Scientific Committee on Consumer Safety
13th plenary Meeting

Held on 13-14 December 2011 in Brussels

MINUTES

1. WELCOME AND APOLOGIES

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

The chairman also welcomed Prof. G. Eisenbrand (rapporteur for the opinion on nitrosamines and secondary amines) Prof. W. Uter (rapporteur for the opinion on fragrance allergy) and Dr. J.D. Johansen (member of the WG on sensitisation).

2. DECLARATIONS OF INTEREST

No member declared any interest that could prevent him/her from participating in the discussion of the items on the agenda.

3. APPROVAL OF THE DRAFT AGENDA

The agenda was approved.

4. ADOPTION OF THE DRAFT MINUTES OF THE 12TH PLENARY MEETING

The minutes of the 12th plenary meeting of 20 September 2011 were approved.

5. INFORMATION FROM CHAIRMAN/MEMBERS/COMMISSION

No specific points were raised.

6. REPORTS FROM THE WORKING GROUPS

6.1. Cosmetic Ingredients

The Chairperson of the WG reported on the ongoing work. Two meetings had taken place since the previous plenary meeting of 20 September 2011. Five draft opinions had been prepared which were tabled for adoption.

6.2. 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 p-Aminophenol (A16), 1-Hydroxyethyl-4,5-diamino pyrazole sulfate (A154), Quinolinium, 4-formyl-1-methyl-, salt with 4-methylbenzenesulfonic acid (1:1) (A157), Basic Yellow 87 (B117) and Basic Orange 31 (B118) were prepared and tabled for adoption.

6.3. Methodologies

One WG meeting had taken place since the previous plenary meeting, during which the following issues were discussed: intestinal models to assess oral bioavailability, bio-monitoring and inhalation.
Further to the assessment of parabens in children cosmetics, the WG discussed the general aspects that need to be taken into account for the risk assessment for children.

These issues will be considered in the next update of the Notes of Guidance.

6.4. Nano-materials in Cosmetics

The Chairperson of the WG reported on the on-going work. Three meetings had taken place since the previous plenary meeting. The WG continues its work on the draft opinions on Zinc oxide and Titanium dioxide. A draft guidance document for the safety assessment of nanomaterials in cosmetics was tabled for comments.

6.5. TTC

Two WG meetings had taken place since the previous plenary meeting, during which the proposed changes to SANCO SC draft opinion were discussed and the WG was updated on developments of the EFSA opinion after public consultation.

6.6. Nitrosamines

The Chairperson informed that two WG meeting had taken place since the previous plenary meeting.
The WG is still working on its opinion on NDELA in cosmetics and Nitrosamines in balloons. The draft opinion on Nitrosamines and Secondary amines in Cosmetics was tabled for adoption.

6.7. Sensitisation & Fragrances

The Chairperson said that three WG meetings had taken place since the previous plenary meeting. The update of the opinion on fragrance allergens was tabled for adoption.

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

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

7. DRAFT OPINIONS - DISCUSSION AND POSSIBLE ADOPTION

7.1. Nitrosamines and secondary amines

The SCCS was asked to answer the following questions:

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 trialkylamines 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 answered each of the above questions in a concrete manner and it pronounced itself on the requested cases.

The preliminary opinion was approved for public consultation.

7.2. Updated scientific opinion on the labelling of 26 fragrance substances

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?*

The SCCS concluded as follows:
The present opinion updates the SCCNFP opinion with a systematic and critical review of the scientific literature to identify fragrance allergens, including natural extracts, relevant to consumers. Clinical, epidemiological and experimental studies were evaluated, as well as modelling studies performed, to establish lists of (i) established fragrance allergens, (ii) likely fragrance allergens and (iii) possible fragrance allergens.
The studies since the SCCNFP opinion on fragrance allergy in consumers confirm that the fragrance allergens identified by SCCNFP in 1999 are still relevant fragrance allergens for consumers from their exposure to cosmetic products. The review of the clinical and experimental data published since then shows that many more fragrance substances have been shown to be sensitisers in humans. Based on the clinical experience alone, 82 substances can be classified as established contact allergens in humans, 54 single chemicals and 28 natural extracts. Of these, 12 chemicals and 8 natural extracts were found to pose a high risk of sensitisation to the consumer, considering the high number of reported cases.
In particular one ingredient stood out, hydroxyisohexyl 3-cyclohexene carboxaldehyde, having been the cause of more than 1500 reported cases since the 1999 opinion.

