



EUROPEAN COMMISSION
HEALTH & CONSUMERS DIRECTORATE-GENERAL
Public Health and Risk Assessment
Risk assessment

Scientific Committee on Consumer Safety
8th plenary Meeting

Held on 21 September 2010 in Brussels

MINUTES

1. WELCOME AND APOLOGIES

The chairman of the SCCS welcomed all the participants. Apologies were received from Prof. J. Angerer; Dr. Q. Chaudry, Dr. C. Rousselle and Prof. K. Savolainen.

2. DECLARATIONS OF INTEREST

No 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/1371/10

The agenda was approved without changes.

4. ADOPTION OF THE DRAFT MINUTES OF THE 7TH PLENARY MEETING SCCS/1363/10

The minutes of the 7th plenary meeting of 22 June 2010 were approved.

5. INFORMATION FROM CHAIRMAN/MEMBERS

Information from the Chairman

The chairman said that he attended the 10th Congress of the European Society of Contact Dermatitis on 15 to 18 September 2010 in Strasbourg. The Congress focussed on the prevention of skin allergy in Europe.

Prof. Platzek and Dr. J. van Benthem participated in an expert meeting organised by the German Federal Institute for Risk Assessment (BfR) on "Mutagenicity/Genotoxicity Testing without Animals?" in Berlin on 24-25 June 2010. The proceedings of this meeting will be further discussed in the WG on Methodologies.

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. SCCS

- Request for a scientific clarification/opinion on Entry 411, Annex II, Secondary alkyl- and alkanolamines and their salts, and the possible impacts on Annex III, entry 60, Fatty acid dialkylamides and dialkanolamides and their salts, entry 61, Monoalkylamines, monoalkanolamines and their salts, and entry 62, Trialkylamines, trialkanolamines and their salts
- Request for an opinion on nitrosamines in cosmetic products and balloons

6.2. Mandates for other / all Committees

- Assessing Human Exposures for Risk Assessment and Risk Management: An International Perspective (SCHER, participation from other Committees welcome)
- Expressing the Uncertainties for Risk Assessment and Risk Management: An International Perspective (SCHER, participation from other Committees welcome)

7. REPORTS FROM THE WORKING GROUPS

7.1. Cosmetic Ingredients

The Chairperson of the WG reported on the ongoing work. Draft opinions on diethylene glycol monoethyl ether (DEGEE) and on parabens (P82) were prepared and tabled for formal adoption.

7.2. Hair Dyes

The Chairperson of the WG reported on the ongoing work. Draft opinions on reaction products of oxidative hair dye ingredients formed during hair dyeing processes, 1,5-Naphthalenediol (A18), 2,7-Naphthalenediol (A19), 2,4-Diaminophenoxyethanol (sulphate salt) (A42), Picramic acid (B28), HC Red n° 13 (B31), HC Yellow n° 2 (B41), 4-Nitrophenyl aminoethylurea (B70) and on HC Yellow n° 7 (B80) were prepared and tabled for formal adoption.

7.3. Methodologies

The Chairperson of the WG said that no WG-meeting had taken place since the previous plenary meeting of 22 June 2010. A meeting is planned on 6 October 2010 which will focus on genotoxicity/mutagenicity testing without animals and on the ECVAM report on alternative methods for the testing of cosmetic ingredients.

7.4. Nano-materials in Cosmetics

As the Chairperson was not able to attend, the secretariat said that no WG meeting had taken place since the previous plenary meeting. However, there was a meeting on 6 July 2010 with industry representatives where remaining questions on the dossier on ETH-50 were discussed.

7.5. TTC

The Chairperson said that no WG-meeting had taken place since the previous plenary meeting of 22 June 2010. A WG meeting is planned on 27 September 2010 to finalise the draft opinion.

7.6. Sensitisation & Fragrances

The Chairperson said that one WG-meeting had taken place since the previous plenary meeting of 22 June 2010. The Working Group continues the revision of the opinion on the labelling of 26 fragrance substances.

7.7. Food imitating products

As the Chairperson was not able to attend, the secretariat said that a first draft opinion has been prepared which was tabled for discussion.

