

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

2nd Meeting of the Working Group on the update of the guidelines on the benefit-risk assessment of the presence of phthalates in certain medical devices.

13 June 2023

Minutes (AUDIO)

1. Welcome and apologies

The Chair welcomed the participants who attended the audio meeting, in particular experts from EMA, EFSA, ECHA and an observer from DG JRC. There was no apology.

2. Adoption of the agenda

The agenda was adopted without changes.

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. One member declared a participation last year in EFSA Working Group (WG) preparing protocol for hazard assessment of phthalates and other substances potentially used as plasticisers; the WG is currently not active. As this is a sister organisation dealing with food, there is no conflict identified.

4. Discussion on the mandate, work to update the guidelines, expert needs, literature search, and allocation of tasks/timeline

The structure of the guidelines was discussed by the members to focus the work. The WG identified additional expertise needed for the work of the WG and is grateful for the involvement of other EU Agencies. The literature search results were partly assessed; some tasks were allocated among the WG members. The <u>call for information</u> is still running until 17 July. The draft updated guidelines is planned to be published early April 2024 to run the public consultation during four weeks. The deadline is mid-June 2024 for the final document to be delivered to the mandating DG SANTE.

5. Any Other Business

Next meetings will be on 13 July, 28 August and 22 September 2023.