



Scientific Committee on Consumer Safety
18th plenary Meeting

Held on 26 February 2013 in Brussels

MINUTES

1. WELCOME AND APOLOGIES

The chairman of the SCCS welcomed all the participants. Apologies were received from Prof. J. Angerer, Dr. C. Chambers, Prof. G. Degen, Dr. S. Rastogi 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 17TH PLENARY MEETING

The minutes of the 17th plenary meeting of 11 December 2012 were approved.

5. INFORMATION FROM CHAIRMAN/MEMBERS/COMMISSION

5.1. Follow-up of previous opinions

The Commission informed the Committee on the status and coming steps on the joint opinion on Improvement of Risk Assessment and New challenges. The concerns expressed by the SCCS have been taken into account into the revised documents, which are foreseen to be adopted in the coming weeks by written procedure.

The Commission briefed the Committee on the outcome of the Working Group on Cosmetic Products which took place in February. At this meeting the SCCS Opinion on Fragrance allergens in cosmetic products (SCCS/1459/11) was notably discussed as it has triggered interest among member states and stakeholders.

The commission informed the committee on the status of the cosmetic products notification under Article 16 of the Cosmetic products Regulation (EC) 1223/2009.

5.2. Other points

The Committee agreed that a dedicated workshop on genotoxicity testing strategy should be organised in the short term.

6. NEW AND UPCOMING REQUESTS

7. ON-GOING WORK

7.1. 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 11 December 2012. Two draft opinions had been prepared which were tabled for adoption.

7.2. WG on Hair Dyes

The chairman of the WG reported on the on-going work. Two WG meetings had taken place since the previous plenary meeting of 11 December 2012. Seven draft opinions had been prepared and tabled for adoption.

7.3. WG on Methodologies

No WG meetings had taken place since the previous plenary meeting of 11 December 2012. However, a number of meeting dates were set. On the agenda of the WG are issues such as substances with low bioavailability, which was discussed in a dedicated workshop which took place in November and where different stakeholders participated; and recent changes proposed at the EU and OECD level for mutagenicity/genotoxicity testing. Furthermore, a number of new *in vitro* methods became recently available as well as the new concept of AOPs. Both issues need to be considered from the perspective of cosmetics.

7.4. WG on Nano-materials in Cosmetics

The Chairperson of the WG reported on the on-going work. Two meetings had taken place since the previous plenary meeting, on one of which industry representatives were invited to discuss some unclear issues regarding the dossier of one of the nanomaterials under assessment. The draft opinion on S79 (2,2'-Methylene-bis-(6-(2H-benzotriazol-2-yl)-4-(1,1,3,3-tetramethylbutyl) phenol) was tabled for discussion and possible adoption.

7.5. Participation of Members in activities of other Scientific Committees

The members involved in the working party of EFSA on endocrine disruptors briefed the participants on the development of the opinion.

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*

8. DRAFT OPINIONS – FOR DISCUSSION AND POSSIBLE ADOPTION

8.1. P64, Climbazole

The SCCS was asked to answer the following question:

Does the SCCS consider that climbazole is safe for the consumers, when used as a preservative in cosmetic products up to a maximum concentration of 0.5% if the product categories face and hair products, as recommended by the former SCCP opinion (SCCP/1204/08) are extended to include foot care products?

The SCCS concluded that the non-preservative use of Climbazole at a maximum concentration of 0.5% either in a foot care cosmetic and used alone, or in combination with either shampoo (at a maximum concentration of 2%) or face cream (at a maximum concentration of 0.5%) or hair lotion (at a maximum concentration of 0.5%) does not pose a risk to the health of the consumer. In case 3 products, each containing Climbazole at the maximum concentration requested (being safe when used separately) are applied within the same 24 hour period, the combinations of either shampoo, hair lotion and a foot care product, or face cream, hair lotion and a foot care product cannot be considered safe for the consumer.

The above also applies when the 4 different types of products, all containing Climbazole at the highest concentration, are topically applied within the same 24 hour period.

This opinion does not address the possible environmental concerns about the use of climbazole in cosmetic products.

The opinion was adopted.

