



Scientific Committee on Consumer Safety
15th plenary Meeting

Held on 26-27 June 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. T. Platzek, Dr. J. van Benthem and Prof. R. Waring.

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 14TH PLENARY MEETING

The minutes of the 14th plenary meeting of 27 March 2012 were approved.

5. INFORMATION FROM CHAIRMAN/MEMBERS/COMMISSION

5.1. Renewal of the Scientific Committees

The Commission reported that no decision has been taken yet regarding the renewal/new structure of the scientific committees. The members 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

No specific points were raised.

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 27 March 2012. Four draft opinions had been prepared which were tabled for adoption.

7.2. WG on Hair Dyes

In the absence of the chairman, a representative of the WG reported on the on-going work. Two meetings had taken place since the previous plenary meeting. Five draft opinions had been prepared and tabled for adoption.

7.3. WG on Methodologies

No WG meeting had taken place since the previous plenary meeting. No further meetings have been planned yet.

7.4. WG on Nano-materials in Cosmetics

The Chairperson of the WG reported on the on-going work. Five meetings had taken place since the previous plenary meeting. The draft opinion on Zinc oxide and the draft guidance document for the safety assessment of nanomaterials in cosmetics were tabled for adoption.

7.5. WG on TTC

One WG meeting had taken place since the previous plenary meeting. The Chairman said that the opinion was adopted on 8 June 2012 by written procedure.

7.6. WG on Nitrosamines

Two WG meetings had taken place since the previous plenary meeting. The draft opinion on NDELA in cosmetics and nitrosamines in balloons was tabled for final adoption.

7.7. WG on Sensitisation & Fragrances

Two WG meetings had taken place since the previous plenary meeting. The draft opinion on fragrance allergens in cosmetics was tabled for final adoption.

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. Fragrance allergens in cosmetic products

The SCCS was asked to answer the following questions:

1. *Does the SCCS still consider that the fragrance allergens currently listed in Annex III, entries 67-92, for labelling purposes represent those fragrance ingredients that the consumer needs to be made aware of when present in cosmetic products?*
2. *Can the SCCS establish any threshold for their safe use based on the available scientific data?*
3. *Can the SCCS identify substances where processes (e.g. metabolism, oxidation and hydrolysis) may lead to cross-reactivity and new allergens which are relevant for the protection of the consumer?*

In 1999, the former SCCNFP identified 26 well-known fragrance allergens and measures were introduced that required these substances to be listed individually on the label of cosmetic products containing them.

Since 1999, much more information on fragrance allergens has become available. Therefore the European Commission requested the SCCS to review the current knowledge and to check whether the list of fragrance allergens relevant for consumers needed to be modified and whether safe limits could be established for the most frequent allergens.

In its opinion, the SCCS identified fragrance ingredients which are established contact allergens in humans, based on human clinical and epidemiological evidence. This includes 26 substances identified by the SCCNFP, an additional 30 individual chemicals and 26 natural extracts.

The SCCS's list also ingredients likely to cause allergy in humans, on basis of evidence from animal studies and analysis of chemical structures. Chemical processes which can transform seemingly innocuous fragrance chemicals into allergens were also scrutinised by SCCS and the present state of knowledge is presented in the opinion.

With regard to fragrance allergens reported to cause a high number of allergy cases, the SCCS derived a concentration limit expected to protect most patients from allergies to these ingredients or from reacting to the cosmetics which contain them. The SCCS also considers this concentration limit as appropriate to prevent non-allergic consumers from developing allergy to these fragrance ingredients.

The opinion was prepared following stakeholder input during a public consultation and a public hearing on the draft version.

The opinion was adopted.

