



Scientific Committee on Consumer Safety
14th plenary Meeting

Held on 27 March 2012 in Brussels

MINUTES

1. WELCOME AND APOLOGIES

The chairman of the SCCS welcomed all the participants. No apologies were received.

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 13TH PLENARY MEETING

The minutes of the 13th plenary meeting of 13-14 December 2011 were approved.

5. INFORMATION FROM CHAIRMAN/MEMBERS/COMMISSION

5.1. Renewal of the Scientific Committees

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

5.2. Follow-up of previous opinions

No specific points were raised.

5.3. Other points

No specific points were raised.

6. NEW REQUESTS

Request for a scientific opinion on:

- Methylene glycol (CAS n° 463-57-0)
- Acetaldehyde (CAS 75-07-0)

7. ONGOING WORK

7.1. WG on Cosmetic Ingredients

The Chairperson of the WG reported on the ongoing work. Two meetings had taken place since the previous plenary meeting of 13-14 December 2011. Two draft opinions had been prepared which were tabled for adoption.

7.2. WG on Hair Dyes

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

7.3. WG on Methodologies

One WG meeting had taken place since the previous plenary meeting, during which the following issues were discussed: risk assessment for inhalation exposure, safety testing of substances with low bioavailability, update to the Notes of Guidance (intestinal models to assess oral bioavailability; bio-monitoring) and the guidance for annex I of the cosmetics regulation.

7.4. WG on Nano-materials in Cosmetics

The Chairperson of the WG reported on the on-going work. Four meetings had taken place since the previous plenary meeting. The WG continues its work on the draft opinions on Zinc oxide and Titanium dioxide.

The draft guidance document for the safety assessment of nanomaterials in cosmetics was tabled for adoption.

7.5. WG on TTC

One WG meeting had taken place since the previous plenary meeting. EFSA gave an update on the developments of its opinion after public consultation.

The contributions received since the last meeting and the modifications to the current draft were discussed. An updated draft was tabled for principal approval.

7.6. WG on Nitrosamines

The Chairperson informed that three WG meetings had taken place since the previous plenary meeting.

The WG is still working on its opinion on NDELA in cosmetics and on nitrosamines in balloons. The revised opinion on nitrosamines and secondary amines in cosmetics, after public consultation, was tabled for final adoption.

7.7. WG on Sensitisation & Fragrances

The Chairperson said that a public hearing on the preliminary opinion on fragrance allergens and a WG meeting had taken place since the previous plenary meeting.

On 5 March 2012, a scientific hearing on the preliminary opinion on fragrance allergens in cosmetic products was organised. The hearing aimed to complement the internet

consultation and to provide stakeholders and the public the opportunity to present scientific evidence and argumentation on the subject.

The Chairman said that the WG is still discussing the outcome of the hearing and the contributions received during the public consultation. The revised opinion will be presented during the next plenary meeting.

7.8. 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 Chemical mixtures
- Joint opinion on Improvement of risk assessment
- Joint opinion on New Challenges in Risk Assessment

8. DRAFT OPINIONS - DISCUSSION AND POSSIBLE ADOPTION

8.1. Furfural

The SCCS was asked:

- *to review the new evidence in relation to the carcinogenicity of furfural and, if necessary, to revise the risk assessment made by the SCCNPF in 2004*
- *to assess whether furfural can be considered safe for the consumer when used up to the proposed pragmatic concentration limit of 10 ppm in finished cosmetic products (assuming inclusion and exclusion of oral products)*

The SCCS reviewed the new evidence on mutagenicity/genotoxicity in relation to the carcinogenicity of furfural and concludes that the tumours in two year carcinogenicity study by US NTP are likely to be induced by a threshold mechanism.

Based on the new data provided, the SCCS concluded that the use of furfural with a maximum concentration limit of 10 ppm in the finished cosmetic product, including oral products, does not pose a risk to the health of the consumer.

The opinion was adopted.

8.2. P72, Soytrimonium chloride

The SCCS was asked to answer the following questions:

1. *Does SCCS consider soytrimonium chloride safe when used in oxidative and non-oxidative hair colorants products in a concentration on-head up to maximum 3.0% for purposes other than as a preservative?*
2. *And/or does the SCCS have any further scientific concern with regard to the use of soytrimonium chloride in cosmetic products?*

The SCCS concluded that a final evaluation of the safety of soytrimonium chloride for the intended uses of non-oxidative and oxidative conditions of hair dyeing was not possible due to some missing data and studies:

- The stability of soytrimonium chloride under intended uses, in particular under oxidative conditions of hair dyeing, requires clarification.
- No information on the irritant potential of soytrimonium chloride under oxidative conditions in skin is available. Appropriate studies with oxidised soytrimonium chloride would be required to determine irritant potential.
- No information on the sensitizing potential of soytrimonium chloride under oxidative conditions is available. Appropriate studies with oxidised soytrimonium chloride would be required to determine sensitizing potential.
- Appropriate studies with soytrimonium chloride are required according to the Notes of Guidance to determine a mutagenicity/genotoxicity potential.

