



Scientific Committee on Consumer Safety
16th plenary Meeting

Held on 18 September 2012 in Brussels

MINUTES

1. WELCOME AND APOLOGIES

The chairman of the SCCS welcomed all the participants. Apologies were received from Prof. J. Angerer, Prof. G. Degen and Dr. J. van Benthem.

2. APPROVAL OF THE DRAFT AGENDA

The agenda was approved.

3. DECLARATIONS OF INTEREST

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

4. ADOPTION OF THE DRAFT MINUTES OF THE 15TH PLENARY MEETING

The minutes of the 15th plenary meeting of 26 - 27 June 2012 were approved.

5. INTRODUCTION OF MR. TAPANI PIHA, HEAD OF UNIT SANCO D3

Mr. Piha introduced himself as the new Head of the Unit responsible for risk assessment. A medical doctor by training, he described his previous tasks at the Finnish Ministry of Social Affairs & Health, WHO-Europe and in the Commission services.

6. INFORMATION FROM CHAIRMAN/MEMBERS/COMMISSION

6.1. Follow-up of previous opinions

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6.2. Other points

The Commission reported that no decision has been taken yet regarding the renewal/new structure of the scientific committees. The members were asked whether they would be willing to remain in office until they are replaced or their appointments renewed.

7. NEW AND UPCOMING REQUESTS

Mrs G. Ciarlo, Unit B2, announced a mandate to evaluate a new study on parabens.

8. ON-GOING WORK

8.1. WG on Cosmetic Ingredients

The Chairperson of the WG reported on the on-going work. Two meetings had taken place since the previous plenary meeting of 26-27 June 2012. Two draft opinions had been prepared which were tabled for adoption.

8.2. WG on Hair Dyes

The chairman of the WG reported on the on-going work. Two meetings had taken place since the previous plenary meeting. Nine draft opinions had been prepared and tabled for adoption.

8.3. WG on Methodologies

No WG meeting had taken place since the previous plenary meeting. A meeting is planned for 11 October 2012.

8.4. WG on Nano-materials in Cosmetics

The Chairperson of the WG reported on the on-going work. One meeting had taken place since the previous plenary meeting. The draft opinion on Zinc oxide was tabled for adoption.

8.5. Participation of Members in activities of other Scientific Committees

The members involved in the activities of WGs developing joint opinions, reported on the progress of the work on:

- Joint opinion on Improvement of risk assessment
- Joint opinion on New Challenges in Risk Assessment

9. DRAFT OPINIONS – FOR DISCUSSION AND POSSIBLE ADOPTION

9.1. Acetaldehyde

The SCCS was asked to answer the following questions:

- *Is acetaldehyde safe when present up to 100 ppm in cosmetic products taking into account the new data provided?*
- *And/or does the SCCS recommend any other concentration limit with regard to the use of Acetaldehyde as an ingredient in cosmetic products?*
- *Does the SCCS have any further scientific concerns regarding the use of Acetaldehyde in mouth-washing products?*

The SCCS concluded that acetaldehyde, present up to 100 ppm in cosmetic products, is not safe based on life time cancer risk. However, the calculations are based on a number of worse case considerations which will lead to an overestimation of the risk.

Exposure from the dermal, inhalation and oral route cannot be properly assessed. In addition, there are no data available on metabolism of acetaldehyde in the skin.

Acetaldehyde should not be used as an intended ingredient in cosmetic products except used as a fragrance/flavour ingredient at a maximum concentration of 0.0025% (25 ppm) in the fragrance compound (as assessed in the SCCNFP opinion SCCNFP/0821/04) resulting in approximately 2 ppm in the finished cosmetic product or 4 ppm in fine fragrances.

IARC has recently concluded that the increased risk of alcohol-related cancer in particular of the upper aero-digestive tract may be due to the formation of acetaldehyde. This supports the findings from inhalation studies that acetaldehyde in direct contact with mucous epithelium can induce tumours. SCCS is of the opinion that acetaldehyde should not be intentionally used in mouth-washing products.

The opinion was adopted.

9.2. Dichloromethane

The adoption of the opinion was postponed.

9.3. Zinc oxide, nano-form (S76)

The SCCS was requested to answer the following questions:

- *Does the SCCS consider zinc oxide in its nano-form safe for use as a UV-filter with a concentration up to 25% in cosmetic products taking into account the scientific data provided?*
- *Does the SCCS confirm that zinc oxide in its non-nano form is safe for use as a UV-filter with a concentration up to 25% as stated in the SCCP clarification (SCCP/1215/09)?*
- *And/or does the SCCS have any further scientific concern with regard to the use of zinc oxide in cosmetic products?*

The SCCS adopted an opinion in accordance with the above terms of reference. The replies to the various questions can be found in document n° SCCS/1489/12.

