



EUROPEAN COMMISSION
HEALTH & CONSUMERS DIRECTORATE-GENERAL

Public Health and Risk Assessment
Risk assessment

Scientific Committee on Consumer Safety
6th Plenary Meeting

Held on 23 March 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. Degen, Prof. C.L. Galli, Dr. J. van Benthem and Prof. R. Waring.

2. DECLARATIONS OF INTEREST

Prof. V. Rogiers declared a conflict of interest in relation to the dossier on melatonin. 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/1317/10

The agenda was approved without changes.

4. ADOPTION OF THE DRAFT MINUTES OF THE 5TH PLENARY MEETING

SCCS/1289/10

The minutes of the 5th plenary meeting of 8 December 2009 were approved.

5. INFORMATION FROM CHAIRMAN/MEMBERS

Information from the Chairman

No specific points were raised.

Commission follow-up to earlier opinions

A representative of the SANCO, Unit B2 - Cosmetics and Medical Devices – said that the following legal implementations for cosmetic ingredients were made since the last plenary of 8 December 2009:

- Ethyl Lauroyl Arginate HCl: insertion in Annex III, part 1 (non-preservative purposes, entry n° 207) and in Annex VI, part 1 (preservative purposes, entry n° 58)
- Hair dyes: prolongation of the deadline of the hair dyes listed in Annex III, part 2
- HC Orange n° 2: insertion in Annex III, part 1 (entry n° 208)
- 2-Hydroxyethylamino- 5-nitroanisole: insertion in Annex III, part 1 (entry n° 209)
- Terpene terpenoids sinpine: these words are replaced by 'Terpenes and terpenoids' in Annex III, part 1, entry n° 130
- Verbena oil: modification of its entry in Annex II (entry n° 450) and insertion of Verbena absolute in Annex III, part 1 (entry 155)

Other information

The SANCO Unit B2 - Cosmetics and Medical Devices - reported that ECVAM, with the participation of experts nominated by stakeholders, is working on a technical report on the status of alternative methods in relation to the 2013 deadline for the use of animal data for certain endpoints in safety dossiers for Cosmetics. The SCCS, as well as the other SCs, were asked to nominate experts for the working groups.

6. NEW REQUESTS

6.1. JOINT MANDATES

A joint mandate is planned on the assessment of mixtures of chemicals. The SCCS will be asked to participate when the mandate is issued.

7. REPORTS FROM THE WORKING GROUPS

7.1. COSMETIC INGREDIENTS

The Chairperson of the WG reported on the ongoing work of the Working Group. He said that draft opinions on cyclomethicone, melatonin and vitamin K1 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 Resorcinol (A11), 4-Chlororesorcinol (A12), Hydroxyethyl-p-phenylenediamine sulfate (A80), Acid Black 1 (B15), N,N'-bis-(2-hydroxyethyl)-2-nitro-p-phenylenediamine (B34), Basic Yellow 57 (C10), Disperse Violet (C64) and on Disperse Black 9 (C106) were prepared and tabled for formal adoption.

7.3. METHODOLOGIES

The Chairperson of the WG said that one Working Group meeting had taken place since the plenary meeting of 8 December 2009. Main task of the WG is the revision of the Notes of Guidance.

The current practice of using 700 cm² as scalp surface area in exposure calculations in particular for hair dyes was discussed as it likely represents an overestimation. The Committee agreed that in the future a scalp area of 580 cm², which has been published in the scientific literature, will be used in the safety assessment of hair dyes and others substances.

7.4. NANO-MATERIALS IN COSMETICS

As the Chairperson was not able to attend, the secretariat said that a request for additional data on TiO₂ and on ETH50 was sent to the applicants.

7.5. TRICLOSAN (ANTIMICROBIAL RESISTANCE)

The Chairperson said that the WG finalised its work and that a draft opinion was tabled for formal adoption.

7.6. TTC

The Chairperson said that comments on the draft opinion were received from SCHER, which will be discussed during the WG meeting of 7 June 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 the WG initiated its work on an opinion on food imitating products.

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:

- anti-microbial resistance
- heavy metals in jewellery
- CMR in toys
- possible improvements in risk assessment
- nano-definitions
- Fluoride in drinking water

8. DRAFT OPINIONS - DISCUSSION AND POSSIBLE ADOPTION

8.1. A11, RESORCINOL

The SCCS was asked to assess the safety of resorcinol in oxidative hair dye formulations at a maximum on-head concentration of 1.25%.

The SCCS concluded that, based on the information provided, the use of resorcinol as an ingredient in oxidative hair dye formulations with a maximum on-head concentration of 1.25% does not pose a risk to the health of the consumer, apart from its sensitising potential.

