



7th Plenary Meeting of the Scientific Committee on Consumer Safety (SCCS)

21-22 June 2018, Luxembourg

Minutes

21 June 2018

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

The Chair welcomed all participants, in particular the SCHEER representative. The Chair announced two apologies. The agenda was adopted.

The minutes of the previous plenary meeting were adopted by the SCCS via written process and published on the website on 6 March 2018.

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

2. List of points discussed and conclusions

2.1 Follow-up of adopted Opinions

The following specific point was reported by the Secretariat:

Commission Regulation (EU) 2018/885 of 20 June 2018 amending Annex VI to Regulation (EC) No 1223/2009 of the European Parliament and of the Council on cosmetic products was published in the OJ L158 on 21.06.2018, p. 1-4: (MBBT nano)

https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2018.158.01.0001.01.ENG&toc=OJ:L:2018:158:TOC

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):

The following mandate was adopted by written procedure on 25 May 2018 and published:

- Addendum to the Opinions on preservative climbazole. A rapporteur was already designated.

https://ec.europa.eu/health/scientific_committees/consumer_safety/requests_en

- SCCS/1510/13 -Chloro-p-phenylenediamine and its salts :

https://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_o_139.pdf

Upon request from mandating DG, the SCCS went through the dossier and in particular genotoxicity studies again, and according to that, SCCS confirmed that:

- the 2013 Opinion does not cover salts
- the 2013 Opinion scope can be extended to hairs on head (conclusion is not safe due to genotoxic potential).

However, even though salts are not specifically covered by the 2013 Opinion they should also be handled with the same caution until proven to be safe because they carry the same core structure (potential genotoxicity).

2.3 Opinions for adoption:

Cosmetic Ingredients

The following final Opinion has been adopted and published:

- Addendum to the Opinions on preservative climbazole

https://ec.europa.eu/health/scientific_committees/consumer_safety/opinions_en#fragment2

The following preliminary Opinions have been adopted and published:

- A33 - 1,2,4-trihydroxybenzene (1,2,4-THB), CAS 533-73-3, Submission VI
- Fragrance Vetiver Oil - submission III

https://ec.europa.eu/health/scientific_committees/consumer_safety/opinions_en#fragment0

The commenting period runs until 10 September 2018.

Nanomaterial in cosmetic ingredients

The following final Opinion has been adopted and published:

- 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

https://ec.europa.eu/health/scientific_committees/consumer_safety/opinions_en#fragment2

The following Opinions will be further discussed at the next WG meeting (11/07):

- Solubility of Synthetic Amorphous Silica (SAS),
- Titanium Dioxide (nano form) coated with Methicone (in combination with hydrated silica and aluminium hydroxide) and Perfluorooctyl Triethoxysilane (in combination with hydrated silica and aluminium hydroxide) as UV-filter in dermally applied cosmetic products.

The corrigendum of the following Opinion has been adopted and will be published:

- New conclusion of the Opinion on Titanium Dioxide (nano form) coated with Cetyl Phosphate, Manganese Dioxide or Triethoxycaprylylsilane as UV-filter in dermally applied cosmetic (SCCS/1580/16) (upon request of mandating DG GROW).

2. Draft Opinions (progress report):

The following draft Opinion has been discussed and further tasks among members distributed. This draft Opinion will be further discussed at the next WG meetings (12-13/07):

Cosmetic Ingredients

- Salicylic Acid

The following draft Opinions are "on hold" until end of 2018 due to requests sent to the Applicants:

- A166 - Methylimidazoliumpropyl p-phenylenediamine
- A165- Hydroxypropyl p-Phenylenediamine
- C170 - Indigofera tinctoria, submission III
- Aluminium

Nanomaterial in cosmetic ingredients

- The draft Guidance on the Safety Assessment of Nanomaterials in Cosmetics has been discussed and further tasks among members distributed: it will be further discussed at the next WG meeting (11/07).
- Opinion on Colloidal Silver (nano): comments received during the commenting period will be further discussed at the next WG meeting (11/07).

22 June 2018

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

The Chair welcomed all participants. The Chair announced two 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 matters on the agenda.

Methodology

- The Secretariat reported on the state of play of the next (10th) revision of the SCCS Notes of Guidance on the testing of the cosmetic ingredients and their safety evaluation. Some contributions are still expected from SCCS members and slot of discussion will be made available during the next meeting of the working group on cosmetic ingredients (12-13/07) in order to check that all expected contributions have been received by summer. The goal is to have a draft ready for adoption by next plenary meeting in October.
- The European Commission Joint Research Centre (JRC) has launched a study to review available education and training resources that support the 3Rs approach: Replacement,

Reduction and Refinement of animal procedures used for scientific purposes. A survey targets mainly the education and training providers, however it can also be filled in by those who are aware of or have participated in such courses: <https://ec.europa.eu/eusurvey/runner/3Rs-Education-and-Training>. Deadline end of June. The result will be a snapshot view of how, where and to whom the 3Rs principles and alternative-to-animal approaches are currently being taught keeping in mind that many such initiatives might not be "3R labelled". The review is expected to be completed during 2019 and the information gathered will be made publicly available.

- Final EU-ANSA Research Cluster on '*Innovative 3Rs (Replacement, Reduction and Refinement of animal testing) approaches for the prediction of properties of chemicals, medicines, environmental contaminants and other regulated products*' will be published soon and the link shared on the web site of the Scientific Committees too. ECHA/EFSA/EMA grateful to the SCs for their contribution and collaboration.

