

Location: Webconference

Attendees:

- o Working Group Members: Ursula Gundert-Remy
- o EFSA: Alicia Paini (SC, MESE)

I. Welcome and apologies for absence

The Chair welcomed the participant.

II. Adoption of agenda

The agenda was adopted without changes .

III. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence¹ and the Decision of the Executive Director on Competing Interest Management², EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting and the preparatory meetings listed under agenda item "Preparatory meeting/s with Risk Assessment". No conflicts of interest related to the issues discussed in these meetings have been identified during the screening process, and no interests were declared orally by the Working Group members at the beginning of these meetings.

IV. Scientific topic(s) for discussion

The meeting was set up to receive an independent advice on uncertainty factors (UF) and possibilities of ADME training. The expert supported maintaining the current toxicokinetic (TK) and toxicodynamic (TD) UF of 100, while noting that greater alignment with approaches adopted by ECHA and EMA should be considered. The expert considered the proposed EFSA tiered interpretation of MOE values (<1,000, 1,000-10,000, and >10,000) to be a pragmatic and scientifically justified compromise. The T25-based approach was also discussed, and it was agreed that no changes are currently warranted to the MOE value of 25,000 but the tiered approach could be applied also here. Examples were provided where the UF were changed to derive a chemical safety adjustment factor. The meeting ended with discussion on possible ADME training for EFSA staff and panels.

V. Next meeting

The next ADME&PBK ADVICE meeting will be held in December via web conference.

¹ https://www.efsa.europa.eu/sites/default/files/corporate_publications/files/independence-policy-2024.pdf

² https://www.efsa.europa.eu/sites/default/files/corporate_publications/files/decision-ed-on-competing-interest-management-2024.pdf

Location: Webconference

Attendees:

- o Working Group Members:
Emanuela Testai (Chair); Ursula Gundert-Remy; Keyvin Darney; Nynke Kramer; Cecilia Tan.
- o Hearing Experts¹:
Not Applicable
- o Applicants participating in a technical hearing²:
Not Applicable
- o European Commission and/or Member States representatives:
ECHA: Waqar Muhammad Ashraf
- o EFSA:
MESE: Alicia Paini; PREV: Jochem Louisse; CSO: Jean Lou Dorne; FIP: Zainab Al Harraq

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¹ As defined in Article 34 of the document "Implementing Rule of the Management Board of the European Food Safety Authority laying down the rules on the selection, appointment and operations of the Scientific Committee, Scientific Panels and of their Working Groups":
<https://www.efsa.europa.eu/sites/default/files/paneloperation.pdf>

² As defined in the "EFSA's Catalogue of support initiatives during the life cycle of applications for regulated products":
<https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/sp.efsa.2021.EN-6472>

³ https://www.efsa.europa.eu/sites/default/files/corporate_publications/files/independence-policy-2024.pdf

⁴ https://www.efsa.europa.eu/sites/default/files/corporate_publications/files/decision-ed-on-competing-interest-management-2024.pdf



IV. Scientific topic(s) for discussion

This meeting kickoff the work of the ADME&PBK working group (WG) following two mandates (M-2026-00072 - [Open EFSA](#), M-2026-00026 [Open EFSA](#)), which will develop two guidance documents on ADME testing strategies and qualification, validation of PBK models and in parallel provide advice to EFSA and training on the topic. The meeting started with presentations on the mandate terms of reference. The meeting focused on interpreting the TORs by defining scope, prioritising topics, and establishing a practical framework for the work to be carried out by the WG. The discussion centered on the appropriate use of in vitro, in vivo, and in silico information, the role of uncertainty and data quality in risk assessment, and how kinetic information can support regulatory decision-making. Participants also explored how existing initiatives, guidance, and research activities could be leveraged to avoid duplication and support harmonised assessment approaches. The session concluded with agreement on initial workstreams, information-gathering activities, and organisational arrangements for the working group.

V. Next meeting

The next meeting will be held on 9th November 2026 via web conference.

WG ADME & PBK

