4th Plenary Meeting of the Scientific Committee on Consumer Safety (SCCS)

06 and 07 June 2017, Luxembourg

Minutes

06 June 2017

1. Approval of the agenda, minutes and declaration of interests

The Chair welcomed the participants and announced two apologies. The agenda was adopted.
The minutes of the previous plenary meeting were adopted by the SCCS via written process on 31 March and published on the website on 03 April 2017.

The Chair invited participants to declare any interest regarding matters on the agenda. None of the participants declared any interest conflicting with the matter on the agenda.

2. List of points discussed and conclusions

2.1 Follow-up of adopted opinions

There was no specific update reported by DG GROW.

The new legislative Acts are posted on the website of the scientific committees with a link to DG GROW website: http://ec.europa.eu/growth/sectors/cosmetics/legislation_en

2.2 New mandate(s):

- 2-(4-tert-butylbenzyl)propionaldehyde (BMHCA) – Submission II

A rapporteur was selected and appointed by the Commission.
The mandate will be published:
http://ec.europa.eu/health/scientific_committees/consumer_safety/requests/index_en.htm

2.3 Draft opinions (on hold):

Cosmetic Ingredients

- Fragrance Vetiver Oil - Submission III

  A request for clarification was sent to the Applicant following the previous WG meeting on cosmetic ingredients (2 May 2017). A response was received and discussed. An additional request for clarification will be sent to the Applicant. The draft Opinion is

planned to be discussed at the next WG meeting of the cosmetic ingredients on 30 June 2017 should the SCCS receive an answer from the Applicant.

- 2-(4-tert-butylbenzyl)propionaldehyde (BMHCA) – Submission II

  The group looked at the quality of the dossier received. Further tasks among members were distributed. A draft Opinion is planned to be discussed at the next WG meeting of the cosmetic ingredients on 30 June 2017.

- Aluminium

  The draft Opinion was not discussed as further input from the members is still needed. It is planned to be discussed at the next WG meeting of the cosmetic ingredients on 30 June 2017.

- Di-HEMA Trimethylhexyl Dicarbamate, HEMA and Urethane acrylates

  Missing references were received from the Applicant. A draft Opinion is planned to be discussed at the next WG meeting of the cosmetic ingredients on 30 June 2017.

- Quantitative Risk Assessment method (QRA 2) – ***methodology point***

  The request for clarification was sent to the Applicant following the previous WG meeting on cosmetic ingredients (2 May 2017). A response was received and discussed. The draft Opinion is planned to be discussed at the next WG meeting of the cosmetic ingredients on 30 June 2017.

Nanomaterial in cosmetic ingredients

- Styrene/acrylates copolymers (nano) CAS No 9010-92-8, EC No 927-710-1 and Sodium styrene/Acrylates copolymer (nano) CAS No 9010-92-8

  A request for information and clarification was sent back to Applicants with a deadline by 30 September 2017.

- Colloidal Silver (nano) CAS No 7440-22-4, EC No 231-131-3

  A request for information and clarification was sent back to Applicants with a deadline by 30 September 2017.

2.4 Comments on opinions

Cosmetic Ingredients

- Dimethylpiperazinium Aminopyrazolopyridine HCl (A164) - SCCS/1584/17

  No comment was received during the commenting period. Therefore the SCCS adopted the final version of this Opinion that is published:
  https://ec.europa.eu/health/sites/health/files/scientific_committees/consumer_safety/docs/sccs_o_209.pdf

  Methoxypropylamino Cyclohexenylidene Ethoxyethylcyanoacetate (S87) - Submission I - SCCS/1587/17

Comments were received during the commenting period and discussed. The SCCS will prepare a draft response to be discussed at the next meeting on 30 June.

- Water-soluble zinc salts used in oral hygiene products - Submission I - SCCS/1586/17

  Comments were received during the commenting period and discussed. The SCCS will prepare a draft response to be discussed at the next meeting on 30 June.

- Basic Blue 99 (C059) - SCCS/1585/17

  A comment was received during the commenting period and discussed. The SCCS prepared and finalised a response that was adopted and will be sent out by the Secretariat. No change occurred in the final version of this Opinion that is published: https://ec.europa.eu/health/sites/health/files/scientific_committees/consumer_safety/docs/sccs_o_205.pdf

Nanomaterial in cosmetic ingredients

- Titanium Dioxide (nano form) as UV-Filter in sprays - SCCS/1583/17
  The response received from the Applicant is under assessment by the SCCS.

3. Information from Commission

The SCCS Chair gave the floor to the Secretariat for an update on the state of play of the following issues:

Administrative information

- Vitamin A (SCCS/1576/16) – the SCCS response to a clarification request was sent out.

- PHMB – Submission III – the conclusion of the Opinion have been published in the Regulatory Toxicology and Pharmacology Journal.

- Format of the final opinion: the Commission suggested changing the format of the future opinions for example by starting with the mandate and the conclusion (as for SCHEER). The SCCS will consider this proposal for the next update of the SCCS Notes of Guidance.