(Note post-meeting: here is the link: <http://www.emcdda.europa.eu/about/partners/euansa>)

- SCCS Methodology working group would like to organise a scientific thematic workshop with a number of SCCS members, scientists and university scientists involved in NAMs. The idea would be to see in a practical way, how risk assessment could be envisaged without animal testing, whether possible at all. Non-binding recommendations could then be further used by the SCCS. Commission will explore the possibility.

3. Comments on Preliminary Opinions

SCCS draft responses to comments received were discussed for:

Cosmetic Ingredients

- The safety of Butylphenyl methylpropional (p-BMHCA) in cosmetic products - Submission II - SCCS/1591/17
- The safety of cosmetic ingredients HEMA and Di-HEMA Trimethylhexyl Dicarbamate – SCCS/1592/17
- Water soluble Zn salts used in oral hygiene products – submission I (SCCS/1586/17)
- UV filter S86 Phenylene Bis Diphenyltriazine, (CAS n. 55514-22-2) – submission II

The following final Opinions have been adopted and published:

https://ec.europa.eu/health/scientific_committees/consumer_safety/opinions_en#fragment2

- Di-HEMA Trimethylhexyl Dicarbamate, HEMA and Urethane acrylates
- Water soluble Zn salts used in oral hygiene products – submission I

The following Opinion is "*on hold*" due to request sent to Applicant:

- Fragrance 2-(4-tert-butylbenzyl)propionaldehyde (BMHCA) – submission II

The following Opinion will be further discussed at the next WG meetings in July (12-13):

- UV filter S86 Phenylene Bis Diphenyltriazine, (CAS n. 55514-22-2) – submission II

Methodology

Responses were discussed for the following Opinion that will be further discussed at the next WG meetings in July (12-13):

- Skin Sensitisation Quantitative Risk Assessment for Fragrance Ingredients (QRA2) - Submission I

4. Information from Commission and members of the SCCS

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

From Commission

- To meet the anticipated increase in submission of safety dossiers based on alternative (non-animal) methods and read-across models due to the EU animal testing ban for cosmetics, the SCCS with the Directorate General for Health and Food Safety decided to launch a call for expression of interest to appoint experts who will assist the work of the SCCS. They will be appointed in their personal capacity as external experts to appropriate working groups of the SCCS. The SCCS was consulted and agreed on the following request for expertise:

- Experience in risk assessment related to consumer safety is essential. Preference will be given to experts who can cover 4 or more of the following areas of expertise for the assessment of chemical toxicity, with experience on interpretation of non-animal data in relation to human risk assessment and physiology:

- regulatory toxicology,
- alternative testing methods (e.g. *in vitro* tests),
- alternative non-testing methods (e.g. QSAR models, read-across tools),
- omics methods,
- integrated testing approaches,
- *in vitro/in vivo* extrapolation,
- weight of evidence in risk assessment.

(Note post-meeting:

The call is opened until 1st October 2018 and has been published here:

https://ec.europa.eu/health/scientific_committees/call_experts/call_experts_cosmetic2018_en)

- New SCs' publication including mandates and Opinions is online: https://ec.europa.eu/health/sites/health/files/scientific_committees/docs/overview_opinions_042018_en.pdf

- JRC invited a representative from SCCS and SCHEER in participating in PARERE meetings (+/- 1X/year). *Vera Rogiers* will represent SCCS and *Renate Krätke*, SCHEER.

PARERE is a group of representatives nominated by their Member State and Commission REGULATORY services (not the Secretariat of the SCs). Recent discussions where the

possibility to include a SCs' representative in PARERE was raised by JRC due to the scientific advice provided, which is then translated (or not) into regulatory decisions.

- Guidance for the identification of endocrine disruptors in the context of Regulations (EU) No 528/2012 and (EC) No 1107/2009 has been published on 7 June 2018: <https://www.efsa.europa.eu/en/efsajournal/pub/5311>

The guidance will be used for the assessment of biocides from 7 June. For pesticides, it will be used in the assessments of those substances for which a decision is scheduled on or after 10 November 2018. This is because the criteria for identifying endocrine disruptors in pesticides were agreed later than those for biocides.

- CHECKLIST was updated for compliance with animal testing ban and agreed with SCCS on 16/05 and published

https://ec.europa.eu/health/sites/health/files/scientific_committees/consumer_safety/docs/sccs_o_210.pdf

- Secretariat participated in the Cosmetics Europe annual event in Brussels on 13-14 June to promote SCCS work – a feedback from Secretariat was provided to the group.

- *Peter Hoet* resigned from Nano WG for personal reasons and lack of time. He remains member of SCHEER.

- 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.

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 cosmetic ingredients, methodology and nanomaterials (11-12-13 /07/2018).

6. Next meeting(s)

- WG Cosmetic ingredients: 12-13 July, 30 August, 26 September
- WG Methodology: 31 August, 27 September
- WG Nanomaterials in cosmetics: 11 July, 25 September
- SCCS Plenary meetings: 24-25 October 2018/ 26-27 February 2019/ 20-21 June 2019

7. A.O.B

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8. List of participants

SCCS Members

1. Dr Ulrike BERNAUER
2. Dr Laurent BODIN
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. Dr Maciej STEPNIK
12. Prof. Tamara VANHAECKE
13. Dr Susan WIJNHOFEN

SCHEER Member

14. Dr Renate Krätke

Apologies

1. Dr Christophe ROUSSELLE
2. Prof. Vera ROGIERS (Vice-chair SCCS)

SCCS Secretariat (DG SANTE C2)

3. Diana HEROLD
4. Natacha GRENIER

DG GROW D4

5. Federica DE GAETANO
6. Olga TKACHENKO