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.

Resorcinol is also used as a food additive and was recently evaluated by EFSA. The exposure from other sources has not been considered in this EFSA-opinion.

The opinion was adopted.

8.2. A12, 4-CHLORORESORCINOL

The SCCS was asked to assess the safety of 4-chlororesorcinol in oxidative hair dye formulations at a maximum on-head concentration of 2.5%.

The SCCS concluded that, based on the information provided, the use of 4-chlororesorcinol itself as an oxidative hair dye substance at a maximum on-head concentration of 2.5% does not pose a risk to the health of the consumer, apart from its moderate skin sensitising potential.

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.

8.3. A80, HYDROXYETHYL-P-PHENYLENEDIAMINE SULFATE

The SCCS was asked to assess the safety of hydroxyethyl-p-phenylenediamine sulfate in oxidative hair dye formulations at a maximum on-head concentration of 2.0%.

The SCCS concluded that, based on the information provided, the use of hydroxyethyl-p-phenylenediamine sulfate itself as an ingredient in oxidative hair dyes at a maximum concentration on-head of 2% does not pose a risk to the health of the consumer, apart from its strong sensitising potential.

Hydroxyethyl-p-phenylenediamine sulfate itself has no mutagenic potential *in vivo*. However, 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.

8.4. B15, ACID BLACK 1

The SCCS was asked to assess the safety of Acid Black 1 in non-oxidative hair dye formulations at a maximum on-head concentration of 0.5%.

The SCCS concluded that, based on the information provided and based on the low margin of safety, the use of Acid Black 1 as a direct hair colouring agent in non-oxidative hair dye formulations at a maximum on-head concentration of 0.5% poses a risk to the health of the consumer.

Acid Black 1 (CI 20470) is listed in Annex IV, part 1 – List of colouring agents allowed for use in cosmetic products, field of application: 4 – colouring agents allowed exclusively in cosmetic products intended to come into contact only briefly with the skin.

The use of Acid Black 1 (CI 20470) as a cosmetic colorant should be evaluated.

The opinion was adopted.

8.5. B34, N,N'-BIS-(2-HYDROXYETHYL)-2-NITRO-P-PHENYLENEDIAMINE

The SCCS was asked to assess the safety of N,N'-Bis-(2-hydroxyethylamino)-2-nitro-p-phenylenediamine at concentrations on-head up to 1.5% in non-oxidative or up to 1.0% oxidative hair dye formulations.

The SCCS decided that, based on the information provided, a conclusion on the gene mutation potential of N,N'-bis-(2-hydroxyethyl)-2-nitro-p-phenylenediamine cannot be drawn without further testing.

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.

N,N'-bis-(2-hydroxyethyl)-2-nitro-p-phenylenediamine is a secondary amine and prone to nitrosation. The nitrosamine content in the dye should be <50 ppb. It should not be used in the presence of nitrosating agents.

The opinion was adopted.

8.6. C10, BASIC YELLOW 57

The SCCS was asked to assess the safety of Basic Yellow 57 in non-oxidative hair dye formulations at a maximum on-head concentration of 2.0%.

The SCCS concluded that there is insufficient data to assess the safety of Basic Yellow 57 when used as an ingredient in non-oxidative hair dye formulations at a maximum on-head concentration 2.0%.

The physico-chemical data on Basic Yellow 57 should be completed and further information on the safety of methylsulfate is required.

The toxicological equivalency of the test batches should be demonstrated. Information on the presence of methylsulfate in commercial batches of basic yellow 57 should be provided.

A sensitising potential of Basic Yellow 57 cannot be excluded.

The opinion was adopted.

8.7. C64, DISPERSE VIOLET

The adoption of the opinion was postponed.

Additional data was submitted on the physico-chemical properties and on mutagenicity, which must be first evaluated by the WG.

8.8. C106, DISPERSE BLACK 9

The SCCS was asked to assess the safety of Disperse Black 9 in non-oxidative hair dye formulations at an on-head concentration of 0.3% Disperse Black 9, corresponding to 0.15% 2,2'-[4-(4-aminophenylazo)phenylimino]diethanol.

The SCCS concluded that, based on the information provided, the use of Disperse Black 9 as a non-oxidative hair dye with a maximum on-head concentration of 0.3% (corresponding to 0.15% 2,2'-[4-(4-aminophenylazo)phenylimino]diethanol dispersed in lignosulfate) does not pose a risk to the health of the consumer.

A sensitising potential cannot be excluded.

The opinion was adopted.

8.9. CYCLOMETHICONE D4 / D5

Because of concerns raised during the discussion regarding the exposure estimations, the SCCS concluded to postpone the adoption of the opinion.