Climbazole regarding potential development of (cross)-resistance

The SCCS is asked to answer the following questions:

- 1. In light of the EMA opinion and the information contained therein, can climbazole still be considered safe for use as an ingredient in cosmetic products?*
- 2. If the answer to question 1 is yes, does the SCCS consider that any aspects of the previous assessment of climbazole needs to be revised on the basis of the dossier produced by EMA on this ingredient?*
- 3. If the answer to question 1 is yes, does the SCCS consider that Climbazole is safe for the consumers, when used up to a concentration of 0.5% in foot care products in addition to the previous evaluated uses (i.e. hair cosmetics and face cosmetics up to 0.5%, rinse-off hair cosmetics up to 2.0%)*
- 4. Does the SCCS have any further scientific concern with regard to the use of climbazole in cosmetic products?*

On question 1, the SCCS concluded that in light of the EMA opinion, providing only indirect arguments of concern with respect to the use of Climbazole and the development of resistance in the different fungi causing invasive fungus infections in humans, and on the other hand the clear opinion of an internationally famed expert in the field, that actually Climbazole can be considered as a safe ingredient with respect to antimicrobial resistance, in rinse-off as well as in leave-on cosmetic products.

On question 2, the SCCS concluded that, in the light of the opinion provided by the external expert with respect to (cross-) resistance, the dossier of Climbazole contains the necessary elements to allow risk assessment for human health according to the SCCS's Notes of Guidance for the testing of cosmetic ingredients and their safety evaluation.

On question 3, the SCCS concluded that: in the risk assessment (opinion on P64) of December 2012 the SCCS came to the conclusion that the non-preservative use of Climbazole either in foot care cosmetics alone at a concentration of up to 0.5% or in

combination with either shampoo (at a maximum concentration of 2%) or face cream (at a maximum concentration of up to 0.5%) or with hair lotion (at a maximum concentration of up to 0.5%), does not pose a risk to the health of the consumer. In the case, however, that 3 products, although each safe when used separately, are combined, the combinations of either shampoo, hair lotion and a foot care product or face cream, hair lotion and a foot care product (all containing Climbazole at the maximum requested concentration) cannot be considered safe for the consumer.

On question 4, the SCCS concluded that the scientific literature should be carefully followed with respect to potential (cross-) resistance of Climbazole and related compounds. When new information with respect to (cross)-resistance development becomes available, re-evaluation of the situation with respect to fungal resistance might be necessary.

The opinion was adopted

8.2. DEGEE (Diethylene glycol monoethylether)

The SCCS was asked to answer the following questions:

- 1. On the basis of available information, the SCCS is asked to assess whether a maximum concentration of 2.6% of DEGEE can be considered safe, also taking into account the other uses previously assessed (10% in rinse-off products, 7.0% in oxidative and 5.0% in non-oxidative hair dye formulations).*
- 2. Taking into account the provided exposure data, the SCCS is asked to assess the safety of DEGEE when used in spray products in a concentration up to 2.6%.*
- 3. Does the SCCS have any further scientific concerns with regard to the use of DEGEE?*

The SCCS concluded that:

- The use of DEGEE at a maximum concentration of 2.6% in cosmetic products taking into account the other uses previously assessed (10% in rinse-off products, 7.0% in oxidative and 5% in non-oxidative hair dye formulations) does not pose a risk to the health of the consumer.
- the use of DEGEE in the following spray products, fine fragrances, hair sprays, and antiperspirants and deodorants in a concentration up to 2.6% does not pose a risk to the health of the consumer.
- The use of DEGEE in products for oral hygiene and the eyes has not been evaluated. The level of ethylene glycol in DEGEE used should be less than 0.1% (grades conforming to this specification are commercially available).

Aggregate exposure to diethyleneglycol monoethyl ether (DEGEE) from non-cosmetic sources has not been considered.

The opinion was adopted.

8.3. 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 use of 2,6-diaminopyridine as oxidative hair dye with a maximum concentration on head of 0.15% does not pose a risk to the health of the consumer, apart from its sensitising potential.

2,6-Diaminopyridine is an extreme sensitiser.

The opinion was adopted.