The SCCS examined available elicitation dose-response data to decide whether safe thresholds can be established for the fragrance allergens of concern, i.e. those found to pose a high risk of sensitisation to consumers. The SCCS considers that thresholds based on elicitation levels in sensitised individuals will be sufficiently low to protect both the majority of sensitised individuals as well as most of the non-sensitised consumers from developing contact allergy.

The review also lists fragrance substances that can act as prehaptens or prohaptens, forming new or more potent allergens by air oxidation and/or metabolic activation. Such activation processes are of concern as they increase the risk of sensitisation and also the risk for cross-reactivity between fragrance substances. In addition to known prehapten fragrance substances, the SCCS performed SAR analyses to identify fragrance substances with structural alerts that indicate that they are possible prehaptens. While in the case of prohaptens the possibility of becoming activated is inherent to the molecule and cannot be avoided, the activation of prehaptens can be prevented by appropriate measures.

The preliminary opinion was approved for public consultation.

7.3. Quaternium-15, P63

The SCCS was asked to answer the following questions:

1. *Based on the scientific data provided, does the SCCS consider that Cis-1-(3-chloroallyl)-3,5,7-triaza-1-azoniaadamantane chloride is safe for the consumers, when used as a preservative in a concentration up to 0.2% in cosmetic products?*

2. Does the SCCS have any scientific concerns for the continued use or any modification in the specifications for the substance?

The SCCS concluded that the safety of Cis-1-(3-chloroallyl)-3,5,7-triaza-1-azoniaadamantane chloride cannot be assessed because (i) the available dermal absorption values are not sufficiently reliable to calculate the dermal uptake of cis-CTAC, and (ii) appropriate toxicity studies are lacking to establish a reliable NOAEL.

Taking into account the CMR classification of Cis-1-(3-chloroallyl)-3,5,7-triaza-1-azoniaadamantane chloride and considering the absence of relevant toxicological data, the SCCS considered its continued use in cosmetic products may not be safe for the consumers.

The opinion was adopted.

7.4. Polidocanol

The SCCS was asked to answer the following questions:

1. Does the SCCS see it necessary to change its conclusion on the safe use of polidocanol, especially its safe use in leave-on products or other use conditions taken into account the documentation provided?

2. And/or does the SCCS have any further concerns regarding the use of polidocanol in cosmetic products?

3. On the available data provided can the SCCS express an opinion on the safe use of laureth-7 in cosmetic products?

The SCCS concluded, in a re-evaluation of the earlier SCCP opinion (SCCP/1130/07), taking into account the documentation provided, that it is not necessary to change its conclusions on the safe use of polidocanol in consumer products.

The SCCS has no further concerns regarding the topical use of polidocanol in cosmetic products.

The data presently available indicate that Laureth-7 is used in numerous cosmetic products and in sun protection products. Laureth-7 seems to have stronger local anaesthetic effects than polidocanol. As no other data on the pharmacological and toxicological properties of Laureth-7 is available, the SCCS is presently not in the position to evaluate its safe use in cosmetic products.

The opinion was adopted.

7.5. Hydroxyisohexyl 3-cyclohexene carboxaldehyde (HICC)

The SCCS was asked to answer the following questions:

1. Does the SCCS consider, with the data provided that 3 and 4-(4-Hydroxy-4-methylpentyl)-3-cyclohexene-1-carboxaldehyde is safe for the consumers, when exposed to 0.02% 3- and 4-(4-Hydroxy-4-methylpentyl)-3-cyclohexene-1-carboxaldehyde in lip products, deodorants and antiperspirants and 0.2% 3- and 4-(4-Hydroxy-4-methylpentyl)-3-cyclohexene-1-carboxaldehyde in other cosmetic products except oral products?

