

Scientific Committee on Cosmetic and Non-Food Products

Minutes of the 20th Plenary Meeting

Brussels, 4 June 2002

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

1. Adoption of the Agenda (doc. n° SCCNFP/0580/02)

The agenda was adopted.

2. 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.

3. Approval of the minutes of the 19th plenary meeting of 27 February 2002, doc. n° SCCNFP/0559/02

The minutes were approved.

4. SCCNFP - Working Groups

4.1 Alternatives

Report of the Co-ordinator

In his report, Prof. Loprieno said that four main items were under consideration :

- * a complete revision of the Notes of Guidance; a task the WG would like to finalise before the end of their present mandate (October 2003),
- * the re-evaluation of the exposure data,
- * the actual status of alternative methods, and
- * a proposal for a strategy for testing hair dye chemicals for their genotoxic/mutagenic potential.

Memorandum concerning the actual status of alternative methods to the use of animals in the safety testing of cosmetic ingredients, doc. n° SCCNFP/0546/02

One of the tasks of the SCCNFP is to act as a resource of scientific expertise to the European Commission with regard to the development of alternative methods. As such, the SCCNFP advises the European Commission on the status of alternative methods to animal testing of

cosmetic ingredients on an on-going basis and particularly, in accordance with Art. 4,1(i) of Council Directive 76/768/EEC.

The SCCNFP therefore closely follows the scientific developments of alternative methods by academia, industry and public institutions and this in a broader context in order to identify the alternative methods that are applicable to the safety evaluation of cosmetic ingredients and finished products.

For the moment, the number of validated alternative methods, fitting into the 3Rs concept (Reduction, Replacement, Refinement) and available for the practical application in regulatory testing and risk assessment of cosmetic ingredients, is limited.

The aim of this memorandum is not to discuss the existing techniques but to present the committee's view on the actual status of alternative methods to the use of animals in the safety testing of cosmetic ingredients.

The document was adopted.

In the margin of the discussion on alternative methods, a short update was given on recent developments regarding the draft 7th amendment of Directive 76/768/EEC on cosmetics.

Proposal for a strategy for testing hair dye cosmetic ingredients for their potential genotoxicity/mutagenicity, doc. n° SCCNFP/0566/02

As a follow-up of its opinion on the use of permanent hair dyes and bladder cancer risk (doc. n° SCCNFP/0484/01), the SCCNFP adopted during the 19th Plenary Meeting of 27 February 2002 a draft discussion paper on assessment strategies for hair dyes. In this discussion paper, the committee states that, amongst others, data on genotoxicity conforming to internationally accepted guidelines and to modern testing strategies, are required.

In order to elucidate this request, the present proposal describes a strategy for testing hair dye cosmetic ingredients for their potential genotoxicity/mutagenicity. The proposed strategy is indicative and based on current scientific knowledge. It will be incorporated into the Notes of Guidance at a later stage.

The paper was adopted.

4.2 Detergents, Household & Similar Products

Report of the Co-ordinator

Prof. Vives Rego reported on the following issues :

- detergents : the Working Group expressed its regret that its work is not properly endorsed by a mandate. Moreover, it appeared that the reference to the SCCNFP has been withdrawn from the latest version of the revised draft legislation on detergents; it was argued that the consumer is sufficiently protected/informed by current horizontal legislation.

- on 22 April 2002, the WG discussed its preliminary discussion paper on an inventory of detergent ingredients with industry. It appeared that a special meeting with industry experts would be required to clarify all the questions concerning nomenclature. At the same meeting, AISE presented the HERA-initiative : the objectives, progress to date and forecast.
- biocides : as no special mandate was issued on biocides, the WG decided to suspend their work on biocides for the time being and to wait for further developments/actions in the frame of the biocides directive.

Position Statement on fragrance chemicals in detergents and other household products, doc. n° SCCNFP/0588/02

Investigation of the presence of fragrance chemicals in detergents and other household products has revealed that these products may contain, to certain extent, the same fragrance materials as those used in cosmetic products : 22 of the potential fragrance allergens identified by the SCCNFP were found in these types of consumer products.

Following the elucidation of the fragrance allergy problem in consumers caused by the use of cosmetics, the SCCNFP is of the opinion that fragrance chemicals in detergents and other household products should be regarded in a similar way as in cosmetic products.

A person sensitised to a certain fragrance material will elicit an allergic response when exposed to this fragrance from any product whether cosmetic or detergents under similar exposure conditions. Thus, it is important that consumers have information on the presence of fragrance chemicals in the respective products.