- Minutes of WG meetings to be published: the minutes of all WG meetings need to be approved by the SCCS before publication, according to new rules on expert groups.

- Latest update of the EFSA Scientific Committee WG on Weight of Evidence: the public consultation is over. The WG is working on the amendment of the document accordingly and EFSA plans to go to the EFSA Scientific Committee for adoption of the document in July. The same with regards to the timelines apply for the relevant guidance document on biological relevance.

Future events

- The Secretariat is going to participate in Cosmetics Europe Week on 15 June in Brussels and present the recently adopted and published checklist for completeness of

dossier to be submitted by applicants to DG GROW and to SCCS for the risk assessment.

- European Union Reference Laboratory for alternatives to animal testing (EURL-ECVAM hosted by JRC): The next joint PARERE (EURL ECVAM's Network for Preliminary Assessment of Regulatory Relevance) - ESTAF (ECVAM Stakeholder Forum) meeting will be held on 28-29 November 2017 and SCCS Vice-Chair (*Vera Rogiers*) is planning to participate.

All members were invited to send information to the Secretariat about their (future) participation in any relevant meeting in case there could be a potential conflict of interest.

4. Chair and members' reports

- SCCS member (*Maria Dusinska*) participated in Genotoxicity Task Force of Cosmetics Europe (International workshop) on April 27 in Brussels, Belgium as SCCS observer. She reported to the group as new models in genotoxicity testing are of core interest: three advanced in vitro genotoxicity models were presented and discussed at the workshop. These were in rank order of development: first the reconstructive skin micronucleus (RSMN), then the 3D skin comet assays (RSCA) and, finally, the chicken hen's egg micronucleus test. The workshop gave a useful overview on these promising assays that, after proper validation and being taken up in an OECD TG, can have a larger implication in the hazard assessment of compounds relevant for dermal exposure. They are of particular importance for cosmetic substances (and thus for SCCS risk assessments) for which a positive outcome in one of the in vitro tests of the official in vitro test battery occurs, which according to regulation 1223/2009 disqualifies the ingredient for further use. The tests described can then be used to be included in a battery of tests to be applied in a Weight of Evidence (WoE) approach to follow up the positive result and to de-risk the compound under investigation.

- SCCS member (*Corrado Galli*) participated in DG ENV workshop event on development and validation of endocrine disrupting chemicals on 30 May and 1st June 2017. He will report to the SCCS in next meetings the main points concerning development and validation of test methods and testing approaches for evaluating endocrine disruptors.

5. Next steps

To collect all input from the members related to the revision of the draft opinions and to prepare respective new versions for the next working group meetings on nano and cosmetic ingredients (29-30 June 2017 respectively).

6. Next meeting(s)

- WG Nanomaterials in cosmetics: 29 June 2017, 29 August, and 12 December.
- WG Cosmetic ingredients: 30 June 2017, 30 August, 26 September and 13 December.
- WG Methodology: 31 August (inhalation exposure), 27 September and 14 December.
- SCCS Plenary meetings: 24-25 October 2017, 22 February 2018

7. List of participants

SCCS Members

1. Dr Ulrike BERNAUER
2. Dr Leonardo CELLENO
3. Prof. Qasim CHAUDHRY (Chair SCCS)
4. Prof. Pieter-Jan COENRAADS (Vice-chair SCCS)
5. Prof. Maria DUSINSKA
6. Dr Janine EZENDAM
7. Dr Eric GAFFET
8. Prof. Corrado L. GALLI
9. Dr Berit GRANUM
10. Prof. Eirini PANTERI
11. Prof. Vera ROGIERS (Vice-chair SCCS)
12. Dr Christophe ROUSSELLE
13. Dr Maciej STEPNIK
14. Prof. Tamara VANHAECKE
15. Dr Susan WIJNHOVEN

Apologies

1. Dr Laurent BODIN
2. Prof. Renate Krätke (SCHEER Member)

SCCS Secretariat (DG SANTE C2)

1. Philippe ROUX
2. Diana HEROLD
3. Natacha GRENIER

07 June 2017

Session on Uncertainty

1. Approval of the agenda and declaration of interests

The Chair welcomed the participants, in particular the speaker *Andy Hart*, and announced five apologies. The agenda was adopted.

The Chair invited participants to declare any interest regarding matters on the agenda. None of the participants declared any interest conflicting with the matter on the agenda.

2. Nature of the meeting

This was a session on uncertainty organised by the Secretariat, introduced and chaired by the SCCS Chair (*Qasim Chaudhry*), and presented by the invited expert speaker, *Andy Hart*, from UK. The session was intended as a moment of reflection for all SCCS members on how to analyse and express uncertainties in the risk assessments they are requested to perform.