2. *Does the SCCS have any other scientific concerns of the use of HICC in cosmetic products based the data provided?*

The SCCS concluded as follows:
HICC has for more than 10 years been recognized as an important contact allergen in humans with more cases of contact allergy documented in the scientific literature than for any other fragrance chemical in this period. HICC has been shown to be a significant cause of disease as many of those with contact allergy to HICC also had reactions to cosmetics, which contained or were likely to contain HICC.

Since 2003, attempts have been made by the fragrance industry to contain the outbreak of HICC allergy, but with no convincing success so far. Recent voluntary restrictions (recommendations to lower use concentrations, at least for some product types, to the level recommended by the SCCS in 2003) are not reflected in available evidence and are considered insufficient.

The SCCS considered that the number of cases of HICC allergy documented over the last decade was exceptionally high and that continued exposure to HICC by the consumer was not considered safe even at concentrations as low as 200 ppm. Therefore, HICC should not be used in consumer products in order to prevent further cases of contact allergy to HICC and to limit the consequences to those who already have become sensitized.

The opinion was adopted.

7.6. Methyl-N-methylanthranilate

The SCCS was asked to answer the following questions:

1. *Does SCCS consider Methyl-N-methylanthranilate safe for use in leave-on products including deodorants and antiperspirants in a concentration up to 0.1% taken into account the scientific data provided?*

2. *Does SCCS consider Methyl-N-methylanthranilate safe for use in rinse-off products in a concentration up to 0.2% taken into account the scientific data provided?*

3. *And/or does the SCCS have any further scientific concerns with regard to the use Methyl-N-methylanthranilate cosmetic products?*

The SCCS concluded as follows:
Methyl-N-methylanthranilate is phototoxic and this is the toxicological endpoint of concern. Whilst up to 0.1% methyl-N-methylanthranilate may be safe for use in many leave-on cosmetic products, including deodorants and antiperspirants, the SCCS concluded that for the use in sunscreen/sun care products or products (including fragrances) intended for use on areas exposed to light (especially face and neck), a risk cannot be excluded. This is because there is no information on UV irradiation given soon after application of methyl-N-methylanthranilate or the effects of repeated low dose exposures with UV irradiation.

The available information suggests that there is no safety concern on the use of methyl-N-methylanthranilate at up to 0.2% in rinse-off products.

Methyl-N-methylanthranilate 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.

There is no information on the possible combination effects of the presence of more than one phototoxic substance in cosmetic products.

The presence of methyl-N-methylanthranilate in essential oils is considered in the above.

The opinion was adopted.

7.7. Kojic acid

The SCCS considered that further discussion on the opinion was needed. The adoption of the opinion was postponed and the opinion will we further discussed at the WG.

7.8. p-Aminophenol, A16

The SCCS was asked to answer the following questions:

1. *Does the SCCS consider p-Aminophenol safe for use as an oxidative hair dye with an on-head concentration of maximum 0.9% taken into account the scientific data provided?*

2. *Does the SCCS recommend any further restrictions with regard to the use of p-Aminophenol in oxidative hair dye formulations?*

The SCCS concluded that, based on the data provided, the use of p-aminophenol with a maximum on-head concentration of 0.9% in oxidative hair dye formulations does not pose a risk to the health of the consumer, apart from its sensitising potential.

The opinion was adopted.

