Advisory Group on Biomarkers of effect (AGoB)
Minutes of the 1st meeting

1 July 2025
13:00-17:00 CET
Minutes agreed on 25 Jul 2025

Location: Online

Attendees:

- *AGoB participants*:

Country	Name	Role
Bulgaria	Georgieva Tzveta	Member
Croatia	Ivana Vinković Vrček	Member
Czechia	Elliott James Price	Member
Denmark	Anne Mette Zenner Boisen	Member
France	Gilles Rivière	Member
Germany	Tewes Tralau	Member
Greece	Denis Sarigiannis	Member
Italy	Francesco Capozzi	Member
Lithuania	Karolina ŽIOGELYTĖ	Member
Malta	Giannella Pisani	Alternate member
Netherlands	Marcel Mengelers	Member
Portugal	Susana Viegas	Member
Slovenia	Manca Ahačič	Member
Spain	Mariana (Marieta) Fernández	Member
Sweden	Mattias Öberg	Member
Switzerland	Robert Pasanen-Kase	Observer
European Commission	Frans Verstraete	Observer
European Commission	Sandrine AMSLER	Observer
N/A	Antonio Hernández-Jerez	Hearing Expert (Chair of EFSA's Scientific Committee working-group on biomarkers of effect)

- *EFSA staff*:

Unit	Name
MESE	Lucian FARCAL (Chair)
MESE	Ana DIGES
FIP	Cristina CROERA
FIP	Zainab AL HARRAQ
ENREL	Cinzia PERCIVALDI

1. Welcome and apologies for absence

The Chair opened the meeting by welcoming participants and introducing the new Advisory Group on Biomarkers of effect (AGoB). The meeting's objectives, agenda, and the group's mandate were outlined. Apologies were received from Milada Syčová (Slovakia).

2. Adoption of agenda

The agenda was adopted without changes.

3. Tour de Table

Participants introduced themselves and outlined their professional backgrounds, which included expertise in toxicology, biochemistry, genomics, medicine and related disciplines. They also shared information on ongoing projects relevant to biomarkers of effect, such as studies on occupational exposure, nanotoxicology, and the development of novel biomarkers. These introductions provided a comprehensive overview of the diverse scientific perspectives and research activities represented in the group, helping to frame the context for future discussions and collaboration within the AGoB on the development of guidance for biomarkers of effect.

4. Project overview and workplan

The AGoB members were provided with an overview of the group's terms of reference (ToR), including its mandate, objectives, and expected deliverables. The AGoB was established as a group of experts representing the EFSA Advisory Forum (AF), to support the development of guidance on the use of biomarkers of effect in regulatory risk assessment. Acting in an advisory capacity, the group aims to foster knowledge sharing and the exchange of best practices, align efforts across EU and international initiatives, and provide scientific and technical input to support methodological harmonisation. The deliverables of AGoB include input to EFSA on documents and processes, meeting minutes with action points, progress updates to the AF, and an annual technical report. The group shall be chaired by a Member State nominated by the AF.

The AGoB members were informed about the overall framework of the project, including its objectives, timeline, and expected deliverables. It was explained that the guidance aims to establish a harmonised framework for the application of biomarkers of effect, thereby supporting consistent, transparent, and scientifically robust safety assessments by both applicants and risk assessors. The project is expected to be completed within 24 months from the start of the new interagency mandate. An interim milestone will focus on delivering a structured outline of the guidance, while the main deliverable will be the final guidance document.

5. Guidance and development plan

The AGoB members were provided with a brief summary of Phase 1 of the project, which concluded with the publication of a Scientific Report by EFSA[1]. This report now serves as the foundation for the further development of guidance on the use of biomarkers of effect.