8.2. NDELA in cosmetic products and nitrosamines in balloons

The SCCS was asked to answer the following questions:

1. *Assess if an additional lifetime cancer incidence of 1×10^{-6} is suitable as a practical approach to differentiate between the risk levels "serious" and "less than serious". Are there other approaches that could provide a rationale for distinguishing between "serious" and "less than serious" risk?*
2. *For the three approaches mentioned in the background (1.1, 1.2, and 1.3) on the additional lifetime cancer incidence of 1×10^{-6} , assess which Virtually Safe Dose (VSD) values should be used for the calculations of NDELA concentrations in cosmetics and nitrosamines in balloons.*
3. *Assess, whatever the approach, if an additional safety factor(s) should be used for children and how it (they) should be applied in the calculations.*

4. Calculate, for all approaches, the concentrations of NDELA in cosmetics and nitrosamines in balloons which differentiate between "serious" and "less than serious" risk.

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/1486/12.

8.3. Guidance on the safety assessment of nanomaterials in cosmetics

The SCCS was requested to develop guidance on:

1. *The essential elements that must form part of safety dossiers for the assessment of nanomaterials in cosmetic products, based on the data requirements for the pre-market notification listed in article 16 of Regulation (EC) No 1223/2009, i.e. taking into account points 3a to 3f of article 16 (identification of the nanomaterial; specification; quantity; toxicological profile; safety data and exposure).*
2. *The possibility to develop criteria and conditions that would allow the safety assessment of nanomaterials on a category based approach rather than on a case-by-case basis.*
3. *The suitability of alternative methods already validated for the assessment of conventional chemical substances for the assessment of nanomaterials in light of the current (as of 2009) ban on animal testing in the EU.*
4. *The set of attributes unique to manufactured nanomaterials that will need to be addressed by newly developed and/or newly validated alternative methods for the testing of toxicological end points for which there will be a ban on the testing on animals after March 2013.*

In elaborating this guidance, and taking into account the growing experience on the matter the SCCS was asked to consider all available documentation on the subject such as the SCCP scientific opinion on safety of nanomaterials in cosmetic products; the documents issued by the OECD Working Party on Manufactured Nanomaterials; the EFSA scientific opinion on guidance on risk assessment of the application of nano-science and nanotechnologies in the food and feed chain.

The SCCS adopted this guidance in accordance with the above terms of reference. The guidance document can be found at http://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_s_005.pdf.

8.4. Zinc oxide, nano-form (S76)

The adoption of the opinion was postponed.

8.5. Dichloromethane

The adoption of the opinion was postponed.

8.6. Kojic acid

The SCCS was asked to answer the following questions:

1. *Does the SCCS consider the use of Kojic Acid in a concentration of up to 1.0% in cosmetic products safe for the consumers given the provided data?*
2. *Does the SCCS foresee further scientific concerns to the safe use of Kojic Acid and/or its derivatives?*

The SCCS concluded that:

Re-examination of the available data for kojic acid, used as a skin whitening agent at a concentration of 1.0% in leave-on creams, which are generally applied to the face and/or hands leads to the conclusion that it is safe for the consumers.

As far as the derivatives of Kojic Acid are concerned (e.g. esters of kojic acid, kojic acid dipalmitate, kojic acid isopalmitate and chloro-kojic acid), the SCCS did not receive any data, meaning that no conclusion can be drawn on the safety of the derivatives.

When human skin barrier is weakened, (e.g. after peelings) or kojic acid is applied on larger skin surfaces, the use of kojic acid is of concern.

The opinion was adopted.

8.7. Methylene glycol

The SCCS was asked to answer the following questions:

1. *Based on the current knowledge on the chemistry, biology and toxicology of methylene glycol, should methylene glycol be considered equivalent to formaldehyde?*
2. *If the answer to question 1 is yes, does the currently established safe level of 0.2% formaldehyde/paraformaldehyde for use as preservatives also ensure the safety of methylene glycol, when used as an ingredient in hair straightening products, taking into account the specific conditions of use of such products?*
3. *If the answer to question 1 is no, can a safe level for the use of methylene glycol in hair straightening products, taking into account the specific conditions of use of such products and the information on current use concentrations, be established?*
4. *Does the SCCS have any further scientific concern with regard to the use of methylene glycol in cosmetic products?*

