

28 September 2026
13:30-17:30 CET
MEETING MINUTES

Location: Online

Participants:

- AGoB members: Ilse Van Overmeire (BE), Ivana Vinković Vrček (HR), Elliott James Price (CZ), Anne Mette Zenner Boisen (DK), Joseph Hannon (IE), Gilles Rivière (FR), Denis Sarigiannis (Chair; EL), Tewes Tralau (DE), Georges Kass (LU), Mark Cassar (MT), Marcel Mengelers (NL), Susana Viegas (PT), Manca Ahačič (SL), Mattias Öberg (SE)
- Observers: Robert Pasanen-Kase (CH), Frans Verstraete (EC)
- Hearing Experts: Nancy Hopf, Antonio Hernández-Jerez
- EFSA: Lucian Farcas and Mina Ristovska (MESE), Zainab Al Harraq and Cristina Croera (FIP), Anna Christodoulidou (FEEDCO), Silvia Valtuena Martinez (NIF).

Apologies were received from Georgieva Tzvetia (BG), Francesco Capozzi (IT), Milada Syčová (SK), Karolina Krištopavičienė (LT), Mariana Fernández (SP) and Athanasios Raikos (EC).

1. Welcome

The Chair welcomed participants to the 6th meeting of this group. The new member, Joseph Hannon (Food Safety Authority of Ireland), was introduced as Ireland's representative to AGoB. Participants were also reminded to complete any outstanding annual DOIs.

2. Adoption of agenda

The agenda was adopted without changes.

3. Regulatory, scientific and technical topics for discussion

3.1 EU guidance development – overview and status update

Presentation by Lucian Farcas (EFSA).

EU guidance development

The group was updated on the status of the joint mandate implementation for the development of a cross-sector guidance on biomarkers of effect by EFSA, EMA and ECHA. Progress on the mandate and the activities of the drafting working group were presented, including the planned development timeline. The first milestone is a concept paper (guidance outline), expected to undergo public consultation in early 2027. The document addresses key topics such as definitions, contexts of use, scope of the guidance, terminology harmonisation. In the next phase, other technical aspects such as a tiered approaches and biomarker qualification will be discussed. A working document is also being prepared to support the December 2026 workshop.

Workshop on biomarkers of effect

The group was updated on preparations for the invitation-only workshop on biomarkers of effect planned for December 2026 in Dublin, Ireland. The draft programme includes discussions on the guidance context and scope, tiered approaches, biomarker qualification, omics biomarkers, occupational biomarkers and related international activities. Participants



discussed the structure and focus of selected sessions, including coordination with ongoing initiatives. It was also noted that workshop outputs should support the ongoing guidance development process, with opportunities for participants to contribute as presenters or rapporteurs.

3.2 Final version of the annex on occupational effect-biomonitoring to enable further harmonisation in risk assessment (based on previous OECD work)

Presentation by Robert Pasanen-Kase (CH) and Nancy Hopf (Hearing Expert).

The group reviewed a revised annex on occupational effect-biomonitoring, based on previous OECD work, and discussed its relationship with the ongoing EU guidance on biomarkers of effect. The annex proposes a tiered assessment framework tailored to occupational settings. It was clarified that the document is intended to complement the broader guidance and does not address environmental assessment contexts.

Following discussion, the group agreed that the annex should be recommended as a non-mandatory annex that could support the future guidance, particularly for applications in occupational settings. Its tiered framework should be aligned with and linked to the broader concepts being developed under the guidance.

The group also noted the relevance of ongoing PARC projects and discussed aspects that could be further explored within the PARC framework.

As next steps, the document will be finalised, incorporating remaining comments, and prepared as a reference document for the December 2026 workshop. A short description and briefing note will be developed to explain the link to the previous OECD work and its context, rationale and potential contribution to the guidance. Following workshop discussions, AGoB recommendations on the document's inclusion in the guidance, particularly regarding occupational applications, should be conveyed to the drafting WG for consideration.

3.3 Exploratory review of approaches using biomarkers of effect in chemical risk assessment

Presentation by Mina Ristovska (EFSA).

The group was presented with an exploratory review of methodologies for applying biomarkers of effect in chemical risk assessment. The review examined published studies using biomarkers to derive reference points and identified a set of methodological elements commonly used across different assessment approaches. Based on the analysis of selected studies, a modular workflow was extracted, covering evidence generation, dose-response analysis, reference-point derivation, kinetic translation, exposure assessment, risk characterisation and uncertainty evaluation.

The findings highlighted differences between in vivo and in vitro applications, with in vitro approaches often relying on additional modelling and mechanistic anchoring to support interpretation and relevance to human health outcomes. The role of AOPs and mechanistic evidence in linking biomarkers to adverse effects was also discussed.

The review was considered a useful resource to support the guidance development process.



As a next step, opportunities to further refine the review methodology and conduct targeted literature searches could be explored, supporting the development of a comprehensive evidence base for the guidance.

4. Any Other Business

AGoB meetings 2027: EFSA will circulate an availability form and schedule the AGoB meetings for Q1 and Q2 2027

Workshop (1 December 2026): the workshop programme will be updated and circulated to AGoB members, including topics descriptions. Participation is expected from all AGoB members.

Occupational biomarker of effect annex: integrate remaining comments, finalise and share the document and accompanying briefing note describing its OECD background, rationale and proposed use as an annex for consideration during the workshop and further by the drafting WG.

AGoB reporting: report relevant outcomes to the Advisory Forum in December 2026. Prepare the annual AGoB report.

Annual Declarations of Interest: members to complete any outstanding annual DOIs

Further information on the AGoB activities is available on EFSA's dedicated webpage: <https://www.efsa.europa.eu/en/advisory-group-on-biomarkers-of-effect>.