7.9. 1-Hydroxyethyl-4,5-diamino pyrazole sulfate, A154

The SCCS was asked to answer the following questions:

1. *Does the SCCS consider 1-hydroxyethyl-4,5-diamino pyrazole sulfate safe for use as an oxidative hair dyes with a concentration on-head of maximum 3.0% taken into account the scientific data provided?*

2. *And/or does the SCCS have any further scientific concern with regard to the use of 1-hydroxyethyl-4,5-diamino pyrazole sulfate in oxidative hair dye formulations?*

The SCCS concluded that the use of 1-hydroxyethyl-4,5-diamino pyrazole sulfate in oxidative hair dye formulations with an on-head concentration of maximum 3.0% does not pose a risk to the health of the consumer, apart from its sensitising potential.

1-Hydroxyethyl-4,5-diamino pyrazole sulphate can be nitrosated (SCCS/1458/11) to generate respective nitrosamine. It should not be used together with nitrosating agents. Nitrosamine content should be <50 ppb.

The opinion was adopted.

7.10. Quinolium, 4-formyl-1-methyl-, salt with 4-methylbenzenesulfonic acid (1:1), A157

The SCCS was asked to answer the following questions:

1. *Does SCCS consider Quinolinium, 4-formyl-1-methyl-, salt with 4-methylbenzenesulfonic acid (1:1) safe for use as an oxidative hair dye (used in the absence or presence of hydrogen peroxide) with a maximum on-head concentration up to 2.5% taken into account the scientific data provided?*

2. *And/or does the SCCS have any scientific concern with regard to the use of Quinolinium, 4-formyl-1-methyl-, salt with 4-methylbenzenesulfonic acid (1:1) in oxidative hair dye formulations?*

The SCCS concluded that, based on the data provided, Quinolinium, 4-formyl-1-methyl-, salt with 4-methylbenzenesulfonic acid (1:1) does not pose a risk to the health of the consumer when used in oxidative hair dye formulations with a maximum on-head concentration of 2.5%.

Quinolinium, 4-formyl-1-methyl-, salt with 4-methylbenzenesulfonic acid (1:1) has no EC number.

The opinion was adopted.

7.11. Basic Yellow 87, B117

The SCCS was asked to answer the following questions:

1. *Does the Scientific Committee on Consumer Safety (SCCS) consider Basic Yellow 87 to be safe for use in non-oxidative and oxidative hair dye formulations up to a concentration of 1.0% on-head taken into account the scientific data provided?*

2. *Does the SCCS recommend any restrictions with regard to the use of Basic Yellow 87 in non-oxidative and oxidative hair dye formulations?*

The SCCS concluded that, based on the data provided, Basic Yellow 87 does not pose a risk to the health of the consumer when used in non-oxidative and oxidative hair dye formulations up to a concentration of 1.0% on-head.

The opinion was adopted.

7.12. Basic Orange 31, B118

The SCCS was asked to answer the following questions:

1. *Does the Scientific Committee on Consumer Safety (SCCS) consider Basic Orange 31 to be safe for use* in non-oxidative hair dye formulations at a maximum on-head concentration of 1.0% and in oxidative hair dye formulations at a maximum on-head concentration of 0.5% *taken into account the scientific data provided?*

2. *Does the SCCS recommend any restrictions with regard to the use of Basic Orange 31 in non-oxidative and oxidative hair dyes formulations?*

The SCCS concluded that, based on the data provided, the use of Basic Orange 31 with a maximum on-head concentration of 1.0% in non-oxidative hair dye formulations and 0.5% in oxidative hair formulations does not pose a risk to the health of the consumer, apart from its sensitising potential.

The opinion was adopted.

7.13. Toxicity and Assessment of Chemical Mixtures (joint opinion)

After public consultation, a revised opinion was presented to SCCS, SCHER and SCENIHR for final adoption.

Based on their analysis of the available scientific literature, the non-food Scientific Committees of the European Commission reached the following conclusions:

1. Under certain conditions, chemicals may act jointly in a way that the overall level of toxicity is being affected.

2. Chemicals with common modes of action may act jointly to produce combination effects that are larger than the effects of each mixture component applied singly. These effects can be described by dose/concentration addition.

