



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

**10th Meeting of the Working Group on
Guidelines on benefit - risk assessment of Phthalates in Medical Devices
05 March 2019 - AUDIO meeting**

Minutes

1. Welcome and apologies

The Chair welcomed all the participants who attended the meeting via audio only. One participant apologised as well as ECHA/EFSA and DG GROW.

2. Adoption of the agenda

The agenda was adopted.

3. Adoption of the minutes of the 9th meeting held on 18-19 February 2019

The minutes were adopted and published on the website on 4 March 2019:

https://ec.europa.eu/health/sites/health/files/scientific_committees/scheer/docs/scheer_miwg_119.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 and information

- Commission Implementing Decision for Dicyclohexylphthalate will be added in the Annex.
- The Guidelines should raise awareness regarding the EFSA public consultation launched on the draft update of its 2005 risk assessments of five phthalates, which are authorised for use in plastic food contact materials.

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

The revised draft document based on comments received from SCHEER WG members was discussed and modified, page per page. The Guidelines and Annexes have been finalised.

7. Distribution of tasks and timeline

The Secretariat will circulate the final clean version to the group by the end of the week. The SCHEER written adoption is foreseen from 8 to 15 March and the public consultation from 18 March to 29 April.

8. Any Other Business

A public hearing will be on 4 April 2019 in Brussels. Details were published beginning of February as registration was mandatory by 6 March 2019 at the latest:

https://ec.europa.eu/health/scientific_committees/events/ev_20190404_en