

Scientific Committee on Consumer Safety (SCCS) WG on Methodologies

Venue: Luxembourg

Meeting date: 08 March 2017

Minutes

1. WELCOME AND APOLOGIES

The Chair, Vera Rogiers, welcomed the participants, in particular the new SCCS external experts Natalie von Götz and Alain Simonnard, as well as two other experts from Cosmetics Europe, Sarah Tozer (P&G) and Cian O'Mahony (Creme Global) and one from the Netherlands National Institute for Public Health and the Environment (RIVM), Martine Bakker.

Matthias Vey (IDEA project manager) from the International Fragrance Association (IFRA) and Filipe Almeida (Issue Manager, Science Affairs) from Cosmetics Europe were observers. One SCCS member apologised.

2. ADOPTION OF THE AGENDA

The agenda was adopted as presented.

3. DECLARATION OF INTEREST ON MATTERS ON THE AGENDA

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.

4. AGGREGATE DERMAL EXPOSURE ISSUE

The WG was informed about the principles of Systemic Aggregate Exposure Assessment

1. Probabilistic Aggregate Exposure Assessment (Natalie von Götz, ETH)

The differences between deterministic and probabilistic approaches were highlighted. Advantages of the probabilistic approach were presented. The main conclusions are that key questions are needed to drive the exposure assessment (e.g. how many people are currently /will be exposed and to which extend), validated tools are lacking and missing data include use patterns for products, representative concentrations in products and transfer factors from products to skin.

One of the benefits of the probabilistic approach is that it is giving more detailed understanding of relative distribution of sources (eg. use to make risk management decision).

2. Calculating Aggregate Exposure with PACEM (Martine Bakker, RIVM)

PACEM is the Probabilistic Aggregate Consumer Exposure Model to get a total exposure of a substance from multiple sources and pathways. It is a personal-based approach. Three examples were shown: parabens in baby products, diethylphtalate (DEP) and geraniol. The conclusions showed a lack of product information and use, a lack of insight in dermal absorption, and the use of many

assumptions. In the future, PACEM could include more study results and could be made publically accessible.

3. Calculating Aggregate Exposure with Creme Care & Cosmetics (Sarah Tozer, P&G)

Principles and examples were presented. High quality data remains the key and the challenges include data gaps (like composition data of formulations) as well as keeping the data in the tools up-to-date (PACEM, Crème Global or other). There is no data on sun care products. The databank with consumer habits on consumer products can be made available to the SCCS. There exist also other sets of data with use levels of fragrances in finished products and in fragrance compounds.

4. Live demonstration of Case Studies (Cian O'Mahony, Creme Global)

The session covered the following principles:

- A) The tiered approach to aggregate exposure
- a. Consider problem formulation
- b. Low tier estimates (deterministic)
- c. High tier models (probabilistic or "variability modelling")
- B) Case studies including preservatives.

New data or new information can be provided to the SCCS via the Secretariat.

5. INFORMATION FROM CHAIR/MEMBERS/COMMISSION

The JRC report on 3Rs knowledge sharing has been published: https://ec.europa.eu/jrc/en/news/reducing-animal-testing-through-better-knowledge-sharing

6. ANY OTHER BUSINESS

- The presentation on Quantitative Risk Assessment method (QRA) done at VUB safety course by Matthias Vey (IDEA project manager) will be shared with SCCS members during the next WG meeting on cosmetics (28/03).
- Next meetings: 03 May (Benchmark Dose BMD), 31 August (Inhalation exposure) and 26 September 2017.

Attendance list of experts other than Commission and SCCS working group members:

<u>Cosmetics Europe team:</u> Sarah Tozer (P&G), Cian O'Mahony (Creme Global), and Filipe Almeida (Issue Manager, Science Affairs – Cosmetics Europe)

The Netherlands National Institute for Public Health and the Environment (RIVM): Martine Bakker

<u>The International Fragrance Association (IFRA):</u> Matthias Vey (IDEA project manager)