JOINT MANDATE ON BIOMARKERS OF EFFECT

1st meeting of the Joint WG Biomarkers of effect EFSA-EMA-ECHA

2-3 Jul 2026
09:00-13:00 / 09:00-13:00 CEST
MINUTES - Agreed on 13 Jul 2026

Location: Online

Attendees:

- Working Group Members: Amélie CRÉPET, Antonio HERNÁNDEZ-JEREZ, Susanne HOUGAARD BENNEKOU, Olga KHOLMANSKIKH, Dominique MASSET, Harry MCARDLE, Christina PIEPER, Tiina SANTONEN (Day 1), Anette Kirstine STARK, Henk VAN LOVEREN
- Hearing Experts[1]: Hennicke KAMP, Mark VIANT (Day 1)
- EFSA: Lucian FARCAL (Co-chair), Mina RISTOVSKA, Maria BASTAKI, Zainab AL HARRAQ, Anna CHRISTODOULIDOU
- EMA: Francisca VAN DOESUM-WOLTERS (Co-chair), Sebastien GIRAULT, Jasmine GRATTON (Day 2)
- ECHA: Ana FERNANDEZ AGUDO, Tomasz SOBANSKI (Co-chair)
- EC: Silvia CASATI (DG JRC), Katarina HRICOVA (DG GROW)

Apologies were received from WG members: Kieran BREEN, Danyel JENNEN; EFSA: Cristina CROERA, Silvia VALTUENA MARTINEZ, Iris MANGAS; EMA: Stefano PONZANO, Emil COCHINO; ECHA: Mounir BOUHIFD; EC: Julia MALINOWSKA.

1. Welcome

The meeting opened with introductory remarks outlining the objectives of the joint WG and the practical arrangements for its activities, including recordings and other participation procedures. Participants then introduced their areas of expertise and expectations for the project. The introductions highlighted the broad range of expertise represented within the group, spanning toxicology, risk assessment, medical science, medicines, chemicals, occupational health, nutrition, omics technologies and different regulatory areas.

2. Adoption of agenda

The agenda has been adopted without changes.

3. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence[2] and the Decision of the Executive Director on Competing Interest Management[3], EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting. 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 this meeting.

[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] https://www.efsa.europa.eu/sites/default/files/corporate_publications/files/independence-policy-2024.pdf
[3] https://www.efsa.europa.eu/sites/default/files/2025-11/decision-ed-on-competing-interest-management-25-11.pdf

4. Project overview

The WG members were informed of the context and background of the work under the EC mandate (M-2025-00074) involving EFSA, EMA and ECHA, formally started in February 2026. The mandate establishes the framework for the development of harmonised EU guidance on the use of biomarkers of effect in risk assessment. The mandate replaces the previous EFSA Scientific Committee self-task while ensuring transfer of knowledge from that work.

The WG was presented with the project structure, governance arrangements and overall timeline for the development of the guidance. The roles and interactions of the coordination group, drafting working group, advisory group and consultation mechanisms were outlined. In particular, this joint WG, composed of experts nominated by EFSA, EMA and ECHA and co-chaired by agencies' staff, was presented as the group responsible for drafting the guidance.

The guidance development is planned over a three-year period, with a draft outline expected by January 2027 and finalisation by April 2029.

The presentation also outlined the stakeholder engagement strategy, as well as collaboration with international organisations and initiatives to ensure broad input, transparency and regulatory alignment throughout the process.

The WG discussed common goals, expectations and implementation considerations for the guidance. It was emphasised that the guidance will be developed through a co-creation process with the aim of achieving scientific consensus, regulatory alignment and harmonised implementation across agencies. Agency representatives outlined their specific expectations, including the need for practical guidance to support risk assessors, robust approaches for translating evidence to human health outcomes and the integration of new approach methodologies (NAMs) and omics into regulatory assessments.

The WG has organised its work into two streams: (A) definitions, context of use, potential impact of the guidance, resource mapping, terminology alignment, etc.; and (B) development of the guidance itself.

5. Scientific and technical topics

5.1 Workstream A - Support activities

The WG discussed several foundational aspects supporting the development of the guidance on biomarkers of effect. Members considered the rationale and need for guidance, emphasising the importance of a framework that is applicable across regulatory sectors, provides practical recommendations, accommodates different regulatory contexts and considers varying evidence requirements depending on the intended use of biomarkers. It was noted that a tiered and context-dependent approach may be needed to support proportionate evidence requirements and implementation across sectors. The discussion also addressed the definition of BoEs in the context of this mandate, the need to reflect recent scientific developments and distinctions between different biomarker types.

The WG further explored the mapping of contexts of use and the potential implications for qualification requirements, noting significant overlap across application areas. Discussions also covered the potential inclusion of environmental risk assessment and whether biomarkers associated with efficacy and beneficial biological responses should fall within the scope of the guidance. As these contexts differ from chemical hazard and risk assessment, which focuses

on adverse effects, the need to clearly define the scope of the guidance and the intended contexts of use for biomarkers of effect was highlighted.

While recognising methodological overlaps across applications, members explored the option of focusing primarily on hazard and adverse-effect assessment, while drawing on relevant methodologies and experience from efficacy settings. The WG also highlighted the importance of addressing variability and uncertainty, considering different biological models and measurement systems, including NAMs, and recognising the growing relevance of multi-marker and omics-based methods. These aspects will be further developed and revisited at future meetings.

5.2 Workstream B - Guidance development

The WG discussed the plan for the guidance development, including the EMA concept paper template and its potential adaptation as a basis for the guidance outline. Relevant elements emerging from the Workstream A discussions will be selected and incorporated into the outline, helping to structure the future development of the guidance. Additional process-related aspects will be further considered by the Coordination Group and communicated to the WG at forthcoming meetings.

6. Any Other Business

6.1 Actions and next steps

The WG agreed on several priorities for future work, including refining biomarker definitions and classifications, further developing the mapping of contexts of use, and clarifying the guidance scope. Members will also review draft text supporting the rationale and need for guidance, collect relevant publications and resources, and consider expert presentations at future meetings to share experience and existing approaches from different organisations and domains.

The next meeting will be organised online, on **14 July 2026**.