Scientific Committee on Consumer Safety (SCCS)
Working Group on Methodologies

Venue: Luxembourg

Meeting date: 03 May 2017

Minutes of the meeting

1. WELCOME AND APOLOGIES

The Chair, Vera Rogiers, welcomed the participants. Five apologies were announced by the Chair.

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. THE BENCHMARK-DOSE APPROACH AND DOSE-RESPONSE MODELLING

A lecture was provided by one of the SCCS members as an introduction to the benchmark-dose approach and dose-response modelling in general. Also reference was made to the new EFSA guidance. In particular the difference between the previous guidance about finding the single best fitting model and the new guidance using model averaging was highlighted.
After some general information on the difference between continuous and quantal data sets and how to deal with these, guided standard computer exercises were carried out by all participants on both types of data using Proast (RIVM) or BMDS (EPA) software.

Additional computer exercises were provided on more difficult, problematic data sets and it was shown how to deal with these. The application of the new EFSA guidance with model averaging using all plausible values that are compatible with the data and averaging all dose-response models to one averaged dose-response model was demonstrated. Also more « à la carte » modelling exercises were explained.
The group will further discuss whether there is a need to amend the SCCS Notes of Guidance SCCS/1564/15 on this topic.

5. INFORMATION FROM CHAIR/MEMBERS/COMMISSION

SCCS Vice-Chair, *Vera Rogiers*, participated in the BfR/RIVM workshop on validation and regulatory acceptance of alternative methods held on 23-24 March 2017:
Most alternative methods are not stand-alone tests and cannot on their own replace the *in vivo* test. Therefore, different methods are combined in so-called testing strategies or integrated approaches. Until now, no official procedure exists to evaluate the driving

parameters mentioned for a testing strategy, which could inhibit its regulatory acceptance. For this reason different stakeholders were invited to discuss the topic and try to come to some expert recommendations. An official report is planned to be produced jointly by the organising BfR and RIVM. This report will be useful for SCCS discussions when to accept *in vitro* methodologies, in particular when different *in vitro* and/or *in silico* methods are being combined which have not been validated individually. The report will be used for the future revision of the SCCS Notes of Guidance.

6. ANY OTHER BUSINESS

- Next meetings: 31 August (*focus on inhalation exposure planned*) and 26 September 2017.