3. For chemicals with different modes of action (independently acting), no robust evidence is available that exposure to a mixture of such substances is of health or environmental concern if the individual chemicals are present at or below their zero-effect levels.

4. Interactions (including antagonism, potentiation, synergies) usually occur at medium or high dose levels (relative to the lowest effect levels). At low exposure levels, they are either unlikely to occur or are toxicologically insignificant.

5. In view of the almost infinite number of possible combinations of chemicals to which humans and environmental species are exposed, some form of initial filter to allow a focus on mixtures of potential concern is necessary. Several criteria for such screening are offered.

6. With regard to the assessment of chemical mixtures, a major knowledge gap at the present time is the lack of exposure information and the rather limited number of chemicals for which there is sufficient information on their mode of action. Currently, there is neither an agreed inventory of mode of actions, nor a defined set of criteria how to characterise or predict a mode of action for data-poor chemicals.

7. If no mode of action information is available, the dose/concentration addition method should be preferred over the independent action approach. Prediction of possible interaction requires expert judgement and hence needs to be considered on a case-by-case basis.

Based upon these conclusions, a decision tree for evaluating the risk of chemical mixtures was proposed.

The SCCS adopted the opinion.

7.14. Improvement of risk assessment (joint opinion)

A joint Working Group of the three SCs was established to:

1) reviewing the current risk assessment (RA) practices,
2) exploring what risk managers and policy makers need from risk assessment, and
3) identifying approaches to risk assessment that can provide results which are based on the best available science and which are informative, consistent, transparent and easy to interpret and communicate. The motivation for this review has been the perception, from all parties, that risk assessments as currently carried out do not inform the risk management process as well as they should.

A preliminary version of the report was presented to SCCS, SCHER and SCENIHR for approval for public consultation.

The preliminary report concludes that the outputs of risk assessment need to be more policy-relevant and this ought to be facilitated by more dialogue between risk assessors and risk managers and the evaluation of possible risk-management options.

Risk assessments should be expressed (whenever appropriate) in terms of value-relevant impacts on humans and ecosystems rather than in terms of the somewhat technical surrogates. This would entail more dialogue between risk assessors and socio-economists.

Risk-assessment reports should be improved in terms of: including the evaluation of different possible scenarios; making full characterization of the whole populations/ ecosystems at risk with attention to particularly sensitive subpopulations/species; including clear expressions of uncertainty; making explicit disclosure of hypotheses used without supporting evidence.

The pre-consultation opinion was approved.

8. COMMENTS ON OPINIONS FROM LAST PLENARY MEETING

Comments on opinions adopted in the SCCS plenary meeting of 20 September 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:

- 2,6-Dihydroxyethylaminotoluene, A138
- 2,6-Diamino-3-((pyridin-3-yl)azo)pyridine, B111
- Basic Violet 2, B115
- 1,3,5-Triazine, 2,4,6tris[1,1'-biphenyl]-4-yl, ETH-50
- Ethyl lauroyl arginate, P95 (plenary of 21 June 2011)

9. APPROACH FOR THE OVERALL EXPOSURE AND RISK ASSESSMENT OF CMR SUBSTANCES ACCORDING TO ARTICLE 15.3 OF REGULATION 1223/2009/EC

The new Cosmetics Regulation (EC) No 1223/2009 foresees that the Commission shall provide guidance for the development and use of overall exposure estimates in assessing the safe use of CMR substances. This guidance shall be developed in consultation with the SCCS, the ECHA, the EFSA and other relevant stakeholders.

A draft guidance document was approved by the SCCS.

10. ANY OTHER BUSINESS

The next plenary meeting will take place on 27 March 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. Rousselle, Prof. V. Rogiers, Prof. T. Sanner (vice-Chair), Dr. J. van Benthem, Dr. J. van Engelen, Prof. M.P. Vinardell, Dr. I.R. White (Chair), Dr. R. Waring

Apologies

None

External experts (participation on selected issues only)

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

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