The initiative was also intended to strengthen the cooperation and synergy with EFSA on methodological issues. Similarly, it could be considered as a source of inspiration for the members of the WG on methodology to update the SCCS Notes of Guidance for the testing of cosmetic ingredients and their safety assessment.

3. List of points discussed and conclusions

The SCCS Chair presented the Committee and gave an overview of the work and tasks of the SCCS. Much of the uncertainty is already dealt with through the protocols/procedures followed by the Applicants in their studies (cf. OECD guidance etc). Further collective or individual piece of evidence is dealt by the experts (members) within the process of forming opinions. Uncertainty is not covered in any specific separate section but communicated as narrative expressions in the form of SCCS comments (qualitative, not quantitative), then in the Discussion and the Conclusions sections. Default values are used in the absence of measured data (usually proposed by the Applicants themselves, following conclusions of their studies).
The issue of animal testing ban and use of alternative methods or non-test modelling extrapolations will bring further uncertainties and Weight of Evidence (WoE) approach is therefore becoming more important.

Issues for SCCS:

- How best cover uncertainty in SCCS opinions?
- Whether qualitative or quantitative analysis of uncertainty?
- How best to communicate uncertainty?

The SCCS and the SCHEER contributed to the public consultation on Preliminary EFSA Guidance on uncertainties. It was explained that the EFSA's Guidance, when finalised, would be mandatory for all EFSA's scientific assessments and that it might have an impact on the methodologies on uncertainties of other EU risk assessment bodies (including SCHEER and SCCS).

The Chair gave the floor to *Andy Hart* for Lecture 1: Why do we need to address uncertainty, and what output is required?
During this session, the following points were discussed:
 What do we mean by uncertainty?
 Why address uncertainty?
 What output is required?
 What are the roles of the assessors & decision-makers?
 Why try to be quantitative?
 What is the role of qualitative methods?
Uncertainty needs to be addressed because is essential information for decision-making and critical for transparency, credibility and trust.

The Chair gave the floor to *Andy Hart* for Lecture 2, Methods for addressing uncertainty. The points discussed were:
 Scales for expressing uncertainty
 Methods for expressing uncertainty and combining uncertainties
o Qualitative
o (Fully) Probabilistic
o Deterministic
o Partial probability statements
 Exploring uncertainty: influence and sensitivity analysis
It was mentioned that all the methods could be applied but the clarity of existent data and the availability of data for risk assessment should be taken into account before making any decision.

The Chair gave the floor to *Andy Hart* for Lecture 3 regarding the EFSA's draft Uncertainty Guidance. The session started with enumerating the main steps of EFSA Framework:
• Plan the assessment strategy
• Identify sources of uncertainty
• Select which uncertainties to assess individually
• Assess individual sources of uncertainty
• Quantify combined uncertainty
• Investigate influence/sensitivity
• Describe unquantified uncertainties, if any
• Decide whether to refine the assessment
• Report on & communicate about the assessment 3

It continued with the key aspects of the EFSA approach, which are enumerated below, and with some examples.

• Mandatory:
 List identified uncertainties and characterise their combined impact on the assessment outcome in a clear and unambiguous manner

• Flexibility:
 Choice of methods & degree of refinement

• Major change:
 More transparent, rigorous, quantitative use of expert judgement

• Main innovations:
 Combined uncertainty assessment
 Pragmatic approach for standardised procedures
 Use of partial probability statements?

• Fit for purpose:
 Scalable to time and resources available

At the end of the session, the following was summarised:

-> *SCCS would have preferred a more positive wording than "uncertainty", which sounds negative.* The guidance could have been written the other way round, being positive, to increase confidence and trusts instead of being "*uncertain*".

-> *SCCS is already dealing with uncertainty at end of each study (*cf. SCCS comments).

-> *<u>Follow-up</u> (from EFSA side)*

- *Uncertainty*

– Trial period ended April/May
– Internal EFSA workshop in June
– Revision of Guidance in light of feedback
– Adoption of final Guidance by end of 2017

– Communication strategy in 2018

- *Weight of Evidence*

– Public consultation closed
– Revision of Guidance underway
– Adoption by end of 2017

4. Next steps

The SCCS will consider the different approaches for analysing and expressing uncertainty and will adopt/adapt the most appropriate ones that are relevant to their risk assessment work. The SCCS will also discuss further potential update of the SCCS Notes of Guidance during a Methodology WG meeting. The SCCS is also particularly interested in how to (better) communicate the uncertainties in scientific Opinions and will be keenly looking towards the future EFSA work in this area.

5. List of participants

SCCS Members

1. Dr Ulrike BERNAUER
2. Dr Leonardo CELLENO
3. Prof. Qasim CHAUDHRY (Chair SCCS)
4. Prof. Pieter-Jan COENRAADS (Vice-chair SCCS)
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15. Prof. Corrado L. GALLI
16. Dr Christophe ROUSSELLE

SCCS Secretariat (DG SANTE C2)

1. Diana HEROLD
2. Natacha GRENIER

Speaker

1. Andy HART