



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

3rd Meeting of the Working Group on Guidance document for benefit - risk assessment of Phthalates in Medical Devices

19 March 2018

Minutes

1. Welcome and apologies

The Chair welcomed the participants who attended the meeting including EFSA, ECHA and EMA. The Chair announced one apology. Mandating DG GROW and JRC colleagues were participating as observer. Four participants followed via audio.

2. Adoption of the agenda

The agenda was adopted.

3. Adoption of the minutes of the 2nd meeting held on 8 December 2017

The minutes were adopted on 20 January and already published.

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. Clarification on the mandate

The additional questions formulated for DG GROW between meetings were clarified.

6. Additional expertise needed for the WG

The group welcomed three external experts from the reserve list and the open database of experts who were appointed members of the working group to cover the needs identified. It was confirmed that there is no need for additional expertise for the time being.

7. Literature search

Some studies have been exchanged among members.

8. ECHA presentation

ECHA presented how the Agency is performing benefit risk assessment under REACH and the outline of the ECHA guidance.

9. Outline of the template for the Guidance document

A second draft general structure of the Guidance Document has been discussed and commented. A subgroup to deal with methods section of the Guidance has been set up.

10. Distribution of tasks

Some tasks were allocated among the WG members and all should revise the literature documents.

11. Any Other Business

None.