8.4. A160, 2-Methoxy-methyl-p-phenylenediamine

The SCCS was asked to answer the following questions:

1. *Does the SCCS consider 2-methoxy-methyl-p-phenylenediamine (A160) safe for use as an oxidative hair dye with a concentration on-head of maximum 1.8% taken into account the scientific data provided?*
2. *And/or does the SCCS recommend any further restrictions with regard to the use of 2-methoxy-methyl-p-phenylenediamine (A160) in any hair dye formulations?*

The SCCS concluded that the use of 2-methoxy-methyl-p-phenylenediamine and its sulfate salt as oxidative hair dye with a concentration on head of maximum 1.8% does not pose a risk to the health of the consumer, apart from its sensitising potential.

The opinion was adopted.

8.5. B15, Acid Black 1

The SCCS was asked to answer the following questions:

1. *Does the SCCS consider Acid Black 1 safe for use in non-oxidative hair dye formulations with a concentration of maximum 0.5% in the finish product taken into account the scientific data provided?*
2. *And/or does the SCCS recommend any restrictions with regard to the use of Acid Black 1 in non-oxidative hair dye formulations (e.g. maximum concentration in the finish cosmetic product, dilution ratio with hydrogen peroxide, warning)?*

The assessment of Acid Black 1 was for its use in non-oxidative hair dye formulations only.

Documentation of the high quality of commercial Acid Black 1 compared to the test batches of Acid Black 1 was not provided.

The SCCS concluded that the use of Acid Black 1 as a non-oxidative hair dye with a concentration on head of maximum 0.5% poses a risk to the health of the consumer.

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

The opinion was adopted.

8.6. C63, Acid Violet 43

The SCCS was asked to answer the following questions:

1. *Is benzenesulfonic acid, 2-[(9,10-dihydro-4-hydroxy-9,10-dioxo-1-anthracenyl)amino]-5-methyl-, monosodium salt safe for use in semi-permanent hair dye formulations at a maximum concentration of 0.5% of active dye, taken into account the data provided?*
2. *And/or does the SCCP recommend any restrictions with regard to the use of benzenesulfonic acid, 2-[(9,10-dihydro-4-hydroxy-9,10-dioxo-1-anthracenyl)amino]-5-methyl-, monosodium salt in hair dye formulations?*

The safety assessment of Acid Violet 43 relates to batch Ext D&C Violet n° 2 0609RA (purity of 94%).

The SCCS concluded that the use of Acid Violet 43 as a non-oxidative hair dye with a maximum on head concentration of 0.5% active dye does not pose a risk to the health of the consumer.

A sensitising potential cannot be excluded.

Acid Violet 43 is also used as a cosmetic colorant but this use has not been assessed in this opinion.

The opinion was adopted.

8.7. C178, Acid Green 25

The SCCS was asked to answer the following questions:

1. *Does the Scientific Committee on Consumer Safety (SCCS) consider Acid Green 25 safe for use in non-oxidative hair dye formulations with a concentration of maximum 0.3% in the finished product taking into account the scientific data provided?*
2. *Does the SCCS recommend any restrictions with regard to the use Acid Green 25 in hair dye formulations?*

The SCCS concluded that the use of Acid Green 25 as a non-oxidative hair dye with a maximum on head concentration of 0.3% does not pose a risk to the health of the consumer.

Acid Green 25 is also used as a cosmetic colorant. However, this use has not been assessed in this opinion.

The opinion was adopted.

8.8. C182, HC Blue 15

The SCCS was asked to answer the following questions:

1. *Does the SCCS consider HC Blue n° 15 safe for use as non-oxidative and oxidative hair dye formulations with a concentration of maximum 0.2% in the finish product taken into account the scientific data provided?*
2. *And/or does the SCCS recommend any restrictions with regard to the use of HC Blue n° 15 in oxidative and non-oxidative hair dye formulations (e.g. maximum concentration in the finish cosmetic product, dilution ratio with hydrogen peroxide, warning)?*

The SCCS concluded that the use of HC Blue n° 15 in oxidative and non-oxidative hair dye formulations at a maximum on-head concentration of 0.2% does not pose a risk to the health of the consumer.

