EUROPEAN COMMISSION
HEALTH & CONSUMERS DIRECTORATE-GENERAL

Public Health and Risk Assessment
Risk assessment

Scientific Committee on Consumer Safety
7th Plenary Meeting

Held on 22 June 2010 in Brussels

MINUTES

1. WELCOME AND APOLOGIES

The chairman of the SCCS welcomed all the participants. Apologies were received from Dr. Q. Chaudry, Prof. G. Eisenbrand, Prof. K. Savolainen and Prof. R. Waring.

The chairman welcomed Ms. Z. Roithova, MEP, Ms. H. Carlsen-Nielsen and Ms K. Huliciusova, who expressed their interest in attending as observers a plenary meeting of the SCCS in the framework of their responsibilities within the IMCO-committee of the European Parliament.

2. DECLARATIONS OF INTEREST

Prof. V. Rogiers declared a conflict of interest in relation to the dossier on melatonin as her institution has provided consultancy on this dossier. The Committee decided that she should not participate in the discussion and voting on this opinion.

Dr. J. van Engelen said that she was involved in the drafting of a Dutch RIVM report on Dihydroxyacetone. The Committee decided that she should not participate in the discussion and voting on this opinion.

No other member declared any interest that could prevent him/her from participating in the discussion of the items on the agenda.

3. APPROVAL OF THE DRAFT AGENDA SCCS/1349/10

The agenda was approved without changes.

4. ADOPTION OF THE DRAFT MINUTES OF THE 6TH PLENARY MEETING SCCS/1337/10

The minutes of the 6th plenary meeting of 23 March 2010 were approved.

5. INFORMATION FROM CHAIRMAN/MEMBERS

Information from the Chairman
No specific points were raised.

Commission follow-up to earlier opinions
In the absence of a representative of SANCO Unit B2 - Cosmetics and Medical Devices – the secretariat said that no legal implementations for cosmetic ingredients were made since the last plenary of 23 March 2010.

6. NEW REQUESTS

6.1. Joint mandates

The Commission will consult the SCCS on the expected ECVAM report on alternatives when it is published.

7. REPORTS FROM THE WORKING GROUPS

7.1. Cosmetic Ingredients

The Chairperson of the WG reported on the ongoing work of the Working Group. Draft opinions on cyclomethicone, boron compounds, sodium perborate and perboric acid, dihydroxyacetone, parabens (P82) and polysilicone-15 (S74) were prepared and tabled for formal adoption.

7.2. Hair Dyes

The Chairperson of the WG reported on the ongoing work of the Working Group. Draft opinions on o-aminophenol (A14), HC Yellow n° 9 (B69) and on Disperse Violet 1 (C64) were prepared and tabled for formal adoption.

7.3. Methodologies

The Chairperson of the WG said that the memorandum on Episkin and the basic criteria for the in vitro assessment of dermal absorption have been revised/updated and tabled for adoption.

7.4. Nano-materials in Cosmetics

As the Chairperson was not able to attend, the secretariat reported that one meeting had taken place since the last plenary of 23 March 2010. Further data requested on the ongoing evaluations are expected in autumn 2010.

7.5. Triclosan (Antimicrobial resistance)

The Chairperson said that the opinion on triclosan (P32) - antimicrobial resistance – has been finalised after consideration of the comments received during the public consultation period. The opinion is tabled for formal adoption.

7.6. TTC

The Chairperson said that more work is needed to align the opinion to the outcome of the meeting of 9 June 2010. A further meeting is planned for 27 September 2010.

7.7. Sensitisation & Fragrances

The Chairperson reported on the work of the Working Group: the revision of the opinion on the labelling of 26 fragrance substances.

7.8. Food imitating products

The Chairperson said that a draft opinion is expected to be presented during the next plenary meeting on 21 September 2010.

7.9. Participation of Members in activities of other Scientific Committees

The members involved in the activities of SCHER and SCENIHR reported on the progress of the draft opinions on:

- heavy metals in jewellery
- CMR in toys
- Fluoride in drinking water

8. DRAFT OPINIONS - DISCUSSION AND POSSIBLE ADOPTION

8.1. Cyclomethicone D4 / D5

The SCCP was asked to assess the risk to consumers when octamethylcyclotetrasiloxane is used in cosmetic products.

The SCCS concluded that cyclomethicone (D4, D5) does not pose a risk for human health when used in cosmetic products. Other uses were not considered in this risk assessment.
This conclusion is based on the currently available in-use concentrations as cited in this opinion.
It should be noted that D4 is classified as a reprotoxic substance, category 3 [ECB 2006]. The NOAEL for systemic toxicity (150 ppm) used for this risk assessment also covers reprotoxic effects (NOAEL = 300 ppm).
The Commission Services should consider whether an environmental risk assessment associated with the use of cyclomethicone (D4/D5) in cosmetic products is required.