The SCCS concluded the following:

Although formaldehyde and methylene glycol are different molecules from a scientific chemical point of view, there is a close interrelationship of formaldehyde and methylene glycol in aqueous solution and a rapid mutual conversion in a dynamic equilibrium. Therefore, from a practical point of view, it is justified to consider the aqueous mixture of gaseous formaldehyde and methylene glycol as "free formaldehyde" and the quantities as "formaldehyde equivalents" (preferably expressed as formaldehyde concentration) in aqueous solutions. The term "formaldehyde equivalents" adequately describes the fact that methylene glycol is continuously converted to gaseous formaldehyde in aqueous solution, and vice versa, at any equilibrium, which can be easily shifted by heating, drying, and any other conditions that increase or decrease the amount of gaseous formaldehyde.

Therefore, the SCCS, in line with the position of other bodies and panels (American Chemical Council 2010, CIR 2012, OSHA 2010, considers methylene glycol as a formaldehyde equivalent.

Methylene glycol produces gaseous formaldehyde under the intended conditions of use in hair straightening products due to the application of heat by straightening irons and/or blow drying.

When methylene glycol/formaldehyde is used in hair straightening products at a concentration of 0.2% formaldehyde equivalent, the amount of gaseous formaldehyde released may exceed 0.1 mg/m³ (0.08 ppm), which is the WHO indoor air quality guideline for short term exposure.

Therefore the use of methylene glycol/formaldehyde at 0.2% formaldehyde equivalent is not considered safe in hair straighteners.

The SCCS considered questions 3 and 4 as 'not applicable'.

The opinion was adopted.

8.8. P96, Benzisothiazolinone

The SCCS was asked to answer the following questions:

- 1. Does SCCS consider benzisothiazolinone safe when used as a preservative up to a maximum authorised concentration of 0.01% in cosmetic products, based on the provided data?*
- 2. And/or does the SCCS have any scientific concern with regard to the use of benzisothiazolinone in cosmetic products?*

The SCCS concluded the following:

Benzisothiazolinone is safe for use as a preservative in cosmetics products up to 0.01% with respect to systemic toxicity.

However, its sensitising potential is of concern.

Sensitisation from related isothiazolinones is an important problem in consumers. This has occurred because there has been consumer exposure before safe levels of exposure relevant to sensitisation have been established. Benzisothiazolinone is a skin sensitiser in animal models with potency similar to methylisothiazolinone.

Methylisothiazolinone, at 100 ppm (0.01%) in cosmetic products is causing contact allergy and allergic contact dermatitis in the consumer. Benzisothiazolinone is known to be a sensitiser in man and has induced sensitisation at circa 20 ppm in gloves.

There is no information on what may be safe levels of exposure to benzisothiazolinone in cosmetic products from the point of view of sensitisation.

Until safe levels of exposure have been established, the use of benzisothiazolinone in cosmetic products as a preservative or for other functions cannot be considered safe in relation to sensitisation.

The opinion was adopted.

8.9. A5, Toluene-2,5-diamine

The SCCS was asked to answer the following questions:

1. Does the SCCS consider toluene-2,5-diamine and its sulfate salt, safe for use as an oxidative hair dye with a concentration on-head of maximum 2.0% (3.6% calculated as sulfate salt) taken into account the scientific data provided?
2. If not, does the SCCS recommend any other concentration limit with regard to the use of toluene-2,5-diamine and its sulfate salt as an oxidative hair dye?
3. And/or does the SCCS recommend any further restrictions with regard to the use of toluene-2,5-diamine and its sulfate salt, in oxidative hair dye formulations?

The SCCS concluded the following:

Using the conventional risk assessment approach, a Margin of Safety of 18 was calculated.