A sensitising potential cannot be excluded.

The opinion was adopted.

8.9. C184, HC Blue 17

The SCCS was asked to answer the following questions:

1. *Does the SCCS consider HC Blue 17 safe for use as an oxidative and a non-oxidative hair dye with a concentration on-head of maximum 2.0% taken into account the scientific data provided?*
2. *And/or does the SCCS recommend any further restrictions with regard to the use of HC Blue 17 in any hair dye formulations?*

The SCCS concluded that the use of HC Blue 17 at a maximum on-head concentration of 2.0% in both oxidative and non-oxidative hair dye formulations does not pose a risk to the health of the consumer.

The discrepancies and uncertainties related to the purity of the different batches should be clarified.

HC Blue 17 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.

A sensitising potential cannot be excluded.

The opinion was adopted.

8.10. S79, 2,2'-Methylene-bis-(6-(2H-benzotriazol-2-yl)-4-(1,1,3,3-tetramethylbutyl) phenol)

The SCCS was asked to answer the following questions:

1. *Does the SCCS consider 2,2'-methylene-bis-(6(2H-benzotriazol-2-yl)-4-(1,1,3,3-tetramethylbutyl)phenol) in its nano form safe for use as a UV-filter with a concentration up to 10 % in cosmetic products taking into account the scientific data provided?*
2. *Does the SCCS have any further scientific concern with regard to the use of 2,2'-methylene-bis-(6(2H-benzotriazol-2-yl)-4-(1,1,3,3-tetramethylbutyl)phenol) in its nano form in cosmetic products?*

The SCCS concluded that, since no data on genotoxicity were available and the inhalation data were insufficient, no conclusion on the safety of this substance can be drawn.

In addition there are some aspects that need further attention:

- in the study in rats, clinical effects (pain and vocalization) after dermal application were noted at concentrations of 20% (500mg a.i. /kg bw/d and higher), it is worthwhile to monitor possible irritation effects via the existing cosmetovigilance programs

- attention needs to be paid to identification/presence in selected tissues to obtain information on potential bioaccumulation given the physicochemical properties (lipophilicity) of the substance.

The SCCS noted that MBBT is toxic to the aquatic environment. The use of MBBT as ingredient in sunscreen products might lead to environmental exposure.

The opinion was adopted.

8.11. Further Memorandum on hair dye chemical sensitisation

A "Memorandum on hair dye chemical sensitisation", has been prepared by the SCCS as follow up of the previous one adopted by the SCCP in 2006. It contains an updated review of the sensitizing potency of the hair dye chemicals now evaluated by the SCCS, the former SCCP and SCCNFP. The SCCS confirms the views expressed in the earlier Memorandum, that hair dye substances which fulfil the criteria for classification as R43 may not be safe for consumers and that this is particularly so for hair dye substances categorised as extreme and strong sensitizers.

The memorandum was adopted and the committee urged DG Sanco to publish it.

9. COMMENTS ON OPINIONS FROM LAST PLENARY MEETING

Comments on opinions adopted in the SCCS plenary meeting of 11 December 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:

- Dichloromethane
- A33, 1,2,4-Trihydroxybenzene
- A94, 5-Amino-6-chloro-o-cresol
- A155, 2,2'Methylenebis-4-aminophenol HCl
- B87, 4-amino-2-nitrodiphenylamine-2'-carboxylic acid
- C9, Basic Brown 16

10. ANY OTHER BUSINESS

The first plenary of the newly mandated SCCS will take place on 11 April 2013

Annex 1: List of Participants

Annex 1

List of Participants

Members of the SCCS

Dr. U. Bernauer, Dr. Q. Chaudhry, Dr. W. Lilienblum (associate scientific advisor), Dr. E. Nielsen, Prof. T. Platzek, Dr. C. Rousselle, Prof. V. Rogiers (vice-Chair), 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, Dr. C. Chambers, Prof. G. Degen, Dr. S. Rastogi, Dr. J. van Benthem

SCCS Secretariat (DG SANCO)

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

Observers: Stefan Schreck, Donata Mernoni, Natacha Grenier

DG SANCO B2

Mrs. F. de Gaetano