The opinion was adopted.

8.2. Boron compounds

Boron compounds

The SCCS was asked to:

(1) based on the current knowledge on the chemistry, biology and toxicology of boron, inform the Commission which of the substances listed in the annex II, newly classified substances to this mandate, are covered by the entries 1a and 1b of Annex III, of the Cosmetics Directive 76/768/EEC

The SCCS concluded that all substances listed in Annex II of this mandate with the exception of dibutyltin hydrogen borate, are covered by the entries 1a of Annex III of the Cosmetics Directive 76/768/EEC. Tetraborates, as identified in table 1 of this opinion, are also covered by entry 1b of the same annex.

(2) based on the answer to question 1, and taking into account the scientific data used in the classification of these substances, if:

(a) the substances that are covered by the entries 1a and 1b of Annex III and which are currently restricted by Directive 76/768/EEC at a maximum use concentration above the specific concentration limits for classification set out in the Commission

Regulation 790/2009 are safe when used in cosmetic products below the specific concentration limits set out in the Commission Regulation 790/2009?

The SCCS pointed out that a threshold can be established for the reproductive toxicity of boron compounds. On this basis boric acid, borates and tetraborates are safe when used under the conditions laid down in entry 1a of Annex III. Moreover, tetraborates are safe under the conditions laid down in entry 1b of Annex III if the maximum authorised concentration in the finished cosmetic products is reduced to < 5.5% (by mass as boric acid). Sodium perborate and perboric acid are discussed in a separate Opinion (SCCS/1345/10).

Exposure to borate compounds from uses other than cosmetics was not taken into account for this risk assessment.

(b) the substances that are not covered by the entries 1a and 1b of Annex III can safely be used in cosmetic products at concentrations levels below the specific concentrations limits laid down the Commission Regulation 790/2009?

In Annex II of this mandate, the SCCS has only identified dibutyltin hydrogen borate that is not covered by entries 1a and 1b of Annex III. No specific concentration limit is given for this substance in Commission Regulation 790/2009; therefore no risk assessment for the use in cosmetic products has been performed.

Octaborates

(3) Based on the current scientific knowledge on the chemistry, biology and toxicology of boron and its compound does the SCCS consider that octaborates are covered by Annex III of the Cosmetics Directive, entry 1a and 1b? If covered, considering that octaborates are not classified, should the current restrictions limits of Annex III entry 1a and 1b be applied for the octaborates?

SCCS concluded that, based on the chemistry, biology and toxicology available, the threshold for the reproductive toxicity of octaborates is similar to that for other boron compounds. On this basis octaborates are safe when used under the conditions laid down in Annex III, entry 1a of the Cosmetics Directive. Moreover, octaborates are safe under the conditions laid down in entry 1b of Annex III if the maximum authorizes concentration in the finished cosmetic products are reduced to < 5.5% (by mass as boric acid). The SCCS notes, however, that octaborates are not classified as toxic for reproduction and no specific concentration limits are assigned to them.

The opinion was adopted

8.3. Sodium perborate and perboric acid

The SCCS was asked:
(1) Based on the current knowledge on the chemistry, biology and toxicology of sodium perborate and perboric acid, does the SCCS consider that sodium perborate and perboric acid can be considered as "hydrogen peroxide" releasing substances in the sense as the already regulated substances in Annex III, entry 12 of the Cosmetics Directive 76/768/EEC?

The SCCS concluded that sodium perborate and perboric acid can be considered as "hydrogen peroxide" releasing substances and thus are covered by the entries 12 of Annex III, of the Cosmetics Directive 76/768/EEC,

(2) If the answer to question 1 is yes, does the SCCS consider that the general restrictions applicable to hydrogen peroxide releasing substances should apply to sodium perborate and perboric acid?

The SCCS considered that the general restrictions applicable to hydrogen peroxide releasing substances should apply to sodium perborate and perboric acid. As laid out in opinion SCCS/1249/09, the substances listed in the Annex I of this mandate are, in addition to entry 12 of Annex III, also covered by entry 1a of Annex III of the Cosmetics Directive 76/768/EEC. The more restrictive of the two entries should be applied.

(3) Furthermore, does the SCCS consider with the provided scientific data that sodium perborate is safe, when used in (powdered), oxidative hair dye formulations up to a maximum concentration on the head of max.3.0% calculated as boric acid corresponding to a release of x volume percentage hydrogen peroxide?