7.8. 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. Potential health risks posed by food-imitating and child-appealing chemical consumer products

The plenary discussed the draft. The final draft, taking into account the comments received, will be presented at the next plenary.

8.2. Parabens (p82)

The adoption of the opinion was postponed.

8.3. Diethylene glycol monoethyl ether (DEGEE)

The SCCS was asked to consider whether the use of DEGEE as a solvent in cosmetic products in a concentration up to 5.5% in leave-on products and/or in a concentration up to 10% in rinse-off products is safe for the consumer. And whether an additional use of the substance DEGEE as solvent in an on-head concentration up to 7.0% in oxidative hair dye formulations and in an on-head concentration up to 5.0% in non-oxidative hair dye formulations is safe.

The SCCP previously concluded in its opinion of 16.12.08 (SCCP/1200/08) that the use of diethylene glycol monoethyl ether (DEGEE) as a solvent in an on-head concentration of up to 7.0% in oxidative hair dye formulations and in an on-head concentration of up to 5.0% in non-oxidative hair dye formulations in addition to the use of DEGEE at concentrations up to 1.5% in all cosmetic products, except products for oral hygiene and eye products, does not pose a risk to the health of the consumer, provided that the level of ethylene glycol in DEGEE used is < 0.2%.

Based on the new information submitted, SCCS concluded that:

1. the use of DEGEE as a solvent in cosmetic products in a concentration up to 10% in rinse-off products does not pose a risk to the health of the consumer.
2. the use of DEGEE as a solvent in cosmetic products in a concentration up to 5.5% in leave-on products does pose a risk to the health of the consumer.
3. an additional use of the substance DEGEE as solvent in an on-head concentration up to 7.0% in oxidative hair dye formulations and in an on-head concentration up to 5.0% in non-oxidative hair dye formulations does not pose a risk to the health of the consumer.
4. the additional use of DEGEE at concentrations up to 1.5% in all cosmetic products does not pose a risk to the health of the consumer.
5. DEGEE must not be used in products for oral hygiene and the eyes. The level of ethylene glycol in DEGEE used should be less than 0.2%

The opinion relates to the dermal application of cosmetic products only and does not include any other cosmetic exposure, such as exposure from possible aerosol/spray products. Aggregate exposure to diethylene glycol monoethyl ether (DEGEE) from non-cosmetic sources has not been considered.

The opinion was adopted.

8.4. Reaction products of oxidative hair dye ingredients formed during hair dyeing processes

The SCCS was asked, in the light of the current data submission and the available data base from previous submissions, to evaluate the consumer health risk by products and intermediates of oxidative hair dyes formed during the hair dyeing process.

Based on the data yet available, the SCCS raised no major concern regarding genotoxicity and carcinogenicity of hair dyes and their reaction products currently used in the EU. However, at present, the data base on genotoxicity on reaction products underpinning this conclusion is small and therefore some degree of uncertainty remains. Enlargement of the data base with data on additional reaction products would strengthen the above conclusions drawn from the limited data currently available and further reduce the level of uncertainty.

At present, confirmation of safety regarding genotoxicity and carcinogenicity could only be achieved by the use of *in vivo* studies, which, however, are no longer permitted according to EU legislation. In the future, modern methodologies (e.g. skin models, -omics, SAR) may allow the assessment of safety without animal experimentation.

The opinion was adopted.

8.5. A18, 1,5-Naphthalenediol

The SCCS was asked to assess the safety of 1,5-naphthalenediol in oxidative and non-oxidative hair dyes with a maximum concentration up to 1.0%.

The SCCS concluded that 1,5-naphthalenediol as an ingredient in oxidative and non-oxidative hair dye formulations at a maximum on-head concentration of 1% does not pose a risk to the health of the consumer, apart from its sensitising potential.

The results from a LLNA study indicate that 1,5-naphthalenediol is a moderate skin sensitiser.

1,5-Naphthalenediol 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.