8.10. MELATONIN

The SCCS was asked to assess the safety of melatonin at a concentration of 0.0033% w/w (33 µg/g) in cosmetic hair care products.

The SCCS concluded that, based on the information provided, the use of melatonin in hair products at a concentration of 0.0033% w/w (33 µg/g) does not pose a risk for the health of the consumer.

The opinion was adopted

8.11. TRICLOSAN (ANTI-MICROBIAL RESISTANCE)

The SCCS was asked whether they consider a continued use of triclosan as a preservative in cosmetic products as safe taking into account the new provided documentation on resistance development by certain micro-organisms and on cross-resistance.

The SCCS concluded that:

At present, several distinct hazards have been identified: (i) the effect of triclosan on the triggering/regulation of resistance genes in bacteria (ii) the existence of mechanisms which can promote resistance and cross-resistance to biocides and antibiotics in bacteria, (iii) high concentrations of triclosan have been measured in certain environmental compartments, (iv) the presence of resistance genes in soil bacteria, and, (v) bacterial biofilms are widespread in the environment and are able to survive exposure to adverse environmental factors. The first two of these hazards have been identified *in vitro*.

However, the six *in situ* studies and the one meta-analysis quoted in this document have failed to demonstrate an increase in antibiotic resistance following triclosan use. While these results are at first sight reassuring, these *in situ* data are not sufficient to draw a conclusion on whether the continuous use of triclosan is involved in the development of resistance. Thus, additional *in situ* information is needed to provide an answer on the level of risk.

This opinion concerns the safety of triclosan in terms of microbiology, i.e. generation of bacterial resistance harmful for human health. Based on the available scientific information, it is not possible to quantify the risk of development of antimicrobial resistance induced by triclosan applications, including its use in cosmetics. However, there are environmental concentrations in a number of geographically distinct areas high enough to suggest that triggering of bacterial resistance could also occur in the environment. The applications of triclosan which contribute to those high environmental concentrations cannot be properly identified nor quantified at present. This should be taken into account when considering the current and future uses of triclosan in all applications so as to ensure that the demonstrable benefits for human health in certain applications are not compromised.

The preliminary opinion was adopted.

In line with its procedures for stakeholder dialogue, published on 15 September 2007, the European Commission has launching a public consultation on this preliminary opinion.

8.12. VITAMIN K1

The SCCS was asked whether the new scientific data submitted supersedes the concern about the allergenic potential of vitamin K1 when used in cosmetic products in a concentration up to 1.0%.

The SCCS concluded that the new data submitted does not supersede concerns about the allergenic potential of vitamin K1 when used in cosmetic products in a concentration up to 1.0%.

Although the risk for sensitisation from cosmetic products containing 1% Vitamin K1 cannot be quantified from the available data, case reports show that Vitamin K1 is a contact allergen in man. In cases of pre-existing sensitisation acquired by topical application of Vitamin K1 present in cosmetics, an individual might not be able to receive Vitamin K1 therapeutically or experience

allergic reactions upon Vitamin K1 treatment. Therefore, the SCCS considers that vitamin K1 is not safe when used in cosmetic product in a concentration up to 1%.

In addition, the database, especially for genotoxicity and developmental/reproductive toxicity, is not considered adequate. No reliable critical effect level can be derived for a risk assessment of Vitamin K1 in cosmetic products.

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

- A94, 5-Amino-6-chloro-o-cresol
- A98, Hydroxyethyl-3,4-methylenedioxyaniline HCl
- B36, HC Red n° 7
- B38, HC Yellow n° 4

After consideration of the comments received, the SCCS concluded that there were no grounds to change the opinions, apart from the change in scalp surface area (from 700 to 580 cm²).

- Alkyl (C16, C18, C22) triethylammoniumchloride

In response to the comments received regarding the dose level of P72 as the amount applied per square cm, the SCCS decided to insert the respective table from the original submission in the opinion.

- P56, Methylchloroisothiazolinone / methylisothiazolinone (CMI/MI)

Because of the comments received, the SCCS decided to re-address the opinion to the respective Working Group for further consideration.

10. ANY OTHER BUSINESS

- Next Plenary meeting: 22 June 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. Eisenbrand, Prof. T. Platzek, Dr. S.C. Rastogi, Prof. V. Rogiers (vice-Chairman), Dr. C. Rousselle, Prof. T. Sanner (vice-Chairman), Prof. K. Savolainen, 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. Degen, Prof. C.L. Galli, Dr. J. van Benthem, Prof. R. Waring

SCCS Secretariat (DG SANCO)

Mr. T. Daskaleros, Mrs K. Kilian, Mr. A. Van Elst

DG SANCO B2

Mrs. A. Orloff