



Luxembourg, 8 December 2021

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

29 November 2021, Luxembourg

### Minutes

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

The SCCS Chair welcomed the participants.  
One apology was received.  
The agenda was adopted without changes.

The minutes of the previous meeting held on 28 May 2021 were endorsed by written procedure by the WG members and published on the website:  
[https://ec.europa.eu/health/scientific\\_committees/consumer\\_safety/minutes\\_wg\\_meetings\\_en](https://ec.europa.eu/health/scientific_committees/consumer_safety/minutes_wg_meetings_en)

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**

Presentation by external speakers (open session):

*Physiologically Based Pharmacokinetic Modelling - PBPK:*

Internal presentations were made by representatives from Cosmetics Europe (CoE). Their team presented the PBPK modelling concepts and discussed the potential implementations for risk assessment, and other projects within Cosmetics Europe. They focused on the modelling concept, the development in the modelling software, industrial applications, evaluation of different guidelines, and aspects to build valid models. With a number of examples, they walked through the process to build valid PBPK models for phenoxyethanol, homosalate and benzophenone-4, and discussed different scenarios and challenges regarding the data availability. Observers from CoE and IFRA participated in the meeting. An interesting discussion took place.

The SCCS stressed the importance to be kept informed about further developments and will continue to discuss internally proposals CoE may send. The presentations from CoE were made available for the meeting participants only. A structured way of NGRA examples + PBPK (also linked) are expected by the SCCS (e.g. framework in a standardised way) that can eventually be adapted to be taken up in the SCCS Notes of Guidance.

Presentation by external speakers (open session):

*Next Generation Risk Assessment (NGRA): Ab Initio and Read-Across (RAX) Case Studies (ADME/Systemic Toxicity)*

Presentations were made by representatives from CoE to update the experts of the SCCS with ongoing research in the field of NGRA. This also could be helpful for later updating of the SCCS Notes of Guidance when considered necessary.

Case studies play a pivotal role in assessing and applying new approaches, and several are being conducted to assess the feasibility of using NGRA to make safety decisions for potential systemic effects of cosmetic ingredients. With regards to the read across, their team illustrated a read-across framework as well as a case study. The team showed how New Approach Methodologies (NAM) can be used in a weight of evidence assessment to support a read-across hypothesis, in addition to the use of NAMs to derive an understanding of internal dose for the *in vitro* to *in vivo* extrapolation. This was followed by an update on the phenoxyethanol case study and overview on how our learnings are shaping their approach for the next case studies.

Observers from CoE and IFRA participated in the meeting.

An animated discussion took place.

The SCCS stressed the importance to be kept informed about further developments and will continue to discuss these topics. The presentations from CoE were available for the meeting participants only. CoE will be able to prepare by first half of 2022 a supplement information including NGRA for an ongoing safety file. The SCCS agreed to have a look at it to check the logical of the approach.

### **3. Information from chairman/members/commission (SCCS internal session only)**

The chair of the WG reported on the different missions she took on behalf of the SCCS. These reports were already made available to the members via the WG on cosmetics.

- 22 September : EU annual Forum on Endocrine Disruptors
- 27 October: European Partnership for Alternative Approaches to Animal Testing (EPAA) Annual conference.
- 15-17 November: BfR-Berlin Symposium on new alternative methods to animal testing.
- 23-24 November (pm): European Partnership for Alternative Approaches to Animal Testing (EPAA) Workshop on New Approach Methodologies (NAMs).

### **4. Next meeting**

10 December (eye irritation).