The SCCS concluded that the use of sodium perborates as an ingredient in oxidative hair dye formulations with a maximum on-head concentration of 3% will not pose a risk to the health of the consumer.
Exposure to sodium perborate and boric acid from other uses, except the use in cosmetics according to Annex III, entry 1a of the Cosmetics Directive 76/768/EEC, was not taken into account for this risk assessment.
The SCCS notes, however, that the hair dye powder formulation as supplied to the consumer contains 30% sodium perborate monohydrate. It other types of consumer products this would require labelling as "Toxic" and such products would not be generally available to consumers.

(4) Sodium perborate and perboric acid have different classifications depending on the percentage content of particles with an aerodynamic diameter below 50 µm. Does the SCCS consider that this has an impact on their safe use in cosmetic products?

The SCCS considered that the percentage content of particles with an aerodynamic diameter below 50 µm does not have an impact on the safety of sodium perborate and perboric acid when used in a liquid cosmetic formulation. However, in connection to the use addressed in question 3, exposure of consumers to powdered formulations can occur. When using powdered formulation, exposure via inhalation can take place when particles with sizes in the inhalable range (i.e. <15um) are present. Therefore the SCCS considers that the different classification with regard to percentage content may indeed have an impact on their safe use in consumer products. However, since no information on the particle size distribution of the powder is available, the risk of inhalation of particles due to use of the powdered formulation cannot be assessed.

The opinion was adopted

8.4. Dihydroxyacetone

After consideration by the plenary, this opinion was found to need further discussion and was referred back to the Working group. The adoption of the opinion was postponed.

8.5. Erythrosine

The SCCP was asked to assess the risk to consumers when CI 45430 (erythrosine) is used as a colorant in toothpaste products with a maximum concentration of 0.0025% (25 ppm).

The SCCS concluded that CI 45430 (erythrosine) safe for consumers when used as a colorant in toothpaste products with a maximum concentration of 0.0025 % (25 ppm).

Concerning intake from cosmetics (use in toothpastes only), erythrosine has a very high MoS and intake represents only a small fraction of the ADI of 0.1 mg/kg/day. However, aggregate exposure to erythrosine is possible due to other uses (e.g. food, medical products). Exposure from sources different from toothpaste has not been addressed in this opinion.

The opinion was adopted.

8.6. P82, Parabens

After consideration by the plenary, this opinion was found to need further discussion and was referred back to the Working group. The adoption of the opinion was postponed.

8.7. S74, Polysilicone-15

The SCCS was asked to assess the risk to consumers when Polysilicone-15 is used in cosmetic products at a concentration up to 10%, taken into account the new provided scientific data on inhalation.

In 1999, the SCCNFP concluded that Polysilicone-15 (Dimethicodiethylbenzalmalonate) is safe for use in cosmetic products as a UV light absorber at a maximum concentration of 10%. In this case only exposure following dermal application was assessed.

In the present assessment, using a weight of evident approach, the SCCS concluded that the use of Polisilicone-15 at a concentration of 0.1% in pressurised hairsprays does not constitute a risk for the consumer.

With regard to the trigger sprays, no risk of the use of Polysilicone-15 is to be expected, as long as the generated particle sizes in the lower tail of the distribution are above the inhalable size (i.e. >15 um).

The opinion was adopted

8.8. P32, Triclosan – antimicrobial resistance

During the 6th plenary meeting of 23 March 2010, the SCCS adopted a preliminary opinion on triclosan – antimicrobial resistance.

In line with the procedures for stakeholder dialogue, published on 15 September 2007, the European Commission opened a public consultation on this preliminary opinion from 29 March to 26 May 2010.

In total, 10 contributions were received of which 5 were from public authorities, 3 from industry and two from individuals with professional links to this issue. Each contribution was carefully considered and a response was formulated.
The opinion has been revised taking into account all relevant comments. The scientific rationale and the opinion were clarified and strengthened in certain respects.

The overall opinion, however, remains unchanged.

8.9. A14, o-Aminophenol

The SCCS was asked to assess the safety of o-aminophenol in oxidative hair dye formulations at a maximum on-head concentration of 0.6%.

The SCCS concluded that, based on the submitted data, no final conclusion on the safety of o-aminophenol can be drawn.

The data provided for physicochemical properties of o-aminophenol are insufficient and inadequate; no scientifically sound expert judgement can be made on the purity of o-aminophenol batches or on the homogeneity or stability of o-aminophenol or its formulations.
Inadequate information on skin sensitising potential was provided.
The studies on dermal absorption had many shortcomings and were not considered suitable for safety assessment.
Due to inadequacy of the studies provided, a mutagenic potential cannot be excluded.