The position statement was adopted.

4.3 Exposure & Risk Assessment

Report of the Co-ordinator

Prof. Schaefer reported on the following :

- *Margin of Safety* : Prof. Schaefer said that it has been decided that for new dossiers, the MOS will be based on a percutaneous absorption expressed in mg/cm². This approach will be inserted in the Notes of Guidance in due course.

- *Presence of UV filters in lip protection products/lipstick* : The Danish EPA stated that 4-MBC (S60), Octyl methoxycinnamate (S28) and Oxybenzone (S38) are used in lip protection products/lipstick up to a concentration of 3.6%. Unless proven otherwise, 100% of the ingredients in these products must be considered to be absorbed. In the case of 4-MBC, this leads to an additional systemic exposure dose of 0.026 mg/kg bw. As lip protection is recommended in combination with sun screen products, the MOS changes from 110 to 96, which is not significantly different.

- *Bio-accumulation* : QSAR calculations have shown that 4-MBC (S60) may have intrinsic properties suggesting a potential for bio-accumulation. The Committee has been asked to further investigate 4-MBC regarding its concentration in the blood and its distribution in the organism.

Prof. Schaefer said that UV filters are normally large molecules with low dermal penetration. As the amount absorbed would be excreted in the urine, the blood levels will be low and consequently would require very sensitive analytical methods to be determined. Moreover, as all lipophilic substances might bio-accumulate and as there are no such previous cases in skin pharmacology, sub-chronic oral exposure could be taken into account to demonstrate it. As a result, the WG concluded that the issue of bio-accumulation cannot be answered until further appropriate studies are available.

4.4 Hair Dyes & Colorants

Report of the Co-ordinator

Prof. Andersen reported on what had happened since the previous plenary meeting :

- during the 19th plenary meeting of 27 February, the committee adopted a discussion paper on assessment strategies for hair dyes (doc. n° SCCNFP/0553/02). The paper was put on the “web” and interested parties were invited for comments. 5 comments were received endorsing the committee’s assessment strategies. Although these comments have not yet been considered in-depth by the WG, Prof. Andersen said that, in his view, only some ‘streamlining’ might be required.
- Lawson : additional genotoxicity data and a new *in vitro* percutaneous absorption had been received since the adoption of a 2nd opinion on Lawson during the 19th plenary meeting of 27 February 2002. A draft 3rd opinion was tabled for adoption. Closely related to lawson, the draft opinion on Henna (*Lawsonia inermis*) was also tabled for adoption.

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

The SCCNFP was requested to evaluate the genotoxicity data and the new *in vitro* percutaneous absorption study enclosed in submission III and to inform the Commission whether these new results justify a modification of the opinions on Lawsone adopted during the 16th plenary meeting of 13 March 2001 and during the 19th plenary meeting of 27 February 2002. The committee stated in both opinions that lawson 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*.

There was complete agreement concerning the mutagenic/genotoxic potential of lawson between Prof. Loprieno and Dr. Laurent, who had both evaluated the submitted dossier independently. However, it appeared that some member(s) had additional information on the genotoxicity data.

In order to discuss this in a transparent manner, Dr. White asked that members should provide full written details of any concerns together with appropriate references to support them. Different points of view are not unusual. It was envisaged that a consensus view would be formulated before the next plenary.

Opinion on C169 – <i>Lawsonia inermis</i> (Henna), doc. n° SCCNFP/0505/01

Because of the link with the opinion on lawsone, the committee decided to postpone the adoption of the opinion on *Lawsonia inermis* to the plenary meeting of 17 September 2002.

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

During its 19th plenary meeting of 27 February 2002, the SCCNFP adopted an opinion on the use of certain azo-dyes in cosmetic products.

Unfortunately, 2 azo-dyes - Acid Red 14 and Food Yellow 3 -, which have been evaluated by the Scientific Committee on Food and considered safe for use in food, were listed in table 1 of the opinion.

As a consequence, the SCCNFP agreed to remove these 2 azo-dyes from table 1 of the opinion.

4.5 Inventory

Report of the Co-ordinator

In his report, Prof. Parra said that, since the previous plenary meeting of 27 February 2002, no meetings of the WG had taken place. He repeated his regret that the work on the 2nd update of the inventory had not yet been initiated by the Commission.

