

Scientific Committee on Health, Environmental and Emerging Risks (SCHEER)

6th Meeting of the Working Group on Guidelines on benefit - risk assessment of Phthalates in Medical Devices

17 September 2018 Minutes

1. Welcome and apologies

The Chair welcomed the participants who attended the meeting. The Chair announced four apologies Five participants followed via audio.

2. Adoption of the agenda

The agenda was adopted.

3. Adoption of the minutes of the 5th meeting held on 19 June 2018

The minutes were adopted on 19 June and published on 29 June:

https://ec.europa.eu/health/sites/health/files/scientific committees/scheer/docs/scheer miwg 091.pdf

4. Declaration of interests 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.

5. Literature search

The EFSA Guidelines document for Uncertainty Analysis has been distributed: https://www.efsa.europa.eu/en/supporting/pub/en-1472

6. Guidelines on benefit - risk assessment of Phthalates in Medical Devices

The draft document has been discussed and revised, in particular the methodology section. Annexes have been added with detailed information.

8. Distribution of tasks

New tasks were allocated among the WG members so that a revised version can be prepared for distribution to the SCHEER members during the next plenary meeting on 11 October.

9. Any Other Business

A tentative timeline is under drafting with the mandating DG GROW.