The SCCS stated that the missing data should be provided by the applicant by the end of 2012.

The opinion was adopted.

8.3. Guidance on the safety assessment of nanomaterials in cosmetics

The Guidance was presented to the SCCS members for discussion and possible adoption. There were some considerations raised at the meeting which had to be taken into account. As a consequence of the discussion opened it was decided to postpone the adoption of the Guidance after clarifying the issues raised.

8.4. Nitrosamines and secondary amines (after public consultation)

In light of the previous SCC, SCCNFP opinions on the subject and the currently available data on the genotoxicity/carcinogenicity of nitrosamines, the SCCS was asked to:

Elaborate an opinion on the potential risks to human health by the presence in cosmetics of nitrosamines or of chemicals with secondary amine groups which may give rise to N-nitroso compounds, to provide guidance to the Commission in revising the relevant entries of Annexes II and III of the Cosmetics directive (76/768/EEC). To this end, the SCCS should:

- 1) *Identify chemical classes that can give rise to nitrosamines.*
- 2) *Provide a definition (or provide a generic definition) of the substances regulated in Annex II 411 and Annex III 60-62, i.e. secondary alkylamine and secondary alkanolamine, fatty acid dialkylamides and dialkanolamides and mono- and tri-alkylamines and alkanolamines.*
- 3) *Comment on the possibility to group chemicals and/or chemical classes with respect to their reactivity towards nitrosating agents and their propensity to give rise to nitrosamines. Identify chemicals or groups/classes for which such grouping with respect to nitrosation may not be possible and case-by-case assessments need to be made.*
- 4) *Identify the factors/conditions that may influence/enhance /inhibit the formation of nitrosamines i.e. N-nitroso compounds (e.g. N-Nitroso-oxazolidines), such as nitrogen oxides, nitrite, preservatives, catalysts (e.g. formaldehyde) or others. Provide a clear definition for nitrosating systems. Clarification is required to address whether a nitrosating agent or a nitrosating system should be basis for the regulation of nitrosamine formation in cosmetic ingredients and cosmetic formulations.*

- 5) *List the nitrosamines found in cosmetics and advise the Commission of approaches to rank nitrosamines that may occur in cosmetics with respect to their carcinogenic potency.*
- 6) *Is there a way to identify chemical classes, and ranking them in terms of their propensity to give rise to carcinogenic nitrosamines and their potency? Inversely, is there a way to relate the carcinogenic potential of nitrosamines formed with the parent chemical class?*
- 7) *Comment on the levels of 50 µg nitrosamine/ kg as set out currently in the Annexes of Directive 76/768/EEC. Should it apply to finished products or to raw materials? Should it be considered for all nitrosamines potentially formed? Should it be modified, following the ranking of carcinogenic potency of nitrosamines in question? Comment on the "maximum secondary amine content (5% in raw materials and 0.5% in finished products)".*
- 8) *On the basis of the answers above SCCS to pronounce itself*
 - *on the specific cases of spermidine (CAS 334-50-9), gerotine (CAS 71-44-3) and dipropylenetriamine (CAS 56-18-8);*
 - *on the "Maximum secondary amine content: 5% (applies to raw materials)" and that "Maximum secondary amine content: 0.5%" in the finished cosmetic products" for the Fatty acid dialkylamides and dialkanolamines listed in entry 60 of Annex III, part I.*

The SCCS adopted an opinion in accordance with the above terms of reference. The replies to the various questions can be found in doc n° SCCS/1458/11.

8.5. A7, p-Phenylenediamine

The adoption of the opinion was postponed.

8.6. A75, 6-Amino-m-cresol

The adoption of the opinion was postponed.

8.7. A136, 2,6-Diaminopyridine

The SCCS was asked to answer the following questions:

1. *Does SCCS consider 2,6-Diaminopyridine safe for consumers when used as an ingredient in oxidative hair dye products with a maximum concentration of 0.15% on the scalp, taken into account the scientific data provided?*
2. *Does the SCCS recommend any further restrictions with regard to the use of 2,6-Diaminopyridine in oxidative hair dye formulations?*

The SCCS concluded that the information submitted is insufficient to allow a final risk assessment to be carried out.

Before any further consideration, data on the characterisation and quantification of the test materials using state of the art methods must be submitted.

The opinion was adopted.

8.8. A158, 2-Amino-5-ethylphenol HCl

The SCCS was asked to answer the following questions:

1. Does the SCCS consider 2-Amino-5-ethylphenol HCl safe for use as an oxidative hair dye with a concentration on-head of maximum up to 1.0 % taken into account the scientific data provided?
2. And/or does the SCCS have any further scientific concerns with regard to the use 2-Amino-5-ethylphenol HCl in oxidative hair dye formulations?