Regarding the request to industry for detailed information on the botanicals used in cosmetic products, Prof. Parra said that a letter from COLIPA has been received in which they state that they are trying to fulfil the requests and to provide the SCCNFP with up-to-date information.

4.6 Preservatives & Fragrances

Report of the Co-ordinator

In his report, Prof. Kemper said that three WG meetings had taken place since the previous plenary meeting of 27 February 2002 during which the following opinions had been prepared :

Opinion on Diethyl phthalate (DEP), doc. n° SCCNFP/0411/01
--

The SCCNFP was requested to review the safety of diethyl phthalate. Diethyl phthalate is currently used through direct addition in cosmetic products or indirectly through fragrance compounds.

As a result, the committee concluded that the safety profile of diethyl phthalate supports its use in cosmetic products at current levels.

The opinion was adopted.

Opinion on benzoic acid and sodium benzoate, doc. n° SCCNFP/0532/01

Benzoic acid, its salts and esters are presently listed in Annex VI, part 1 – list of preservatives allowed – at a maximum authorised concentration of 0.5 % (expressed as acid). However, benzoic acid, its salts and esters bear the symbol (+) and can therefore be used in cosmetics at higher concentrations, as long as they are not employed as preservatives.

The SCCNFP was asked to review the safety data submitted and to answer the question whether benzoic acid, its salts and esters can be safely used for non-preservative purposes in cosmetic rinse-off products at a maximum concentration of 2.5 % and in cosmetic oral care products at a maximum concentration of 1.7%.

Data were only given for benzoic acid and sodium benzoate. No information was provided on the other salts or esters. As most of the data was based on citations in reviews, the SCCNFP did not find the submission appropriate for the safety evaluation of benzoic acid, its salts and esters for the applied “other uses” in cosmetic products. Before any re-assessment, the committee requires the original documentation and complete files not only on benzoic acid and sodium benzoate but also on the other salts used and on the esters.

The opinion was adopted.

Opinion on Salicylic acid, doc. n° SCCNFP/0522/01

Salicylic acid and its salts are presently listed in Annex VI, part 1 (list of preservatives allowed). Salicylic acid and its salts bear also the symbol (+) and can therefore be used in cosmetics at higher concentrations, as long as they are not employed as preservatives.

The SCCNFP was asked to review the safety data submitted and to answer the question whether salicylic acid and its salts can be safely used for non-preservative purposes in leave-on products at a maximum concentration of 2.0 % and in rinse-off products at a maximum concentration of 3.0 %.

On the bases of the information provided, the SCCNFP concluded that salicylic acid can be safely used for non-preservative purposes at a maximum concentration of 2.0 % in the leave-on and rinse-off cosmetic products and at a maximum concentration of 3.0 % in rinse-off hair care products.

The opinion was adopted.

Opinion on Methyl dibromo glutaronitrile, doc. n° SCCNFP/0585/02

Methyl dibromo glutaronitrile (1,2-dibromo-2,4-dicyanobutane) is regulated in the Cosmetic Directive Annex VI, part 1, reference 36 and can therefore be used as a preservative up to a maximum concentration of 0.1% in the finished product. However, it shall not be used in cosmetic sunscreen products at a concentration exceeding 0.025%.

The SCCNFP was asked to review the submitted data demonstrating the rising incidence of contact allergy to methyl dibromo glutaronitrile.

The SCCNFP concluded that :

- * the data show a clear rise in the incidence of contact allergy to methyl dibromo glutaronitrile throughout Europe. This indicates that the current usage of the preservative – concentration and product types – is responsible for this rise. Maximum consumer exposure will occur from use of leave-on products containing 0.1% (the maximum permitted) of the preservative. Therefore, this use is a risk to the consumer.
- * the available data does show a dose response elicitation of allergic contact reactions to the preservative but provides no information on a ‘safe level’.

Until appropriate and adequate information is available to suggest a level of the preservative in leave-on products that poses an acceptable risk to the consumer (compared with the risk to the consumer from other preservatives), the SCCNFP proposed to restrict the use of methyl dibromo glutaronitrile to rinse-off products at the current maximum permitted level of 0.1%.

The opinion was adopted.

