



EUROPEAN COMMISSION
HEALTH & CONSUMERS DIRECTORATE-GENERAL

Public Health and Risk Assessment
Risk assessment

Scientific Committee on Consumer Safety
10th plenary Meeting

Held on 22 March 2011 in Brussels

MINUTES

1. WELCOME AND APOLOGIES

The chairman of the SCCS welcomed all the participants. Apologies were received from Dr. C. Rousselle and Prof. R. Waring.

2. DECLARATIONS OF INTEREST

P. Vinardell declared an interest in relation to point 8.5 of the agenda, due to personal acquaintanceship with researchers involved in the development of this ingredient and voluntarily decided to abstain from the discussion on this subject.

3. APPROVAL OF THE DRAFT AGENDA

SCCS/1417/10

The agenda was approved after addition of the Nitrosamine Working Group to agenda point 7.

4. ADOPTION OF THE DRAFT MINUTES OF THE 9TH PLENARY MEETING

SCCS/1404/10

The minutes of the 9th plenary meeting of 14 December 2010 were approved.

5. INFORMATION FROM CHAIRMAN/MEMBERS

Information from the Chairman

The Chairman informed the members on the outcome of the Risk assessment conference which took place on the 27 and 28 January 2011.

The Commission requested the SCCS to coordinate with the EFSA WG in relation to the concurrent opinions on TTC opinion which are under development. A joint meeting is scheduled to take place in June 2011.

Commission follow-up to earlier opinions

The Commission is in the process of negotiation for amendments of annex III regarding hair dyes.

Work is ongoing on a guideline to implement the Regulation.

6. NEW REQUESTS

No new requests for SCCS or joint opinions were introduced.

7. REPORTS FROM THE WORKING GROUPS

7.1. Cosmetic Ingredients

The Chairperson of the WG reported on the ongoing work. Three meetings had taken place since the previous plenary meeting of 14 December 2010. Draft opinions on N-methyl-2-pyrrolidone (NMP), Triclosan (P32), Bis(butylbenzoate)diaminotriazine aminopropyltrisiloxane (S85), Ethyl lauryl arginate, (P95) and Chloroacetamide (P27), were prepared and tabled for adoption.

7.2. Hair Dyes

The Chairperson of the WG reported on the ongoing work. Two meetings had taken place since the previous plenary meeting. Draft opinions on Toluene-2,5-diamine (A5), 4-Amino-2-nitrophenyl-amine-2'-carboxylic acid (B87), Basic Red 51 (B116), Basic Red 76 (C8) and Acid Orange 7 (C15) were prepared and tabled for adoption.

7.3. Methodologies

The Chairperson of the WG said no WG meeting had taken place since the previous plenary meeting of 14 December 2010. A meeting is planned on 25 May 2011.

7.4. Nano-materials in Cosmetics

The Chairperson of the WG reported on the ongoing work. Three mandates are ongoing, on ETH50, ZnO and TiO₂.

7.5. TTC

No WG meeting had taken place since the previous plenary meeting. The Chairperson said that a workshop on TTC is planned on 8 to 10 June 2011 to discuss the scientific challenges and approaches.

7.6. Sensitisation & Fragrances

The Chairperson said that one WG meeting had taken place since the previous plenary meeting of 14 December 2010. The Working Group continues the update of the opinion on fragrance allergens.

7.7. Food imitating products

The Chairperson said that a modified opinion has been prepared after taken into consideration the comments received during the commenting period which was tabled for approval.

7.8. Nitrosamines

The Chairperson said that the group has started its work on nitrosamines or chemicals which contain secondary amine groups which could give rise to nitrosamines.

The objective of the WG is to elaborate two opinions on:

- the potential risks to human health by the presence of nitrosamines or chemicals which contain secondary amine groups which could give rise to nitrosamines with the view to guide the Commission in revising the relevant entries of Annexes II and III of the Cosmetics Directive (76/768/EEC) and
- the risk assessment approach for NDELA in cosmetic products and nitrosamines in balloons.

7.9. Participation of Members in activities of other Scientific Committees and joint opinions

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

- The toxicity and the assessment of mixtures of chemicals
- Addressing new challenges to risk assessment
- Possible improvements in risk assessment approaches in view of risk management needs and effective risk communication
- CMR in toys
- Fluoride in drinking water

8. DRAFT OPINIONS - DISCUSSION AND POSSIBLE ADOPTION

8.1. Potential health risks posed by chemical products resembling food and /or having child-appealing properties

During the plenary meeting of 14 December 2010, the SCCS approved the opinion on food resembling / child appealing products for public consultation.

