical Ingredients in Cosmetic Products classified as Carcinogenic, Mutagenic or Toxic to Reproduction according to Directive 67/548/EEC (doc. n° SCCNFP/0747/01 of 25 September 2001) does apply to the above-mentioned chemicals as well.

The opinion was adopted.

- \* The SCCNFP decided to postpone the adoption of an opinion on :
  - Zinc oxide, doc. n° SCCNFP/0649/03
  - Uvinul® A plus, doc. n° SCCNFP/0650/03

## 6. Report of the Chairman

In his report, Dr. White said that a meeting will take place on 2 April 2003 in Brussels to discuss the future and possible reorganisation of the 3 Non-Food Committees.

## 7. Any Other Business

\* *7<sup>th</sup> Amendment of Directive 76/768/EEC on cosmetic products* : Dr. Schumann said that 7<sup>th</sup> Amendment has been adopted by the European Parliament and the Council on 27 February 2003. Timetables should be scheduled by DG ENTR for the methods to be used, 6 and 9 years after the entry in force of that regulation.

A major task for the Commission, after consultation of the SCCNFP and of the European Centre for the Validation of Alternative Methods (ECVAM) and with due regard to the development of validation within the OECD, is to establish timetables for the implementation of the provisions of the Directive regarding alternative methods, including deadlines for the phasing out of the various 'animal'-tests. The timetables should be made available to the public not later than 11 September 2004 and be sent to the European Parliament and the Council.

\* *Next Plenary meeting* : 24 and 25 June 2003.

### Attendance List

|            |   |                   |                           |
|------------|---|-------------------|---------------------------|
| Present    | : | Mr K.E. Andersen  | Mr J. Parra               |
|            |   | 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 J. Vives Rego          |
|            |   | Mr N. Loprieno    | Mr I. R. White (Chairman) |
|            |   | Mr J.-P. Marty    |                           |
| Commission | : | Mrs L. D'Ambrosio | DG SANCO                  |
|            |   | Mr T. Hartung     | JRC-ECVAM                 |
|            |   | Mrs R. Schumann   | DG ENTR                   |
|            |   | Mr J. Serratosa   | DG SANCO                  |
|            |   | Mr A. Van Elst    | DG SANCO                  |
|            |   | Mrs V. Zuang      | JRC-ECVAM                 |
| Apologies  | : | Mr R. Anton       |                           |
|            |   | Mr B. Lina        |                           |