9.4. A33, 1,2,4-Trihydroxybenzene

The adoption of the opinion was postponed.

9.5. A159, 2,3-Diaminodihydropyrazolone dimethosulfonate

The SCCS was asked to answer the following questions:

- *Does the SCCS consider 2,3-diaminodihydropyrazolopyrazolone dimethosulfonate safe for use as an oxidative hair dye with a concentration on-head of maximum 2.0 % taken into account the scientific data provided?*
- *And/or does the SCCS have any further scientific concerns with regard to the use 2,3-diaminodihydropyrazolopyrazolone dimethosulfonate in oxidative hair dye formulations?*

The SCCS concluded that the use of 2,3-diaminodihydropyrazolopyrazolone dimethosulfonate with a maximum on-head concentration of 2.0% in oxidative hair dye formulations does not pose a risk to the health of the consumer.

A sensitising potential of 2,3-diaminodihydropyrazolopyrazolone dimethosulfonate cannot be excluded.

The opinion was adopted.

9.6. B28, Picramic acid and sodium picramate

The SCCS was asked to answer the following questions:

- 1. Does SCCS consider Picramic acid and Sodium picramate safe for use as oxidative hair dye with a concentration on-head of maximum 0.6 % taking into account the scientific data provided?*
- 2. And/or does the SCCS recommend any further restrictions with regard to the use of Picramic acid and Sodium picramate in oxidative hair dye formulations?*

The SCCS concluded that the use of picramic acid/sodium picramate with a maximum on-head concentration of 0.6% in oxidative and non-oxidative (see SCCS/1227/10) hair dye formulations does not pose a risk to the health of the consumer, apart from its sensitising potential.

The opinion was adopted.

9.7. B50, HC Red n° 3

The SCCS was asked to answer the following questions:

- 1. Does the SCCS consider HC Red n° 3 safe for use as oxidative hair dye with a concentration on-head of maximum 0.45% taking into account the scientific data provided?*
- 2. And/or does the SCCS recommend any further restrictions with regard to the use of HC Red n° 3 in oxidative hair dye formulations?*
- 3. Does the SCCS consider the conclusion from the previous opinion (SCCS/1293/10) still valid?*

The SCCS concluded that the use of HC Red n° 3 in oxidative hair dye formulations at a maximum on-head concentration of 0.45% and in non-oxidative (see SCCS/1293/10) hair dye formulations at a maximum on-head concentration of 3.0% does not pose a risk to the health of the consumer, apart from its sensitisation potential.

HC Red n° 3 is an extreme contact sensitiser.

HC Red n° 3 is a secondary amine, and thus prone to nitrosation. It should not be used in combination with nitrosating substances. The nitrosamine content should be < 50 ppb.

The opinion was adopted.

9.8. B60, 2-Nitro-5-glyceryl methylaniline

The SCCS was asked to answer the following questions:

1. Does the SCCS consider 2-nitro-5-glyceryl methylaniline, Hair Dye B060, safe for use as an oxidative and non-oxidative hair dye with a concentration on-head of maximum 0.8% and 1.0 % respectively taken into account the scientific data provided?
2. And/or does the SCCS recommend any further restrictions with regard to the use of 2-nitro-5-glyceryl methylaniline, Hair Dye B060, in any hair dye formulations?

The SCCS concluded that the use of 2-nitro-5-glyceryl methylaniline, at a maximum on-head concentration of 0.8% in oxidative and of 1.0% in non-oxidative hair dye formulations does not pose a risk to the health of the consumer.

2-Nitro-5-glyceryl methylaniline is a secondary amine, and thus, prone to nitrosation. It should not be used in combination with nitrosating agents. The nitrosamine content should be < 50 ppb.

A sensitisation potential of 2-nitro-5-glyceryl methylaniline cannot be excluded.

The opinion was adopted.

9.9. B119, HC Blue 16

The SCCS was asked to answer the following questions:

1. Does SCCS consider *N,N*-dimethyl-3- $\{[4-(methylamino)-9,10-dioxo-9,10-dihydro-1-anthracenyl]amino\}$ -*N*-propyl-1-propanaminium bromide safe for use as a non-oxidative hair dye with a concentration on-head of maximum 3.0 % taken into account the scientific data provided?
2. And/or does the SCCS have any further scientific concerns with regard to the use *N,N*-dimethyl-3- $\{[4-(methylamino)-9,10-dioxo-9,10-dihydro-1-anthracenyl]amino\}$ -*N*-propyl-1-propanaminium bromide in non-oxidative hair dye formulations?

The SCCS concluded that the use of HC Blue 16 with a maximum on-head concentration of 3.0% in non-oxidative hair dye formulations does not pose a risk to the health of the consumer.

A sensitisation potential of HC Blue 16 cannot be excluded.