The comments received during this period have been discussed and changes were made where appropriate. The final conclusions of the opinion remained unchanged.

The SCCS formally adopted the final opinion.

8.2. N-methyl-2-pyrrolidone (NMP)

The SCCS was asked to answer the following questions:

Based on the current knowledge on the chemistry, biology, toxicology and taking into account the scientific data used for the classification purposes of N-methyl-2-pyrrolidone classified as a reprotox 1B substance with a specific concentration limit of 5%, does the SCCS consider safe the continuous use of this substance in cosmetic products up to the specific concentration limit set out in the Commission Regulation 790/2009?

The SCCS concluded that based on a worst case assessment with a maximum use concentration of 5% NMP in cosmetic products and a dermal absorption of 100%, the Margin of Safety is considered to be too low. There is an absence of specific information on the actual possible maximum concentrations of NMP present in cosmetic products and specific measurement of dermal absorption of it through skin at relevant concentrations.

With the information available at the time of assessment, the SCCS concluded that the presence of NMP with a maximum use concentration of 5% in cosmetic products is not safe for the consumer. A re-evaluation may be possible should relevant data that addresses the above be provided.

The opinion was adopted

8.3. Bis(butylbenzoate)diaminotriazine aminopropyltrisiloxane, S85

The SCCS was asked to answer the following questions:

- 1. Does SCCS consider that the use of Bis(butylbenzoate) diaminotriazine aminopropyltrisiloxane as an UV-filter in cosmetic products in a concentration up to maximum 10.0% is safe for the consumers taken into account the scientific data provided?*
- 2. Does SCCS have any other scientific concerns for the safe use of the new UV-filter Bis(butylbenzoate) diaminotriazine aminopropyltrisiloxane in finished cosmetic products?*

The SCCS considered that the safe use of Bis(butylbenzoate) diaminotriazine aminopropyltrisiloxane as an UV-filter in cosmetic products in a concentration up to maximum 10.0% cannot be assessed based on the available data. As low oral bioavailability of the substance is anticipated, a quantitative risk assessment based on the oral NOAEL cannot be performed in the absence of adequate information on the extent of internal exposure.

In order to properly assess the safety of Bis(butylbenzoate) diaminotriazine aminopropyltrisiloxane, additional data such as a 90-day dermal toxicity study or sound data on oral bioavailability are required. However, the SCCS is aware that such studies are no longer permitted in the European Union.

Further recommendation

The SCCS already addressed the issue of limited bioavailability in the revisions of its Notes of Guidance and is of the opinion that further efforts should be undertaken to develop a general strategy for the assessment of substances with low solubility and low systemic bioavailability.

The opinion was adopted.

8.4. Triclosan, P32

The SCCS was asked to answer the following questions:

- 1. In the light of this supplementary submission and the preliminary opinion on antimicrobial resistance, does the SCCS consider it necessary to revise the toxicological evaluation made by the SCCP in its opinion SCCP/1192/08? If the answer to question 1 is yes, does the SCCS consider a continued use of Triclosan as a preservative in all cosmetic products as safe for the consumers at the current concentration limit of maximum 0.3%?*
- 2. Taking into account the safe use of Triclosan at a maximum concentration of 0.3% in toothpaste, hand soaps, body soap/shower gels and deodorant sticks ("common use products"), does the SCCS consider an additional use of Triclosan in mouthwashes as*

safe for the consumer at a concentration limit of maximum 0.15%, alternative 0.2% taking into account the provided exposure data and the preliminary opinion on antimicrobial resistance?

3. *Taking into account the safe use of Triclosan at a maximum concentration of 0.3% in toothpaste, hand soaps, body soap/shower gels and deodorant sticks ("common use products"), does the SCCS consider an additional use of Triclosan in nail products as safe for the consumer at a concentration limit of maximum 0.3% taking into account the provided exposure data and the preliminary opinion on antimicrobial resistance?*

The SCCS concluded that:

Question 1:

Taking into account the information provided in the supplementary submission and additional publications on triclosan from the open literature, the SCCS considers the toxicological evaluation made by SCCP in its opinion SCCP/1192/08 still as valid. Thus, the continued use of triclosan as a preservative at the current concentration limit of maximum 0.3% in all cosmetic products is not safe for the consumer because of the magnitude of the aggregate exposure.

Based on the recent revision of the Notes of Guidance (7th Revision) some adjustments for the amount of certain products applied and/or frequency of use were indicated, and resulted in some changes in the consumer exposure assessment and the related safety evaluation.