The AGoB members were also presented with the expected outputs of Phase 2, starting with a draft outline of the guidance. This includes sections on general principles, applications, methodologies, and case studies. It was explained that each section is intended to build towards a comprehensive and structured framework for the use of biomarkers of effect in regulatory risk assessment. The importance of clearly establishing the context of use, such as regulatory drivers and specific applications, was highlighted. Participants also discussed the challenges associated with the analytical and biological characterisation of biomarkers, emphasising the need for clear criteria and methodologies to ensure scientific robustness.

In addition, the group addressed the role of uncertainty analysis and the integration of biomarkers into risk assessment workflows. It was noted that identifying and characterising sources of uncertainty, such as variability in biomarker responses and differences in analytical methods, is essential. Participants stressed the need for structured approaches to integrate biomarkers into existing workflows, including the generation of reference points and the transparent documentation of selected biomarkers, their descriptors, and associated uncertainty factors.

6. Feedback and discussions from related initiatives

The AGoB members received an update on ongoing OECD projects related to occupational biomonitoring and the use of effect biomarkers in risk assessment. These initiatives aim to provide systematic guidance and understanding in the field. Participants discussed opportunities for collaboration and knowledge transfer between the OECD projects and the advisory group's work, particularly through the exchange of methodologies and case studies. It was noted that guiding principles developed under the OECD framework, such as those addressing combined exposures and the application of effect biomarkers, could be considered for integration into the guidance under development.

In addition, participants referred to other initiatives they are involved in, including EU-funded projects such as the European Partnership for the Assessment of Risk from Chemicals (PARC), and reiterated the importance of fostering knowledge sharing and collaboration across initiatives.

The European Commission observer outlined expectations for the guidance, stressing the need for a consistent and harmonised approach to the use of biomarkers of effect across EU agencies and scientific panels.

Looking ahead, participants discussed future directions for the guidance, highlighting the importance of addressing both protective and predictive risk assessments. They emphasised the need to integrate knowledge from related initiatives and projects to ensure a comprehensive and coherent approach. Prioritisation of areas with the greatest potential to improve risk assessment practices was also discussed.

[1] EFSA, (2024). Conceptual basis for the development of guidance for the use of biomarkers of effect in regulatory risk assessment of chemicals. EFSA Journal, 22(12). https://doi.org/10.2903/j.efsa.2024.9153

Discussion highlights on technical and strategic aspects of biomarkers of effect:

- **Toxicological considerations**: the challenge of heterogeneity in biological responses to chemical exposure was highlighted as a key issue in measuring effects and interpreting biomarker data.
- **Knowledge transfer**: a systematic approach was recommended for capturing and integrating new projects and publications into the guidance.
- **Application in hazard and risk assessment**: early biomarkers of effect were recognised as valuable tools for early detection of potential risks before adverse effects develop. However, concerns were raised about the regulatory acceptance of innovative approaches.
- **Regulatory and innovation interface**: the dual role of effect biomarkers in regulatory risk assessment and innovation, such as in drug and chemical development, including within the EU's Safe and Sustainable by Design (SSbD) framework, was discussed. A proposal was made to establish a common working space for regulators and industry developers to balance regulatory requirements with the flexibility needed to support innovation.

7. Any Other Business

Expressions of interest from members willing to take on the Chair role: the AGoB members were invited to express their interest in taking on the role of Chair for the advisory group. It was explained that the Chair would be responsible for leading discussions, prioritising topics, and coordinating the group's activities to support the effective development of the guidance.

Actions: the AGoB members were informed about the upcoming steps in the project. Meeting minutes and an updated version of the guidance outline will be circulated, and members were encouraged to provide ongoing feedback to support the refinement of the document. An updated version will be shared ahead of the next meeting.

Next meetings:

- 18 Sep 2025 (online) to review the updated guidance.
- 2 Dec 2025 (in-person - Copenhagen, Denmark) designed as a broader workshop to facilitate in-depth discussions and wider participation.

Final considerations: continuous collaboration and input from the group were emphasised as essential for the successful development of the guidance.

Participants expressed appreciation for the meeting, noting the productive discussions and the promising potential for successful collaboration in developing the guidance.