However, using a toxicokinetics-based approach based on a new human exposure study *in vivo* the Margin of Safety was calculated using the area under the curve. The applied concentration on-head of maximum 2% (calculated as free base) or 3.6% (calculated as sulfate salt) is considered to be safe with regard to systemic toxicity (toxicokinetics based MoS >25).

Toluene-2,5-diamine is an extreme skin sensitiser. The frequency of allergic reactions in hairdressers and consumers remains a considerable concern for consumer safety.

The opinion was adopted.

8.10.A7, p-Phenylenediamine

The SCCS was asked to answer the following questions:

1. Does SCCS consider p-Phenylenediamine safe for use as an 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 p-Phenylenediamine in any hair dye formulations?

The SCCS concluded the following:

For the final safety assessment of p-phenylenediamine several aspects were taken into account:

- The generally accepted approach for systemic toxicity (MOS approach) according to the Notes of Guidance results in a MoS of 200. When toxicokinetic studies are considered, a minimum MoS of 25 can be set. A number of toxicokinetic studies were performed and the applicant proposed to base the safety on the comparison of AUCs (area under curve). In this approach, the extrapolated AUC in rats resembling a peroral dosage of 8 mg/kg bw/day (corresponding to the NOAEL) was compared to the AUC in humans following application of a hair dye containing 14C-labelled PPD. In this case, a safety margin of 23 was obtained which is considered borderline. However, in view of the intermittent exposure and the fact that human exposure through hair dyeing is mainly to N,N'-diacetyl PPD (a non-mutagenic detoxified metabolite), no concern regarding systemic toxicity is raised.

- On the basis of the available data from carcinogenicity studies alone, no conclusion with regard to carcinogenicity of p-phenylenediamine in oxidative hair dye formulations can be drawn. However, on the basis of the toxicokinetic and mutagenicity data, it is unlikely the p-phenylenediamine in oxidative hair dye formulations would pose a carcinogenic risk for the consumer.

- p-Phenylenediamine was shown to be an extremely potent contact allergen in animals. p-Phenylenediamine is also an important and frequent allergen in consumers. It is recognized that allergic reactions to it may be severe. p-Phenylenediamine is an extreme sensitiser. Unlike other sensitising hair dye chemicals, p-phenylenediamine has/is used during routine diagnostic patch testing in clinical practice, and therefore, the importance of this molecule as a sensitiser for the consumer is very well documented. The continued use of p-phenylenediamine in hair dyes remains a considerable concern for consumer safety.

Additionally, exposure to PPD from so-called temporary tattoos may also result in sensitisation in consumers.

The opinion was adopted.

8.11.A75, 6-Amino-o-cresol

The SCCS was asked to answer the following question:

Does the Scientific Committee on Consumer Safety (SCCS) consider 6-amino-m-cresol safe for consumers, when used in oxidative hair dye formulations with a concentration on the scalp of maximum 1.5% taking into account the scientific data provided?

The SCCS concluded that:

The present results indicate that 2-amino-5-methylphenol has genotoxic potential. In addition the metabolite, N-acetyl-2-amino-5-methylphenol, found in the skin was genotoxic in the in vitro micronucleus test.

There is no adequate experimental evidence that 2-amino-5-methylphenol is completely converted to non-toxic metabolites in the skin *in vivo*.

Therefore, the SCCS considers that 2-amino-5-methylphenol is not safe for consumers, when used in oxidative hair dye formulations with a concentration on the scalp of maximum 1.5% taking into account the scientific data provided.

The dimer of 2-amino-5-methylphenol is probably formed under the oxidative hair dye conditions and was found to be absorbed by human skin in vitro. The dimer was also found in high concentrations in a study with human hepatocytes when the concentration of the substrate 2-amino-5-methylphenol was high. The effects of the dimer require further elucidation.

The opinion was adopted.

