



5th Plenary Meeting of the Scientific Committee on Consumer Safety (SCCS)

24-25 October, Luxembourg

Minutes

24 October 2017

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

The Chair welcomed the participants and announced one apology. The agenda was adopted. The minutes of the previous plenary meeting were adopted by the SCCS via written process on 27 June and published on the website on 28 June 2017.

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 points were reported by DG GROW:

MI

Commission Regulation (EU) 2017/1224 of 6 July 2017 amending Annex V to Regulation (EC) No 1223/2009 of the European Parliament and of the Council on cosmetic products (Methylisothiazolinone) was published in the OJ L174 on 07.07.2017, p. 16 (-> rinse-off 0.0015%):

http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2017.174.01.0016.01.ENG&toc=OJ:L:2017:174:TOC

ZnO

Regulation on restriction of ZnO colorant adopted and published in OJ:

<http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32017R1413&from=EN>

HICC Atranol Chloroatranol

Regulation on fragrance HICC Atranol Chloroatranol adopted and published in OJ:

<http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32017R1410&from=EN>

Tagetes

Regulation proposal on Tagetes (Tagetes minuta flower extract, Tagetes minuta flower oil, Tagetes patula flower extract and Tagetes patula flower oil): Leave-on products 0,01 % and rinse-off products 0,1 %.

[http://ec.europa.eu/growth/tools-](http://ec.europa.eu/growth/tools-databases/tbt/en/search/?tbtaction=search.detail&Country_ID=EU&num=491&dspLang=en)

[databases/tbt/en/search/?tbtaction=search.detail&Country_ID=EU&num=491&dspLang=en
&basdatedeb=01/07/2017&basdatefin=17/07/2017&baspays=&basnotifnum=&basnotifnum2
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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):

- Hair dye Hydroxypropyl p-phenylenediamine and its dihydrochloride salt (A165) (CAS 73793-79-0 and 1928659-47-5) - Submission I
- Addendum to the scientific Opinion on the safety of the preservative Zinc Pyrithione – P81

The selected rapporteurs were appointed by the Commission.

The mandates are published:

http://ec.europa.eu/health/scientific_committees/consumer_safety/requests/index_en.htm

DG GROW informed about the coming mandate on Hair Dye A166.

Both mandates here below have already been adopted by written procedure, respectively on 27 June and on 7 September. They have been published. Rapporteurs have been appointed:

1. Addendum of the Opinion on preservative climbazole
2. S86 UV filter - Phenylene Bis Diphenyltriazine (CAS n. 55514-22-2) – submission II

2.3 Opinions for adoption:

Methodology

- **Quantitative Risk Assessment method (QRA 2)** – the draft Opinion was discussed, **finalised and adopted**. It will be published with commenting period, after editing check.
https://ec.europa.eu/health/sites/health/files/scientific_committees/consumer_safety/docs/sccs_o_211.pdf

Cosmetic Ingredients

- **Addendum of the Opinion on climbazole** – the draft Opinion was discussed, **finalised and adopted**. It will be published after editing check. There will be no

commenting period as requested by the mandating DG GROW because it is focusing on new calculation only.

https://ec.europa.eu/health/sites/health/files/scientific_committees/consumer_safety/docs/sccs_o_212.pdf

- **Di-HEMA Trimethylhexyl Dicarbamate, HEMA** and Urethane acrylates – the draft Opinion has been revised and still **needs to be further discussed at the next meeting (13/12)**.

2.4 Draft Opinions (*progress report*):

Cosmetic Ingredients

- **UV filter (S86)** – submission II – tasks have been allocated to SCCS members. It will be further discussed at the next meeting (13/12).
- **Fragrance Vetiver Oil** - submission III – data from Applicant were received and SCCS will consider them. It will be further discussed at next meeting (13/12).
- **Fragrance 2-(4-tert-butylbenzyl)propionaldehyde (BMHCA)** – submission II – GROW clarification was provided and SCCS is planning to finalise the Opinion at the next meeting (13/12).
- **Aluminium** in cosmetic products – submission II – **on hold** – GROW is waiting for an official feedback from the applicant in order to decide if the timetable proposed for the additional study (9-12 months) is realistic and acceptable. The SCCS will be informed accordingly.

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. No reply has been received. The Opinion will be finalised on the basis of the information already provided by the Applicants.

- 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. Four replies from 3 Applicants have been received and are under assessment.

Methodology

The Chair of the WG reported on state of play of the 10th revision of the SCCS Notes of Guidance (NoG) and contributions from members still expected. The revision of the document should be further discussed at the next methodology meetings in order to present it on the agenda of February Plenary meeting. All members are invited to send their contribution, including on the nano part.

An additional statement in the checklist will be added where the Applicant has the responsibility to explicitly and specifically confirm that the dossier complies with the provisions of Article 18 of Regulation (EC) No 1223/2009 (animal testing and marketing ban).