The use of triclosan at a maximum concentration of 0.3% in toothpastes, hand soaps, body soaps/shower gels and deodorant sticks ("common-use products" as defined by the applicant) is considered safe. Additional use of triclosan in face powders and blemish concealers at this concentration is also considered safe. The use of Triclosan in other leave-on products (e.g. body lotions) is not considered safe for the consumer due to the resulting high exposures.

Inhalation exposure to triclosan from spray products (e.g. deodorants) was not assessed.

Question 2:

An additional use of triclosan in mouthwashes at a concentration limit of 0.15 or 0.2% is considered as safe for the consumer from a toxicological perspective whereas higher concentrations are not. The aspect of microbial resistance is not covered here and was discussed in the separate opinion (SCCP/1251/09, ref. 31).

Question 3:

Consumer exposure from an additional use of triclosan in nail products at a concentration of 0.3% is considered negligible (safe) under the provisions of the intended use (in products for the cleaning of finger and toenails; Ref. 23) and frequency (every 3 to 4 weeks or every 2 weeks as worst-case). The aspect of microbial resistance is not covered in this opinion and was discussed in the separate opinion (SCCP/1251/09, ref. 31).

The opinion was adopted.

8.5. Ethyl lauroyl arginate, P95

The SCCS considered that further discussion of this opinion in the WG was needed. The adoption of the opinion was postponed.

8.6. Chloroacetamide, P27

The SCCS was asked to answer the following questions:

- 1. On the basis of the provided data the SCCS is asked to assess the risk to consumers when 2-chloroacetamide is used in cosmetic products under the current use conditions of 0.3% in cosmetic products.*
- 2. Does the SCCS have any further scientific concern with regard to its use in cosmetic products?*

On the basis of the data available, the SCCS concluded that 2-chloroacetamide is not safe for consumers when used under the current use conditions of 0.3% in cosmetic products.

Human data demonstrate that allergic reactions can be elicited at concentrations lower than 0.3% (use conditions in cosmetics products).

The opinion was adopted.

8.7. Toluene-2,5-diamine, A5

The SCCS was asked to answer the following questions:

- 1. Does SCCS consider toluene-2,5-diamine and its sulfate salt safe for use as an oxidative hair dyes with a concentration on-head of maximum 4.0% (7.2% calculated as sulfate salt) taken into account the scientific data provided?*
- 2. And/or does the SCCS have any scientific concern with regard to the use of toluene-2,5-diamine and its sulfate salt in oxidative hair dye formulations?*

The SCCS concluded that, based on the low Margin of Safety using the conventional risk assessment approach, toluene-2,5-diamine and its sulfate salt cannot be considered safe for use as an oxidative hair dye with a concentration on-head of maximum 4.0% (calculated as free base) or 7.2% (calculated as sulfate salt).

The kinetics-based approach for MoS calculation proposed by the applicant, using the AUC determined in a human in vivo exposure study, was not accepted due to the shortcomings of the underlying study which was not performed according to modern standards. In order to come to a final conclusion, the SCCS is of the opinion that a state of the art human exposure study in vivo would be required.

Toluene-2,5-diamine is at least a strong skin sensitiser.

The opinion was adopted.

8.8. 4-Amino-2-nitrophenyl-amine-2'-carboxylic acid, B87

The SCCS was asked to answer the following questions:

- 1. Does the Scientific Committee on Consumer Safety (SCCS) consider 4-Amino-2-nitrodiphenylamine-2'-carboxylic acid safe for use as a non-oxidative hair dye with an on-head concentration of maximum 2.0% taken into account the scientific data provided?*

2. *Does the SCCS consider 4-Amino-2-nitrodiphenylamine-2'-carboxylic acid safe for use in oxidative hair dye formulations with an on-head concentration of maximum 2.0% taken into account the scientific data provided?*
3. *Does the SCCS recommend any restrictions with regard to the use of 4-Amino-2-nitrodiphenylamine-2'-carboxylic acid in any non-oxidative or oxidative hair dye formulations?*

The SCCS concluded that a conclusion on the gene mutation potential of 4-Amino-2-nitrodiphenylamine-2'-carboxylic acid cannot be drawn without further testing.

Data on the stability in an oxidative environment should be provided.

The opinion was adopted.

8.9. Basic Red 51, B116

The SCCS was asked to answer the following questions:

1. *Does the Scientific Committee on Consumer Safety (SCCS) consider Basic Red 51 to be safe for use in non-oxidative hair dye formulations at a maximum on-head concentration up to 1% and in oxidative hair dye formulations at a maximum on-head concentration of 0.5% taken into account the data scientific provided?*
2. *Does the SCCS recommend any restrictions with regard to the use of Basic Red 51 in non-oxidative and oxidative hair dye formulations?*

Based on the data provided, the SCCS concluded that the use of Basic Red 51 with a maximum on-head concentration of 1% in non-oxidative hair dye formulations does not pose a risk to the health of the consumer. For a final assessment of the use of Basic Red 51 with a maximum on-head concentration of 0.5% in oxidative hair dye formulations, data on the stability in an oxidative environment should be provided.

