



## **Scientific Committee on Consumer Safety (SCCS)**

### **WG on Methodologies**

**Venue: Luxembourg**

**Meeting date: 03 and 04 November 2015**

#### **Minutes**

**3 November 2015**

#### **1. WELCOME AND APOLOGIES**

The Chair welcomed the participants, in particular a representative from the Scientific Committee on Health and Environmental Risks (SCHER), two AD-HOC experts, as well as three representatives and two observers from cosmetic industry. There were three apologies.

#### **2. ADOPTION OF THE AGENDA**

The agenda was adopted as presented.

#### **3. DECLARATION OF INTEREST ON MATTERS ON THE AGENDA**

The Chair requested participants to declare any conflict of interest regarding matters on the agenda. None of the participants declared any conflict of interest.

#### **4. PHARMACOKINETIC AND EXPOSURE MODELLING -> A.M. SESSION OPEN TO EXTERNAL STAKEHOLDERS**

Pharmacokinetic models are quantitative physiological models, i.e. tools to evaluate tissue dose under various exposure conditions in different animal species. Physiological modelling approaches are used to uncover the biological determinants of chemical disposition. Pharmacokinetic models are different between species due to their physiological differences.

The following presentations were provided:

- The introduction on the physiologically based pharmacokinetic (PBPK) model was made by Mel Andersen (The Hamner Institute).
- John Troutman (P&G) presented the use of physiologically-based pharmacokinetic modelling in an example of Risk Assessment (RA).
- An example of exposure modelling was presented by Damien Comiskey (Creme Global).
- Mel Andersen presented a development and validating PBPK model for human RA.
- The use of state-of-the-art exposure methods in cosmetics safety assessment was presented by Camilla Pease (Ramboll Environ).

A general discussion took place with a session of questions and answers.

**5. P.M SESSION INTERNAL MEETING (ONLY WG MEMBERS)**

- **Pharmacokinetic and Exposure modelling**

A general discussion took place to brainstorm on the morning session.

- **SCCS Memorandum on human data on skin sensitisation**

The group discussed a first draft and will revise it during the next working group on cosmetic ingredients to be held on 2-3/12/2015.

**6. ANY OTHER BUSINESS**

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**Attendance list of experts other than SCCS working group members:**

SCHER: Dr Renate Krätke

Industry: Damien Comiskey (Creme Global), M. Andersen (Hamner Institute), Camilla Pease (Ramboll Environ)

Ad hoc experts: Nathalie von Götz (Federal Institute of Technology (ETH) from Zurich) and Ralf Pirow (BfR-DE)

Observers: Filipe Almeida (Cosmetics Europe) and Kathy Plotzke (Dow Corning for CES).

**4 November 2015**

**7. WELCOME AND APOLOGIES**

The Chair welcomed the participants, in particular a representative from the Scientific Committee on Health and Environmental Risks (SCHER), two representatives and one observer from cosmetic industry. There were six apologies.

**8. ADOPTION OF THE AGENDA**

The agenda was adopted as presented.

**9. DECLARATION OF INTEREST ON MATTERS ON THE AGENDA**

The Chair requested participants to declare any conflict of interest regarding matters on the agenda. None of the participants declared any conflict of interest.

**10. THRESHOLD OF TOXICOLOGICAL CONCERN (TTC) APPROACH -> A.M. SESSION OPEN TO EXTERNAL STAKEHOLDERS**

The Threshold of Toxicological Concern (TTC) for the Safety Assessment of Chemical Substances is the threshold below which there is low probability of an appreciable risk to humans.

The following presentations were provided:

- An introduction was made by Prof. Mark Cronin (Liverpool John Moores University) on Cosmos project (see [www.cosmostox.eu](http://www.cosmostox.eu)) focusing on TTC work.
- Dr. Heli Hollnagel (Dow Europe) made the following presentations: non cancer TTC for cosmetics related chemicals, route to route extrapolation, and TTC beyond the Cosmos project.

A general discussion took place with a session of questions and answers.

#### **11. - P.M SESSION INTERNAL MEETING (ONLY WG MEMBERS)**

- **JRC presentation on exposure assessment**

There are developments on exposure assessment that are ongoing at the Joint Research Centre (JRC) and that are of great importance for the SCCS.

A background on aggregate exposure was provided by JRC on methodology and tools. It was followed by a discussion on their different tasks, including:

1. Supporting products safety
2. Supporting exposure determinants
3. Supporting exposure modelling and tools
4. Completing exposure assessment, and way forward

A session of questions/answers followed.

- **Feedback from previous meeting on 3 November on pharmacokinetics and exposure modelling**

A short report was made to inform the group

- **TTC approach**

A general discussion took place to brainstorm on the morning session.

#### **12. ANY OTHER BUSINESS**

Next meeting is planned on 15 March 2016.

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#### **Attendance list of external experts:**

SCHER: Dr Renate Krätke

Industry experts: Prof. Mark Cronin (Liverpool John Moores University) and Dr. Heli Hollnagel (Dow Europe)

Observer: Martina Klaric (Cosmetics Europe)