8.12.B34, N,N'-bis-(2-hydroxyethylamino)-2-nitro-p-phenylenediamine

The SCCS was asked to answer the following questions:

1. *Does SCCS consider N,N'-bis(2-hydroxyethylamino)-2-nitro-p-phenylenediamine safe for use as an oxidative hair dye with a concentration on head of maximum 1.0% and as a non-oxidative hair dye with a concentration up to 1.5% taken into account the scientific data provided?*

2. *And/or does the SCCS have any scientific concern with regard to the use of N,N'-bis(2-hydroxyethylamino)-2-nitro-p-phenylenediamine in oxidative or non-oxidative hair dye formulations?*

The SCCS concluded that:

A conclusion on the gene mutation potential of N,N'-bis-(2-hydroxyethyl)-2-nitro-p-phenylenediamine cannot be drawn without further testing.

On the basis of the submitted data, the SCCS considers N,N'-bis(2-hydroxyethylamino)-2-nitro-p-phenylenediamine not safe for use as an oxidative hair dye with a concentration on head of maximum 1.0% and as a non-oxidative hair dye with a concentration up to 1.5%.

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.

8.13.C181, Pigment Red 57

The adoption of the opinion was postponed.

8.14.C183, Tetrabromophenol Blue

The SCCS was asked to answer the following questions:

1. *Does the Scientific Committee on Consumer Safety (SCCS) consider Tetrabromophenol Blue safe for consumers, when used as a direct dye in oxidative and non-oxidative 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 Tetrabromophenol Blue in any hair dye formulations?*

The SCCS concluded that:

The use of Tetrabromophenol Blue with a maximum on-head concentration of 0.2% in non-oxidative hair dye formulations does pose a risk to the health of the consumer due to the low Margin of Safety.

Tetrabromophenol Blue is a mixture octa-, hepta- and hexa-bromo phenolsulfonphthaleins, and does not contain any Tetrabromo-homologue, therefore the INCI name is misleading. The criteria for meeting the specifications of other batches, similar to the present mixture should be defined.

No acceptable dermal absorption study under oxidative conditions was provided.

An assessment of the use of Tetrabromophenol Blue in oxidative hair dye formulations cannot be performed without an adequate dermal absorption study and stability data in an oxidative environment.

The opinion was adopted.

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

The adoption of the opinion was postponed.

9. COMMENTS ON OPINIONS FROM LAST PLENARY MEETING

Comments on opinions adopted in the SCCS plenary meeting of 27 March 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:

- P72, Soytrimonium chloride
- A136, 2,6-Diaminopyridine
- A158, 2-Amino-5-ethylphenol HCl
- B7, Basic Brown 17
- C53, Acid Red 92
- C179, Disperse Blue 337
- C182, HC Blue n° 15

10. MEMORANDUM ON HAIR DYE CHEMICAL SENSITISATION

A "Memorandum on hair dye substances and their sensitising properties" was adopted during the 10th Plenary of the former SCCP on 19 December 2006 summarising the evaluation on the 48 hair dye substances that had been assessed by the SCCP at that time. The SCCP stated that hair dye substances which fulfil the criteria for classification as R43 (may cause sensitisation by skin contact) may not be safe for consumers and that this is particularly so for hair dye substances categorised as extreme and strong sensitizers.

The SCCS adopted an updated review of the sensitizing potency of the hair dye chemicals. The SCCS confirmed the views expressed in the earlier Memorandum.

11. ANY OTHER BUSINESS

The next plenary meeting will take place on 18 September 2012

Annex 1: List of Participants

Annex 1

List of Participants

Members of the SCCS

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

External Experts

Prof. G. Eisenbrand, University of Kaiserslautern, Germany
Dr. J.D. Johansen, Gentofte Hospital, University of Copenhagen, Denmark
Prof. W. Uter, Friedrich-Alexander University (FAU), Erlangen, Germany

Apologies

Prof. J. Angerer, Prof. T. Platzek, Dr. J. van Benthem, Prof. R. Waring

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