



EUROPEAN COMMISSION
HEALTH & CONSUMERS DIRECTORATE-GENERAL

Health systems and products
Risk assessment

Scientific Committee on Consumer Safety
11th plenary Meeting

Held on 21 June 2011 in Brussels

MINUTES

1. WELCOME AND APOLOGIES

The chairman of the SCCS welcomed all the participants. Apologies were received from Dr. U. Bernauer and Prof. V. Rogiers.

2. DECLARATIONS OF INTEREST

Dr. E. Nielsen declared a possible interest in relation to point 9 of the agenda as background documents to the Danish ban of parabens from children products were prepared at her institute. Although not personally involved in this work, Dr. Nielsen preferred not to take part in the discussion.

Prof. P. Vinardell declared an interest in relation to point 8.4 of the agenda due to the personal acquaintanceship with researchers involved in the development of this substance. She voluntarily decided to abstain from the discussion on this subject.

3. APPROVAL OF THE DRAFT AGENDA

The agenda was approved.

4. ADOPTION OF THE DRAFT MINUTES OF THE 10TH PLENARY MEETING

SCCS/1432/11

The minutes of the 10th plenary meeting of 22 March 2011 were approved.

5. INFORMATION FROM CHAIRMAN/MEMBERS

Information from the Commission

The new Head of Unit of SANCO D5 Unit for Risk Assessment, Dr. W. Penning, introduced himself, describing his previous tasks in the Commission services (JRC, Food and Veterinary office, Regulation of Food additives and Feed).

He invited the Committee members to apply for the Committee's renewal coming up next Year and described the current challenges for the scientific advice structure of the European Commission due to the intensive scrutiny of expert's independence by the EP and NGOs.

Information from the Chairman

- Threshold of Toxicological Concern (TTC), meeting with EFSA

In order to avoid divergent opinions caused by the considerations of different data sets, a joint meeting of the Commission SCs and EFSA was organised. The aim of the meeting was

to make the results from an EFSA-sponsored project for analysis of the databases from which the TTC values are derived available to the Commission SCs and to identify and discuss divergences in their respective draft opinions.

As a result, the meeting revealed no fundamental divergences. It was concluded that a revision of the wording in some parts of the opinions would be sufficient to address the concerns. EFSA will revise their draft opinion following a public consultation (summer 2011). A further meeting will be organised if necessary.

- TTC-Workshop: Scientific Challenges and Approaches, Brussels, 8 – 10 June 2011
The objective of the workshop was to explore the scientific challenges to the application of TTC as a tool to aid decision-making in chemical safety assessment.

Commission follow-up to earlier opinions

No points were raised

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. Two meetings had taken place since the previous plenary meeting of 22 March 2011. A draft opinion on Ethyl lauroyl arginate HCL (P95) was 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 Hydroxyethyl-2-nitro-p-toluidine (B75), Basic Violet (B115) and HC Blue n° 14 (C172) were prepared and tabled for adoption.

7.3. Methodologies

In the absence of the Chairperson of the WG, the Chairman reported that one WG meeting had taken place since the previous plenary meeting. The following issues were discussed: the assessment of inhalation toxicity and exposure, biomonitoring, intestinal models to assess oral bioavailability.

7.4. Nano-materials in Cosmetics

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

7.5. TTC

No WG meeting had taken place since the previous plenary meeting. No further meetings are planned until EFSA has finalised its work on TTC.

7.6. Nitrosamines

The Chairperson said that one WG meeting had taken place since the previous plenary meeting.

The WG is working on an opinion on nitrosamines and secondary amines in cosmetics and on an opinion on NDELA in cosmetics and nitrosamines in balloons.

7.7. Sensitisation & Fragrances

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

7.8. 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:

- Possible improvements in risk assessment approaches in view of risk management needs and effective risk communication
- Fluoride in drinking water

8. DRAFT OPINIONS - DISCUSSION AND POSSIBLE ADOPTION

8.1. Hydroxyethyl-2-nitro-p-toluidine (B75)

The SCCS was asked to answer the following questions:

1. *On the basis of provided data the Scientific Committee on Consumer Safety (SCCS) is asked to assess the risk to consumer when Hydroxyethyl-2-nitro-p-toluidine is used in oxidative and non-oxidative hair dye formulations at a maximum on-head concentration of 1%.*
2. *Does the SCCS recommend any further restrictions with regard to its use in cosmetic products?*

The SCCS concluded that the use of hydroxyethyl-2-nitro-p-toluidine with a maximum on-head concentration of 1.0% in oxidative and non-oxidative hair dye formulations does not pose a risk to the health of the consumer.

A possible sensitising potential of hydroxyethyl-2-nitro-p-toluidine cannot be excluded.

Hydroxyethyl-2-nitro-p-toluidine 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.

