



Luxembourg, 10 October 2018

## Scientific Committee on Consumer Safety (SCCS) Meeting of the Working Group on Methodologies

27 September 2018, Luxembourg

### MINUTES

#### 1. Welcome and apologies, approval of the agenda and declaration of interests

The Chair welcomed the participants. There were three apologies including the representative from SCHEER.

The agenda was adopted.

The minutes of the previous meeting held on 31 August were endorsed by written procedure by the WG members on 10 September and published on the website:

[https://ec.europa.eu/health/sites/health/files/scientific\\_committees/consumer\\_safety/docs/sccs2016\\_miwg\\_046.pdf](https://ec.europa.eu/health/sites/health/files/scientific_committees/consumer_safety/docs/sccs2016_miwg_046.pdf)

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

##### A. Notes of Guidance (NoG) update

Contributions were received from members to revise the Notes of Guidance for the testing of the cosmetic ingredients and their safety evaluation. Last contributions received will be compiled and discussed during the next plenary meeting (24-25/10). The goal is to finalise and adopt the document during the plenary meeting. No commenting period is foreseen as only the following main changes occurred in this 10<sup>th</sup> revision:

### Structural changes

- Information on Regulation 1223/2009/EC and guidance related to finished cosmetic products (Product Information File – PIF – microbiology) is now included in the Annexes.
- A (revised) checklist for submitting a safety dossier to the SCCS has been added.
- An update of the data needed for safety evaluation has been included, and information for re-submitting has also been given in case of a negative opinion.
- References and abbreviations lists have been updated.
- The general structure of the Notes of Guidance has been changed to give priority to non-animal methods, followed by older *in vivo* strategies.
- The exposure chapter has been updated with subdivisions for external and internal exposure – tiered approach and aggregate exposure are discussed.

### Changes in content

- An update on animal toxicological studies for cosmetics ingredients has been included.
- Weight of evidence (WoE) and use of a 'toolbox' (genotoxicity/mutagenicity) are discussed.
- An update of criteria for multi-constituent natural ingredients and chemical identity has been included.
- Threshold of Toxicological Concern concept – TTC – remains the same, i.e. new suggested values in publication have not yet been evaluated.
- A literature overview of consumer exposure data has been added in Appendix 7.

## B. SCCS meeting of the WG on Methodology on 26-27 February 2019

This WG meeting will be organised as an internal scientific workshop in Brussels, back to back with SCCS Plenary meeting.

The idea is 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.

The group started its discussion the day before (during meeting of the WG on cosmetic ingredients) about possible topics for their agenda & invited participants: i.e. from relevant EU Agencies/Scientific Bodies and Commission DGs. The plan is to invite some AD-HOC experts on Non Animal Methods from National Authorities, from Associations, as well as from Universities, Research Institutes etc. to brainstorm on the above topic. It will be a closed meeting of the WG on Methodology, upon invitations only.

### 3. Information from the Commission and WG members

- The 10<sup>th</sup> revision of the SCCS Notes of Guidance is planned to be explained in a factsheet after its adoption.
- A public consultation of the opinion on harmonisation of human, animal and environmental risk assessment on mixtures was launched by EFSA: <https://www.efsa.europa.eu/en/consultations/call/180626-0>. The Secretariat compiled all comments from SCHEER/SCCS and sent a joint contribution.
- ECHA informed about the Public Activities Coordination Tool (PACT) that gives advance notice of the substances that are on an authority's radar for exploring the potential need for regulatory risk management: <https://echa.europa.eu/pact>
- Cosmetics Europe Science Workshop 13 November 2018 – *Vera Rogiers* will replace SCCS Chair in representing SCCS view. Other SCCS members have been invited on their own (Institute) behalf. The Secretariat will also participate.
- DG GROW Unit D4 put in place the replacement of former contact person for the SCCS and informed the Secretariat accordingly.
- *Janine Ezendam* informed that she has been invited to join the Regulatory Advisory Board of the EUToxRisk project. She is invited to represent her institute, the RIVM.
- IFRA (*International Fragrance Association*) has shared the final report of the workshop on Dermal sensitisation that IDEA (International Dialogue for the Evaluation of Allergens) held in May 16-17 in Brussels. This report has been posted on the IDEA website, together with the presentations from the workshop: <http://www.ideaproject.info/eventsmanager/27/16/IDEA-Workshop-on-the-replacement-of-animal-testing-in-QRA-for-skin-sensitization>

### 4. Next steps

To collect all input from the members to prepare new version of the relevant documents for the next meeting (14/12) or for the plenary meeting (24-25/10).

### 5. Next meeting(s)

14 December, 23 January 2019, and 26 or 27 February 2019

### 6. 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. Prof. Vera ROGIERS (Vice-chair SCCS and chair of the WG)
12. Dr Maciej STEPNIK

**SCCS External Experts**

13. Dr Alain SIMONNARD
14. Dr Natalie VON GÖTZ

**Apologies**

1. Dr Renate KRÄTKE (SCHEER Member)
2. Dr Christophe ROUSSELLE
3. Prof. Tamara VANHAECKE

**SCCS Secretariat (DG SANTE C2)**

1. Natacha GRENIER

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