



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

**12th Meeting of the Working Group on
Guidelines on benefit - risk assessment of Phthalates in Medical Devices**

05-06 June 2019

Minutes

1. Welcome and apologies

The Chair welcomed all the participants who attended the meeting. Five members apologised.

2. Adoption of the agenda

The agenda was adopted.

3. 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.

4. Adoption of the minutes of the 11th meeting held on 15-16 May 2019

The minutes were adopted and published on the website on 4 June 2019:
https://ec.europa.eu/health/sites/health/files/scientific_committees/scheer/docs/scheer_miwg_129.pdf

5. Public consultation (18/3->29/4) results:

The table with draft answers to 197 comments received has been finalised.

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

The revised draft document based on comments received during the public consultation was discussed and modified, accordingly. The Guidelines including the Annexes have been finalised.

7. Distribution of tasks and timeline

The Rapporteur will circulate the final version of the documents to the SCHEER members. SCHEER technical adoption is foreseen during their plenary meeting on 18-19 June 2019.

8. Any Other Business

/