8.2. Basic Violet 2, B115

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

8.3. HC Blue n° 14, C172

The SCCS was asked to answer the following questions:

1. *Does the Scientific Committee on Consumer Safety (SCCS) consider HC Blue n° 14 safe for use in non-oxidative hair dye formulations with an on-head concentration of maximum 0.3% taken into account the scientific data provided?*
2. *Does the SCCS recommend any further restrictions with regard to the use of HC Blue n° 14 in non-oxidative hair dyes?*

The SCCS concluded that the use of HC Blue n° 14 at a maximum on-head concentration of 0.3% in non-oxidative hair dye formulations does not pose a risk to the health of the consumer.

HC Blue n° 14 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.

The opinion was adopted.

8.4. Ethyl lauroyl arginate, P95

The SCCS was asked to answer the following questions:

1. *In the light of the data provided, does the SCCS consider that ethyl lauroyl arginate HCl is safe for the consumers, when used up to a maximum concentration of 0.75% in toothpaste and 0.2% in mouthwash products in addition to the currently recommended uses as mentioned above?*
2. *Taking into account the dermal absorption data submitted, the SCCS is requested to revise the exposure assessment for ethyl lauroyl arginate HCl in cosmetics made in opinion SCCP/1106/07.*
3. *Does the SCCS have any other scientific concerns of use for ethyl lauroyl arginate HCl in cosmetic products based on the toxicological profile and foreseeable exposure?*

The SCCS concluded that the additional data provided on mucosal irritation does not alter its earlier opinion on ethyl lauroyl arginate HCl. The concern that in the general population, regular use of toothpaste and possible additional use of a mouthwash containing ethyl lauroyl arginate HCl could cause local mucosal irritation, was not addressed by the submitted studies.

The SCCS has revised the Margin of Safety calculation for ethyl lauroyl arginate HCl in cosmetics based on a new dermal absorption study and maintains its conclusion that there are no systemic safety concerns at the currently authorised use concentrations.

The opinion was adopted.

8.5. Toxicity and assessment of chemical mixtures (joint opinion)

The preliminary opinion concerning toxicity and assessment of chemical mixtures was published for public consultation. The deadline for submission of comments is 9 September 2011.

The comments received will be collected by the secretariat and presented for final discussion during the 12th plenary meeting of 20 September 2011.

8.6. 1,3,5-Triazine, 2,4,6-tris[1,1'-biphenyl]-4-yl-

A draft opinion was presented to the plenary meeting for initial discussion.

9. REQUEST FOR CLARIFICATION ON OPINION SCCS/1348/10 IN THE LIGHT OF THE DANISH CLAUSE OF SAFEGUARD BANNING THE USE OF PARABENS IN COSMETIC PRODUCTS INTENDED FOR CHILDREN UNDER THREE

Head of Unit SANCO B2 Cosmetics and Medical devices, Mrs. Lecrenier, reported on the discussion on parabens in the meeting of the Standing Committee on Cosmetics of 14/15 June 2011. Several Member States supported the Danish initiative to ban the use of parabens from cosmetics for children under three. However, the application of the precautionary principle to ban parabens in these products would need a scientific motivation in relation to the safety of children.

Hence, it was necessary to re-consult the SCCS, specifically on the risk assessment for children and on the reasons given by the Member States why a ban should be introduced.

Documents on the issue were submitted by Denmark and France.

The SCCS decided that the issue should be re-considered by its WG on Cosmetic Ingredients.

10. COMMENTS ON OPINIONS FROM PREVIOUS PLENARY MEETINGS

Comments have been received during the prescribed period on the opinions adopted in the SCCS plenary meeting of 22 March 2011. All comments were discussed and opinions revised as appropriate.

The following opinions have been considered:

- A5, Toluene-2,5-diamine
- B87, 4-Amino-2-nitrodiphenyl-amine-2'-carboxylic acid
- C8, Basic Red 76
- C15, Acid Orange 7
- N-Methyl-2-pyrrolidone (NMP)
- P32, Triclosan
- S85, Bis(butylbenzoate)diaminotriazine aminopropyltrisiloxane

11. ANY OTHER BUSINESS

The next plenary meeting will take place on 20 September 2011

Annex 1: List of Participants

Annex 1

List of Participants

Members of the SCCS

Prof. J. Angerer, 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, Prof. T. Sanner (vice-Chair), Dr. J. van Benthem, Dr. J. van Engelen, Prof. M.P. Vinardell, Dr. I.R. White (Chair)

Apologies

Dr. U. Bernauer, Prof. V. Rogiers

SCCS Secretariat (DG SANCO)

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

DG SANCO B2

Mrs G. Ciarlo, Mrs. F. de Gaetano, Mrs. S. Lecrenier