2.5 Comments on Opinions

Cosmetic Ingredients

- 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 is waiting for a clarification from the Applicant via DG GROW before finalising the Opinion.

Nanomaterial in cosmetic ingredients

- Titanium Dioxide (nano form) as UV-Filter in sprays - SCCS/1583/17
Comments were received during the commenting period and are under assessment by the SCCS. Draft SCCS answers will be discussed at the next meeting (12/12).

25 October 2017

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

The Chair welcomed the participants (one via audio) and announced one apology. 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.

2. 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

- Departure of the former deputy head of unit SANTE C2 and coordinator for the Scientific Committees, Donata Meroni, who has been appointed as head of unit at the Consumers, Health, Agriculture and Food Executive Agency (CHAFEA)
- Changes that occurred in the team of the scientific committees and Secretariat

- Dr Aglaia Koutsodimou from Greece who has appointed as external expert (chemist) in the WG on cosmetic ingredients since August 2017
- The following information has been distributed:
 - the list with mandates and Opinions for both Committees
 - The EU Health Newsletter from July that was dedicated to the SCs' work and SCCS Chair made the editorial:
http://ec.europa.eu/newsroom/sante/newsletter-specific-archive-issue.cfm?newsletter_service_id=261&newsletter_issue_id=4357
- Risk Assessment Day scheduled in October 2017 has been postponed (may be at mid-term)
- ECHA/SANTE C2 videoconference held on 5 October: the Secretariat provided a feedback on their discussion on files of common interest.
- 2016 Members' satisfactory internal survey report: the Secretariat presented the results and conclusions. Suggestions for actions have been discussed at the Inter Committee Coordination Group (ICCG) meeting on 23 October.

From the SCCS members

- *SCCS members taking part in various (industry) events in their private capacity*
A discussion took place at the ICCG meeting on 23 October in order to help assessing the relevance of attending such event/meetings and potential conflicts of interest.
- Publications of SCCS opinions (summaries) in diverse Scientific Journals, including the continuity in Regulatory Toxicology and Pharmacology, are explored.
- *Chair, Qasim Chaudhry*, reported on the discussions at the Global Summit on Regulatory Science in Brazil.
- *Chair, Qasim Chaudhry*, reported on follow-up to the recent SCCS response to ECHA on the cluster report on 3Rs alternative methods of the Network of EU Agencies for Scientific Advice (ANSA).
- *Corrado Galli* attended a Workshop on development and validation of endocrine disrupting chemicals testing on 30-31/05 and 01/06 in Brussels and reported.

Future events to be attended by the SCCS members/Secretariat

- 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.
- 7 December 2017 - "third meeting of the International Dialogue for the Evaluation of Allergens – IDEA Working Group on the feasibility of a study to assess the

effectiveness of Quantitative Risk assessment - QRA" – SCCS Vice-Chair (*Pieter-Jan Coenraads*) is planning to participate as observer.

- 10th EU Network of EU Agencies for Scientific Advice (ANSA) meeting in Lisbon on 21 and 22 November – Secretariat is planning to participate.
- Meeting of the newly established EURL ECVAM Scientific Advisory Committee (ESAC) on 5-6 December in JRC (alternative methods) – Secretariat is planning to participate as observer.

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.

3. Presentation IPCHEM by JRC - Video conference with the JRC

<https://ipchem.jrc.ec.europa.eu/RDSIdiscovery/ipchem/index.html>

IPCHEM - the Information Platform for Chemical Monitoring is the European Commission's reference access point for searching, accessing and retrieving chemical occurrence data collected and managed in Europe. The platform has been developed to fill the knowledge gap on chemical exposure and its burden on health and the environment. It is managed by JRC and is structured into four modules, according to the chemical monitoring data categorisation: Environmental monitoring, Human Bio-Monitoring, Food and Feed, Products and Indoor Air. JRC presented the IPCHEM platform and gave practical examples of information available in the platform.

4. 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 (12 and 13 December, respectively).

5. Next meeting(s)

- WG Nanomaterials in cosmetics: 12 December 2017 and 25 January 2018.
- WG Cosmetic ingredients: 13 December 2017 and 24 January 2018.
- WG Methodology: 14 December 2017 and 23 January 2018.
- SCCS Plenary meetings: 22 February 2018, 21-22 June 2018/ 24-25 October 2018/ 26-27 February 2019

6. A.O.B

- Hair dye Hydroxypropyl p-phenylenediamine and its dihydrochloride salt (A165) (CAS 73793-79-0 and 1928659-47-5) - Submission I. The rapporteur allocated tasks among members.

7. List of participants

SCCS Members

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

SCHEER Member

16. Prof. Renate Krätke

Apologies

17. Dr Christophe ROUSSELLE

SCCS Secretariat (DG SANTE C2)

18. Diana HEROLD
19. Natacha GRENIER

DG GROW D4 (on 24 October only)

20. Federica DE GAETANO