4.7. UV Filters & Absorbers

Report of the Co-ordinator

In his report, Dr. Lina said that two WG meetings had taken place since the previous plenary meeting of 27 February 2002. The following item had been discussed :

- *the use of benzoyl peroxide, hydroquinone and hydroquinone methylether in artificial nail systems* : a draft opinion has been prepared which was tabled for adoption. However, it was noted that the use of acrylate monomers during the process of preparing artificial nails may cause serious sensitisation. As an evaluation of acrylate monomers was not included in the mandate, it will be addressed separately.
- *questions raised by the Danish EPA* : (i) *MOS for sunscreens when used by children* : this question has been answered in the Position Statement on the Calculation of the Margin of Safety of Ingredients incorporated in Cosmetics which may be applied to the Skin of Children, adopted during the 19th plenary meeting of 27 February 2002 (doc. n° SCCNFP/0557/02). The committee stated that there is no general scientific justification for adding an extra uncertainty factor for children for substances used in cosmetics, and in sun screen products in particular.

(ii) *Estrogenic activity of S28, S38 and S60* : weak estrogenic activity of these compounds has been demonstrated. However, a brief statement will be drafted indicating that this information does not influence the previous SCCNFP opinion.

(iii) *effects of S60 on thyroid function* : the toxicity studies and the dermal penetration study are under re-evaluation. In addition, an external expert will be approached to assess the relevance of the thyroid effects.

(iv) *presence of UV filters in products other than sunscreens* : the Danish EPA provided information that UV filters (e.g. S28, S38 and especially S60) may be present at high levels in products other than sunscreens (lip salves, deodorants). This may have consequences for the MOS calculations. The issue was forwarded to the WG 'Exposure and risk assessment'. See also point 4.3 of the minutes.

(v) *bio-accumulation of S60* : according to the Danish EPA, QSAR data provide evidence of bio-accumulation of S60. The Danish EPA now requests additional ADME studies. Again, the WG 'Exposure and risk assessment' has been asked to consider the need for additional studies. The Danish EPA will be requested to send the relevant information to the SCCNFP. See also point 4.3 of the minutes.

Opinion on the use of benzoyl peroxide, hydroquinone and hydroquinone methylether in artificial nail systems, doc. n° SCCNFP/0486/01

Benzoyl peroxide and hydroquinone methylether are presently listed in Annex II of Directive 76/768/EEC on cosmetics, entries n° 382 and 178 respectively. Hydroquinone is listed in Annex III to Directive 76/768/EEC on cosmetics (entry n° 14) and may only be used as an oxidising colouring agent for hair dyeing at a maximum authorised concentration of 0.3% in the finished cosmetic product.

The SCCNFP was asked whether the safety profiles documented in the submitted dossier allow a restricted use of benzoyl peroxide, hydroquinone and hydroquinone methylether in artificial nail systems.

Benzoyl peroxide, hydroquinone and hydroquinone methylether are technical aids in the polymerisation of polymers such as ethyl and methylacrylates. They are used at low concentrations and mainly consumed rapidly during polymerisation. The residue is trapped in the hardened polymer matrix. This reduces the chance of possible systemic exposure, since penetration through the nail plate is slight. Even if the nails are bitten, the quantity that might be absorbed would be very low. However, there was concern that the technique for mixing the two components is open to great operator variation.

Little toxicological data (no data on genotoxicity/mutagenicity) was provided for either hydroquinone or hydroquinone methylether. Assumptions are made but are not corroborated with data. The analytical data for the residual hydroquinone and hydroquinone methylether in the finished nail is inadequate.

Nevertheless, the SCCNFP concluded that, due to the very low exposure to the consumer, the risk is minimal. However, the reaction of benzoyl peroxide-phthalate initiators have been shown to be a source of benzene. This could pose a health risk for the consumer and professional at the time of application.

5. Report of the Chairman

Report of the Chairman

In his report, Dr. White said that a mandate was received on Choline chloride for use as a humectant in soap bars and liquid body soap.

6. Any Other Business

* next meeting : 17 September 2002

Attendance List

Present	:	Mr K.E. Andersen	Mr J.-P. Marty
		Mr R. Anton	Mr J. Parra
		Mrs C. Chambers	Mr T. Platzek
		Mr A. Di Domenico	Mrs V. Rogiers
		Mr V. Kapoulas	Mr T. Sanner
		Mr F. Kemper	Mr H. Schaefer
		Mr C. Laurent	Mr J. Vives Rego
		Mr B. Lina	Mr I. R. White (Chairman)
		Mr N. Loprieno	
	Apologies	:	Mr S. Rastogi
Commission	:	Mrs V. Barwig	DG SANCO
		Mrs S. Clarke	DG SANCO
		Mrs R. Schumann	DG ENTR
		Mr A. Van Elst	DG SANCO