Before any further reconsideration, the following is required:

- a complete set of physico-chemical data
- a study on skin sensitisation according to the state of the art
- a dermal absorption study according to the Notes of Guidance
- a well performed gene mutation test and a chromosomal aberration/micronucleus test in mammalian cells in vitro according to current guidelines to exclude mutagenicity.

Studies on genotoxicity/mutagenicity in finished hair dye formulations should be undertaken following the relevant SCCNFP/SCCP opinions and in accordance with its Notes of Guidance.

The opinion was adopted.

8.10. B69, HC Yellow n° 9

The SCCS was asked to assess the safety of HC Yellow n° 9 in non-oxidative hair dye formulations at a maximum on-head concentration of 0.5%.

The SCCS concluded that, based on the information provided, the use of HC Yellow n° 9 as a non-oxidative hair dye ingredient at a maximum concentration on the head of 0.5% does not pose a risk to the health of the consumer.

A sensitising potential of HC Yellow n° 9 cannot be excluded.

HC Yellow n° 9 is a secondary amine, and thus is prone to nitrosation and formation of nitrosamines. It should not be used in combination with nitrosating substances. The nitrosamine content should be < 50 ppb.

The opinion was adopted.

8.11. C64, Disperse Violet

The SCCS was asked to assess the safety of Disperse Violet 1 in non-oxidative hair dye formulations at an on-head concentration of 0.5%.

The SCCS concluded that, based on the information provided, the use of Disperse Violet 1 in semi-permanent hair dye formulations at a maximum concentration of 0.5% does not pose a risk to the health of the consumer, apart from its moderate skin sensitising potential.

The fully characterised batches of Disperse Violet 1 contained up to 3% Disperse Red 15. According to Cosmetic Directive Annex II, Disperse Red 15 is only permitted as an impurity in Disperse Violet 1, but without concentration limit. The test batches of Disperse Violet 1 used for the main studies of the safety evaluation contained < 1% Disperse Red 15. Therefore, the impurity of Disperse Red 15 in Disperse Violet 1 for hair dye formulations should be <1% (w/w).

The opinion was adopted.

8.12. Updated Memorandum on Episkin

The adoption of the memorandum was postponed.

8.13. Basic Criteria for the in vitro assessment of dermal absorption of cosmetic ingredients

The basic criteria for the *in vitro* assessment of dermal absorption of cosmetic ingredients were last updated in 2006 (doc. n° SCCP/0970/06).

The application of this update, however, resulted frequently in a disagreement on the number of skin samples and donors, the concentrations to be tested, the variability of the test results and the value to be used for the calculation of Margin of Safety (MoS). This led to the non-acceptance of a number of studies submitted.

These disagreements and the use of default values <100% for dermal absorption in the absence of appropriate experimental data, were discussed with experts in a special meeting on dermal absorption in October 2008. The conclusions of this meeting have been incorporated in the present update and will also be included in the on-going revision of the SCCS Notes of Guidance.

The dermal absorption of nanoparticles is not covered by this update.

The document was adopted.

9. COMMENTS ON OPINIONS ADOPTED DURING THE PLENARY MEETING OF 8 DECEMBER 2009

Comments have been received on the following opinions adopted in the SCCS plenary meeting of 23 March 2010:

- Melatonin
- Vitamin K1
- A11, resorcinol
- A12, 4-chlororesorcinol
- A80, hydroxy-p-phenylenediamine sulfate
- B15, Acid Black 1
- B34, N,N'-bis-(2-hydroxyethyl)-2-nitro-p-phenylenediamine
- C10, Basic Yellow 57

After consideration of the comments received, the opinions were revised where appropriate.

10. ANY OTHER BUSINESS

- The next plenary meeting will take place on 21 September 2010

Annex 1: List of Participants

Annex 1

List of Participants

Members of the SCCS
Prof. J. Angerer, Dr. U. Bernauer, Dr. C. Chambers, Prof. G. Degen, Prof. T. Platzek, Dr. S.C. Rastogi, Prof. V. Rogiers (vice-Chairman), Dr. C. Rousselle, Prof. T. Sanner (vice-Chairman), Dr. J. van Engelen, Prof. M.P. Vinardell, Dr. I.R. White (Chairman)

External expert
Dr. J.-M. Pagès (SCENIHR) – opinion on triclosan only

Apologies
Dr. Q. Chaudhry, Prof. G. Eisenbrand, Prof. C.L. Galli, Prof. K. Savolainen, Prof. R. Waring

SCCS Secretariat (DG SANCO)
Mr. T. Daskaleros, Mrs K. Kilian, Mr. A. Van Elst

DG SANCO B2
/

European Parliament – IMCO Committee
Ms. Z. Roithova, MEP
Ms. H. Carlsen Nielsen
Ms. K. Huliciusova