8.6. A19, 2,7-Naphthalenediol

The SCCS was asked to assess the safety of 2,7-naphthalenediol in oxidative and non-oxidative hair dyes with a maximum concentration up to 1.0%.

The SCCS concluded that 2,7-naphthalenediol as an ingredient in oxidative and non-oxidative hair dye formulations at a maximum on-head concentration of 1% does not pose a risk to the health of the consumer, apart from its sensitising potential.

2,7-Naphthalenediol is a moderate sensitizer.

2,7-Naphthalenediol 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.

8.7. A42, 2,4-Diaminophenoxyethanol (sulphate salt)

The SCCS was asked to assess the safety of 2,4-diaminophenoxyethanol in the form of its either dihydrochloride or sulfate salt safe for use as an oxidative hair dye with a concentration on-head of maximum 2.0%.

The SCCS concluded that the use of 2,4-diaminophenoxyethanol dihydrochloride or 2,4-diaminophenoxyethanol sulfate in an oxidative hair dye formulation at a maximum final concentration of 2.0% (after mixing with hydrogen peroxide) 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 opinions and in accordance with its Notes of Guidance.

The opinion was adopted.

8.8. B28, Picramic acid

The adoption of the opinion was postponed.

8.9. B31, HC Red n° 13

The adoption of the opinion was postponed.

8.10. B41, HC Yellow n° 2

The SCCS was asked to assess the safety of HC Yellow n° 2 for use as an ingredient in oxidative hair dye formulations with a maximum concentration of up to 0.75% on the scalp and in non-oxidative hair dye with a maximum concentration of 1.0% in the finished cosmetic product.

The SCCS concluded that the use of HC Yellow n° 2 with a maximum on-head concentration of 0.75% in oxidative and of 1.0% in non-oxidative hair dye formulations does not pose a risk to the health of the consumer.

A possible sensitising potential of HC Yellow n° 2 cannot be excluded.

HC Yellow n° 2 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. B70, 4-Nitrophenyl aminoethylurea

The SCCS was asked to assess the safety of 4-nitrophenyl aminoethylurea for use in non-oxidative hair dye formulations with an on-head concentration of maximum 0.5% and in oxidative hair dye formulations with an on-head concentration of maximum 0.25%.

The SCCS concluded that the use of 4-nitrophenyl aminoethylurea with a maximum on-head concentration of 0.25% in oxidative and 0.5% in non-oxidative hair dye formulations does not pose a risk to the health of the consumer.

4-Nitrophenyl aminoethylurea is a secondary amine. It should not be used in combination with nitrosating substances. The nitrosamine content should be < 50 ppb.

The opinion was adopted.

8.12. B80, HC Yellow n° 7

The SCCS was asked to assess the safety of HC Yellow n° 7 safe for use as a non-oxidative hair dye with an on-head concentration of maximum 0.25%.

The SCCS concluded that the use of HC Yellow n° 7 as a non-oxidative hair dye with a maximum on-head concentration of 0.25% does not pose a risk to the health of the consumer.

The opinion was adopted.

8.13. Episkin

The adoption of the opinion was postponed.

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 22 June 2010:

- Cyclomethicone D4 / D5
- Boron compounds
- Sodium perborate and perboric acid
- A94, 5-amino-6-chloro-o-cresol
- C64, Disperse Violet 1

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

10. ANY OTHER BUSINESS

- The next plenary meeting will take place on 14 December 2010

Annex 1: List of Participants

List of Participants

Members of the SCCS

Dr. U. Bernauer, Dr. C. Chambers, Prof. G. Degen, Prof. T. Platzek, Dr. S.C. Rastogi, Prof. V. Rogiers (vice-Chairman), Prof. T. Sanner (vice-Chairman), Dr. J. van Benthem (associate scientific advisor), Dr. J. van Engelen, Prof. M.P. Vinardell, Prof. R. Waring, Dr. I.R. White (Chairman)

Apologies

Prof. J. Angerer, Dr. Q. Chaudhry, Dr. C. Rousselle, Prof. K. Savolainen

SCCS Secretariat (DG SANCO)

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

DG SANCO B2

/