The SCCS concluded that the use of 2-amino-5-ethylphenol HCl in oxidative hair dye formulations at a maximum on-head concentration of 1.0% does not pose a risk to the health of the consumer, apart from its sensitisation potential.

The opinion was adopted.

8.9. B7, Basic Brown 17

The SCCS was asked to answer the following questions:

1. Does SCCS consider Basic Brown 17 safe for use in non-oxidative hair dyes with a concentration of maximum 2.0% taken into account the scientific data provided?
2. And/or does the SCCS has any further scientific concerns with regard to the use of Basic Brown 17 in non-oxidative hair dye formulations?

The SCCS concluded that the information submitted is insufficient to allow a final risk assessment to be carried out.

Before any further consideration, the following information must be submitted:

- a proper chemical specification of Basic Brown 17 with respect to its purity and impurities;
- data on the stability of Basic Brown 17 in the test solutions and in typical hair dye formulations;
- additional studies to exclude a genotoxic potential of Basic Brown 17.

The opinion was adopted.

8.10.C53, Acid Red 92

The SCCS was asked to answer the following questions:

1. Does the Scientific Committee on Consumer Safety (SCCS) consider Acid Red 92 safe for use in oxidative hair dye formulations with a maximum concentration in the formulation of 2% taken into account the scientific data provided?
2. Does the SCCS consider Acid Red 92 safe for use in non-oxidative hair dye formulations with a maximum concentration in the formulation of 0.4% taken into account the scientific data provided?
3. Does the SCCS consider the mentioned purity criteria for Acid red 92 as colorant CI 45410 relevant or, if not, in which direction should they be modified?

The SCCS concluded that the use of Acid Red 92 with a maximum on-head concentration of 2.0% in oxidative and of 0.4% in non-oxidative hair dye formulations does not pose a risk to the health of the consumer.

Since the restricted impurities for CI 45410 were not reported in the batches of this opinion, the term of reference n° 3 cannot be answered.

The SCCS recommends that the use of Acid Red 92 as a colorant should be assessed separately.

The opinion was adopted.

8.11.C179, Disperse Blue 337

The SCCS was asked to answer the following questions:

- 1. Does the Scientific Committee on Consumer Safety (SCCS) consider Disperse Blue 377 safe for use as a non-oxidative hair dye at a maximum concentration of 2.0% taking into account the scientific data provided?*
- 2. Does the SCCS recommend any restrictions with regard to the use of Disperse Blue 377 in any hair dye formulations?*

The SCCS concluded that the use of Disperse Blue 377 as a non-oxidative hair dye with a maximum on-head concentration of 2.0% does not pose a risk to the health of the consumer.

A sensitisation potential cannot be excluded.

The opinion was adopted.

8.12.C182, HC Blue n° 15

The SCCS was asked to answer the following questions:

- 1. Does the Scientific Committee on Consumer Safety (SCCS) consider HC Blue n° 15 safe for the consumers, when used as a direct dye in any hair dye formulations at a maximum concentration on the scalp of 0.2% taking into account the scientific data provided?*
- 2. Does the SCCS recommend any restrictions with regard to the use of HC Blue n° 15 in any hair dye formulations?*

The SCCS concluded that, based on the low Margin of Safety using a worst case assumption of dermal absorption, HC Blue n° 15 cannot be considered safe for use in oxidative hair dye formulation at a maximum on-head concentration of 0.2%.

To come to a final conclusion, the SCCS concluded that a state of the art percutaneous absorption study would be required.

The opinion was adopted.

8.13.C183, Tetrabromophenol Blue

The adoption of the opinion was postponed.

9. DRAFT OPINIONS – FOR DISCUSSION

The following draft opinions were discussed:

- TTC
- Notes of Guidance 8th revision
- Dichloromethane

10. COMMENTS ON OPINIONS FROM LAST PLENARY MEETING

Comments on opinions adopted in the SCCS plenary meeting of 13-14 December 2011 have been received. All comments were reviewed and discussed by the experts at the WG and opinions were modified as appropriate.

The following opinions have been considered:

- Methyl-N-methylantranilate
- Quaternium-15
- A154, Quinolinium, 4-formyl-1-methyl, salt with 4-methylbenzenesulfonic acid (1:1)
- A154, 1-Hydroxyethyl-4,5-diamino pyrazole sulfate

11. ANY OTHER BUSINESS

The next plenary meeting will take place on 26-27 June 2012

Annex 1: List of Participants

Annex 1

List of Participants

Members of the SCCS

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

Apologies

None

SCCS Secretariat (DG SANCO)

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

DG SANCO B2

Mrs. F. de Gaetano