5th meeting of the Advisory Group on Biomarkers of Effect (AGoB)

27 May 2026
09:00-13:00 CET
MEETING MINUTES

EUROPEAN FOOD SAFETY AUTHORITY

Location: Online

Participants:

- AGoB members: Georgieva Tzveta (BG), Ilse Van Overmeire (BE), Ivana Vinković Vrček (HR), Elliott James Price (CZ), Anne Mette Zenner Boisen (DK), Gilles Rivière (FR), Tewes Tralau (DE), Karolina Krištopavičienė (LT), Georges Kass (LU), Susana Viegas (PT), Manca Ahačič (SL), Mariana Fernández (SP), Mattias Öberg (SE)
- Observers: Robert Pasanen-Kase (CH), Frans Verstraete (EC)
- Hearing Experts: Nancy Hopf, Antonio Hernández-Jerez
- EFSA: Lucian Farcal (Chair) and Mina Ristovska (MESE), Zainab AL Harraq (FIP), Anna Christodoulidou (FEEDCO), Iris Mangas (PREV)

Apologises were received from Denis Sarigiannis (EL), Francesco Capozzi (IT), Marcel Mengelers (NL), Milada Syčová (SK), and Athanasios Raikos (EC).

1. Welcome

The Chair welcomed the participants to the 5th meeting of this group.

2. Adoption of agenda

The agenda was adopted without changes.

3. Project overview and updates

Presentation by Lucian Farcal (EFSA).

The group was updated on the status of the joint mandate implementation. Several preparatory and coordination meetings have been held with partner agencies (EFSA, EMA, ECHA) to support the launch of the guidance drafting.

The WG that will be responsible with the guidance drafting has now been formally established, with experts nominated by each agency. Its kick-off meeting is scheduled for 2-3 July 2026, after which AGoB is expected to begin receiving inputs for review and feedback.

Indicative timelines were presented, with the guidance outline planned for consultation in January 2027.

An overview of the project structure and roles highlighted the importance of consultation and broad stakeholder engagement. Inputs from consultations will feed into the drafting process, while each agency will follow its own procedure for adoption. AGoB remains an important advisory body representing Member States throughout the process.

The work on the guidance is structured into two workstreams: Workstream A covers supporting activities underpinning the guidance (e.g. rationale, context of use, terminology harmonisation and mapping of existing resources), while Workstream B focuses on drafting the guidance. Outputs from Workstream A will inform Workstream B. AGoB supports both workstreams, particularly through knowledge sharing, with Workstream A drawing extensively on existing initiatives (e.g. OECD, PARC).

4. Regulatory, scientific and technical topics for discussion

4.1 Proposal for 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).

A presentation was delivered outlining previous OECD work[1,2,3] and providing an overview of the proposed draft annex intended to support the EU guidance on biomarkers of effect. The presentation and subsequent discussion covered several key aspects, e.g.:

- **Tiered assessment framework**: a tiered framework was introduced, enabling stepwise interpretation of biomarker data and linking evidence strength to risk management decisions.
- **Criteria for biomarker selection and application**: key criteria include links to adverse outcomes, potential for quantification, availability of reference compounds, and sufficient data for threshold derivation, alongside principles ensuring scientific robustness.
- **Case studies and practical implementation**: examples to demonstrate the derivation and use of Occupational Biomonitoring Effect Level (OBELs) across health domains, with a stepwise approach from identifying relevant effects to supporting risk management.
- **Broader applicability and challenges**: challenges were noted in extending the framework to other regulatory contexts, including alignment of terminology and data requirements.

As a next step, AGoB will provide comments and suggestions before the document is shared with the drafting WG at a later stage of the process.

5. Any Other Business

The next AGoB meeting will be held online in September 2026 (the exact time and date to be confirmed, a form will be circulated to agree on the meeting date.).

Another AGoB meeting is planned for 1 December 2026 in Dublin (Ireland), aiming to include a joint workshop with the drafting WG.

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.

[1] OECD. (2025a). Guiding principles for mixture threshold derivation from effect biomarkers (ENV/CBC/HA(2025)4) https://one.oecd.org/document/ENV/CBC/MONO(2025)12/en/pdf

[2] OECD. (2025b). Guiding principles to advance occupational mixture risk assessment with effect biomarkers (ENV/CBC/HA(2025)3). https://one.oecd.org/document/ENV/CBC/MONO(2025)11/en/pdf

[3] Hernández, et al. (2026). Using effect biomarker thresholds in regulatory risk assessment: an OECD-based framework for assessing cumulative exposures to chemical mixtures. Environment International, 211, 110215. https://doi.org/10.1016/j.envint.2026.110215