98TH ADVISORY FORUM
KONGENS LYNGBY, 03-04 DECEMBER 2025

ADVISORY GROUP ON BIOMARKERS OF EFFECT (AGOB)

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EUROPEAN FOOD SAFETY AUTHORITY

AGOB STRUCTURE

- **AF members or experts nominated by AF members as representatives:** BG, BE, HR, CZ, DK, FR, DE, EL (Chair), IT, LT, MT, NL, PT, SK, SI, ES, SE
- **Observers:** CH
- **EC representatives:** DG SANTE
- **Hearing experts**
- **EFSA representatives**

AGOB ROLE

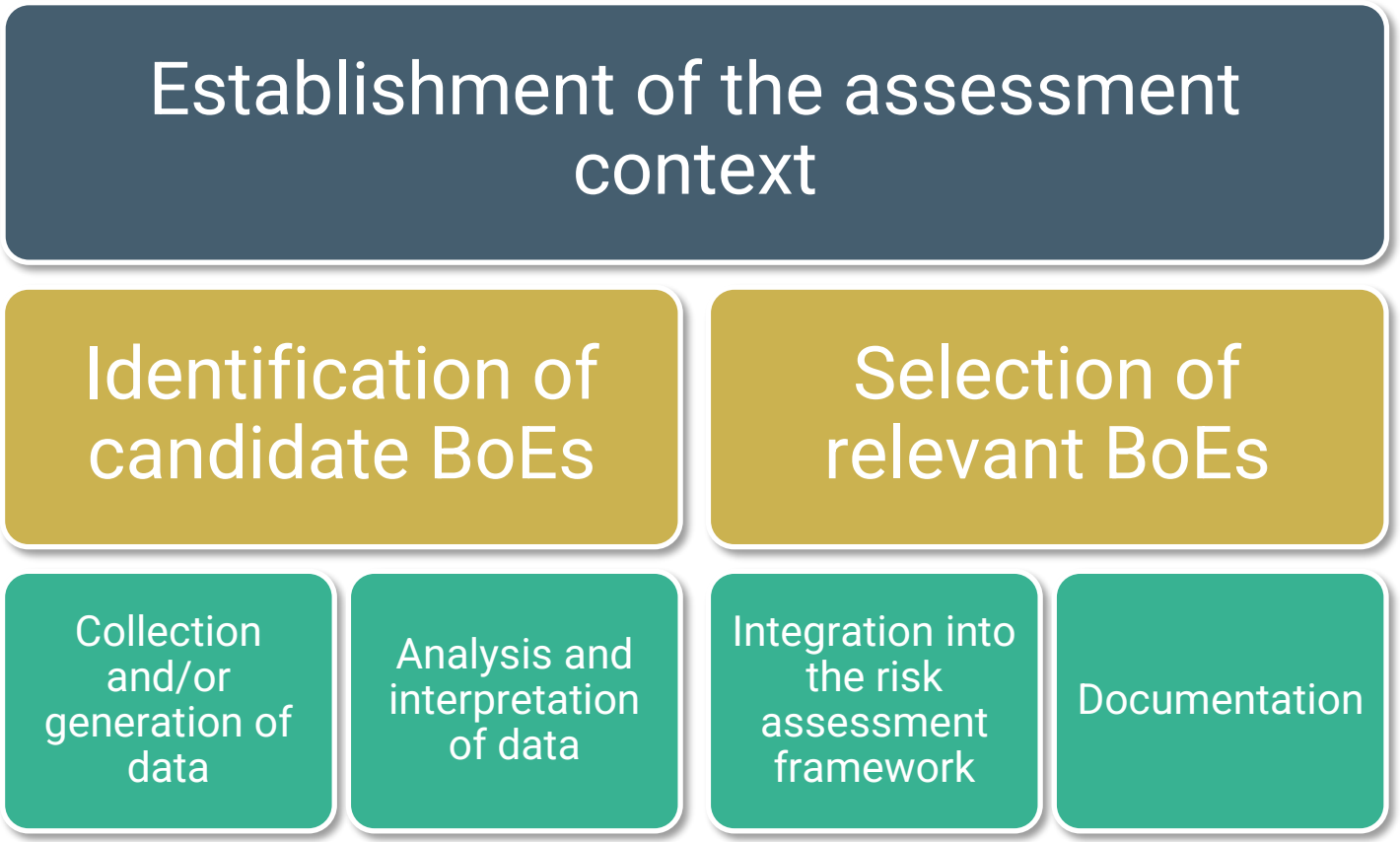
- **Advisory role**: provide input to the activities performed by EFSA together with other EU Agencies (**EC joint mandate**) to develop guidance on the use of biomarkers of effect (BoE) in risk assessment
- **Aim**: knowledge sharing, anticipate and avoid the duplication of activities and divergence of opinions, harmonise the methodology and streamline future risk assessment outputs
- **Knowledge transfer**: EU and international initiatives
- **Feedback**: guidance structure, workflows and development process
- **Meetings 2025**: 1 Jul (online), 18 Sep (online) and 2 Dec (in person)

GUIDANCE OBJECTIVES

Provide a **harmonised framework** for using BoE in risk assessment:

- Define common scientific principles, knowledge and tools across EU Agencies to support harmonised use of BoE, while allowing adaptation to different regulatory contexts.
- Present a methodological approach for identifying, selecting, evaluating and integrating BoE into risk assessments, with options for specific contexts.
- Assess and, where relevant, include NAMs and omics in the methodology.
- Set principles and key considerations for uncertainty analysis.
- Assist in assessing the feasibility of its implementation, considering resources, technical capacity and timelines.
- Recommend further actions and developments where knowledge or methodology gaps exist.

ELEMENTS OF THE PROCESS FOR USING BOE IN RISK ASSESSMENT



- Define the purpose, scope, regulatory drivers for the assessment
- Identify potential BoE relevant to the intended context and mechanistic domain
- Assemble or generate relevant data required for evaluation and interpretation of BoE
- Determine the biological meaning and statistical robustness of BoE data
- Select biomarkers suitable for integration into the risk-assessment framework
- Incorporate the selected BoE within the risk-assessment process
- Record the key characteristics and evidence base for selected BoE in a standardised format

GUIDANCE DEVELOPMENT | AGOB 3RD MEETING 2 DEC 2025

- Guidance development process and timelines
- Approaches and case studies from other initiatives
- Collaboration and knowledge exchange (ECHA, EMA, PARC, OECD, etc.)
- Feedback on the draft guidance
- Representative examples of biomarkers of effect
- Prioritisation of topics and next steps

NEXT STEPS

Next meetings: plan to organise four meetings in 2026 (3 virtual and 1 physical back-to-back with the AF)

AGoB deliverables:

- **Regular input** provided to EFSA on documents, the process and other actions related to the development of guidance
- **Meeting's minutes**
- **Progress updates** at Advisory Forum meetings
- **Annual Report (2025)**

Guidance development process: multiple draft iterations followed by consultations (estimated adoption planned for Q4 2027)

Thank you

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