The opinion was adopted.

8.10. Basic Red 76, C8

The SCCS was asked to answer the following questions:

1. *Does SCCS consider Basic Red 76 safe for use as an ingredient in non-oxidative hair dye formulations with a concentration on the scalp of maximum 2.0% taken into account the scientific data provided?*
2. *And/or does the SCCS have any other concerns with regard to the use of Basic Red 76 in non-oxidative hair dye formulations?*

Based on the data provided, it seems that Basic Red 76 as tested may not pose a risk to the health of the consumer when used as a non-oxidative hair dye with a maximum on-head concentration of 2.0%. Before a final conclusion, however, the applicant should provide information regarding the safety of monomethyl sulphate.

The opinion was adopted.

8.11. Acid Orange 7, C15

The SCCS was asked to answer the following questions:

1. *Does the Scientific Committee on Consumer Safety (SCCS) consider Acid Orange 7 safe for use in non-oxidative hair dye formulations with a concentration on-head of 0.5% taken into account the scientific data provided?*
2. *Does the SCCS consider Acid Orange 7 safe for use in oxidative hair dye formulations with a concentration on-head of 0.5% taken into account the scientific data provided?*
3. *Does the SCCS recommend any restrictions with regard to the use of Acid Orange 7 in oxidative or non-oxidative hair dye formulations (e.g. max conc. in the finish cosmetic product, dilution ratio with hydrogen peroxide, warning?)*

Based on the low margin of safety, the SCCS concluded that the use of Acid Orange 7 as a hair dye ingredient up to a final on-head concentration of 0.5% under oxidative and non-oxidative conditions poses a risk to the health of the consumer.

No dermal absorption study was performed under oxidative conditions. No data on the stability in an oxidative environment has been provided.

The safety of the use of Acid Orange 7 (CI15510) as a cosmetic colorant should be assessed.

The opinion was adopted.

9. COMMENTS ON OPINIONS ADOPTED DURING THE PLENARY MEETING OF 14 DECEMBER 2010

Comments have been received during the prescribed period on the opinions adopted in the SCCS plenary meeting of 14 December 2010. All comments were discussed and opinions revised as appropriate.

With concern to comments received from member state experts, the SCCS decided that applicants should provide data on the stability of direct hair dyes under oxidative conditions, should use under such conditions be intended.

In relation to the opinion on parabens, the Norwegian authorities informed the SCCS that it does not consider the dermal absorption value from a Norwegian assessment cited in the SCCS opinion valid any longer. The opinion was adapted accordingly.

The following opinions have been revised:

- B28, Picramic acid and sodium picramate
- B31, HC Red n° 13
- B102, HC Yellow n° 13
- B114, HC Red n° 16
- B118, Basic Orange 31
- P32, Parabens

10. NOTES OF GUIDANCE - FINAL EDITED VERSION FOR APPROVAL BEFORE PUBLICATION

The Notes of Guidance were principally adopted during the previous plenary meeting of 14 December 2010, but after additional editing the final version was presented for approval before its publication.

11. QUESTIONNAIRE FOR THE IMPACT ASSESSMENT ON THE COSMETICS DIRECTIVE 2013 IMPLEMENTATION DATE FOR THE MARKETING BAN

The Commission services responsible for the Cosmetics legislation is currently preparing an impact assessment relating to the 2013 implementation date for the marketing ban of cosmetic products tested on animals in the Cosmetics Directive and requested input from the SCCS in form of a questionnaire addressed to stakeholders.

The Committee discussed and finalised its response to this request.

12. ANY OTHER BUSINESS

The next plenary meeting will take place on 21 June 2011

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. E. Nielsen (associate scientific advisor), Prof. T. Platzek, Prof. V. Rogiers (vice-Chair), Dr. S.C. Rastogi, Prof. T. Sanner (vice-Chair), Dr. J. van Benthem (associate scientific advisor), Dr. J. van Engelen, Prof. M.P. Vinardell, Dr. I.R. White (Chair)

Apologies

Dr. W. Lilienblum (associate scientific advisor), Dr. C. Rousselle, Dr. R. Waring

SCCS Secretariat (DG SANCO)

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

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Mrs. A. Orloff