HC Blue 16 is a secondary amine, and thus prone to nitrosation. It should not be used in combination with nitrosating substances. The nitrosamine content should be < 50 ppb.

The opinion was adopted.

9.10. C170, Indigofera tinctoria

The SCCS was asked to answer the following questions:

1. Does the SCCS consider *Indigofera tinctoria* safe for the consumers when used as a hair dye taken into account the scientific data provided?

2. *And/or does the SCCS recommend any further restrictions with regard to the use of Indigofera tinctoria in any hair dye formulations?*

The SCCS concluded that the safety of *Indigofera tinctoria* used as a hair dye at a maximum concentration on the head of 25% cannot be assessed due to incomplete information.

The safety of Indigo (CI 73 000) used as a colorant should be re-assessed.

The opinion was adopted.

9.11.C181, Pigment Red 57

The SCCS was asked to answer the following question:

Does the Scientific Committee on Consumer Safety (SCCS) consider Pigment Red 57 safe for consumers when used as a direct dye in non-oxidative hair dye formulations at a maximum concentration on the scalp at 0.4% taking into account the scientific data provided?

The SCCS concluded that, despite some shortcomings in the toxicological dataset, the available data does not indicate toxic effects of Pigment Red 57 at the low systemic exposure level foreseen after its use as a hair dye due to low absorption. Therefore, the SCCS concludes that Pigment Red 57 does not pose a risk to the health of the consumer, when used as a direct dye in non-oxidative hair dye formulations, at a maximum on-head concentration of 0.4%.

However, Pigment Red 57 is also used in other cosmetic products as a colorant leading to additional exposure of the consumers. The SCCS recommends that the safety of Pigment Red 57 for this use should be assessed.

The opinion was adopted.

9.12. Opinion on hair dye substances and hydrogen peroxide used in products to colour eyelashes

The SCCS was asked to answer the following questions:

- *Does SCCS consider the safety data, in particular the data provided on eye irritation, sufficient to conclude that oxidative hair dyes which were found safe for use in hair dye products can be safely used in products to colour eyelashes? If not, which data would be required by SCCS in order to carry out safety assessment for this specific field of application?*
- *Taking into account the scientific data available for the assessment of hydrogen peroxide used in oral hygiene products and tooth whitening products, does SCCS consider hydrogen peroxide safe for use in products to colour eyelashes (after mixing with oxidative hair dyes found safe for use in hair dye products) in concentrations up to 2% applied on eyelashes?*

The SCCS concluded that some of the dyes, which were tested at or near anticipated use concentrations and were found to be not or slightly irritant, can be considered safe. It is unknown what the irritant potential is of those dyes which have not been tested at use concentrations but which are irritant at the concentrations tested. For these substances appropriate information is required before they can be assessed.

The opinion was adopted.

9.13. Joint SCHER/SCCS/SCENIHR opinion on improvement of risk assessment

The adoption of the opinion was postponed.

9.14. Joint SCHER/SCCS/SCENIHR opinion on New challenges in risk assessment

The adoption of the opinion was postponed.

10. COMMENTS ON OPINIONS FROM LAST PLENARY MEETING

Comments on opinions adopted in the SCCS plenary meeting of 26 and 27 June 2012 have been received. All comments were reviewed and discussed by the experts at the WG and opinions were modified as appropriate.

The following draft opinions were discussed:

- A5, Toluene-2,5-diamine
- A7, p-Phenylenediamine
- A75, 6-Amino-m-cresol
- B34, N,N'-bis-(2-hydroxyethylamino)-2-nitro-p-phenylenediamine
- C183, Tetrabromophenol Blue
- Methylene glycol
- NDELA in cosmetic products and nitrosamines in balloons
- P72, Soytrimonium chloride
- P96, Benzisothiazolinone

11. ANY OTHER BUSINESS

The next plenary meeting will take place on 11 December 2012

Annex 1: List of Participants

Annex 1

List of Participants

Members of the SCCS

Dr. U. Bernauer, Dr. C. Chambers, Dr. Q. Chaudhry, Dr. W. Lilienblum (associate scientific advisor), Dr. E. Nielsen, Prof. T. Platzek, Dr. S.C. Rastogi, Dr. C. Rousselle, Prof. V. Rogiers, Prof. T. Sanner (vice-Chair), Dr. J. van Engelen, Prof. M.P. Vinardell, Prof. R. Waring Dr. I.R. White (Chair),

Apologies

Prof. J. Angerer, Prof. G. Degen, Dr. J. van Benthem,

SCCS Secretariat (DG SANCO)

Ms. C. Arranz Aceves, Mr. T. Daskaleros, Ms K. Kilian, Mr. T. Piha, Mr. A. Van Elst

DG SANCO B2

Mrs G. Ciarlo, Mrs. F. de Gaetano