97th Advisory Forum meeting
Online, 8-9 October 2025

UPDATE ON ADVISORY GROUP ON BIOMARKERS OF EFFECT (AGOB)

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BACKGROUND AND CONTEXT | AGOB

- **AGoB establishment**: the Advisory Group on Biomarkers of effect was endorsed by the Advisory Forum at the 95th AF meeting (6-7 Mar 2025)
- **AGoB meetings**: online, 1st Jul and 18th Sep 2025
- **Terms of reference**: act in an advisory capacity, providing input to the activities performed by EFSA together with other EU Agencies to develop guidance on the use of biomarkers of effect 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

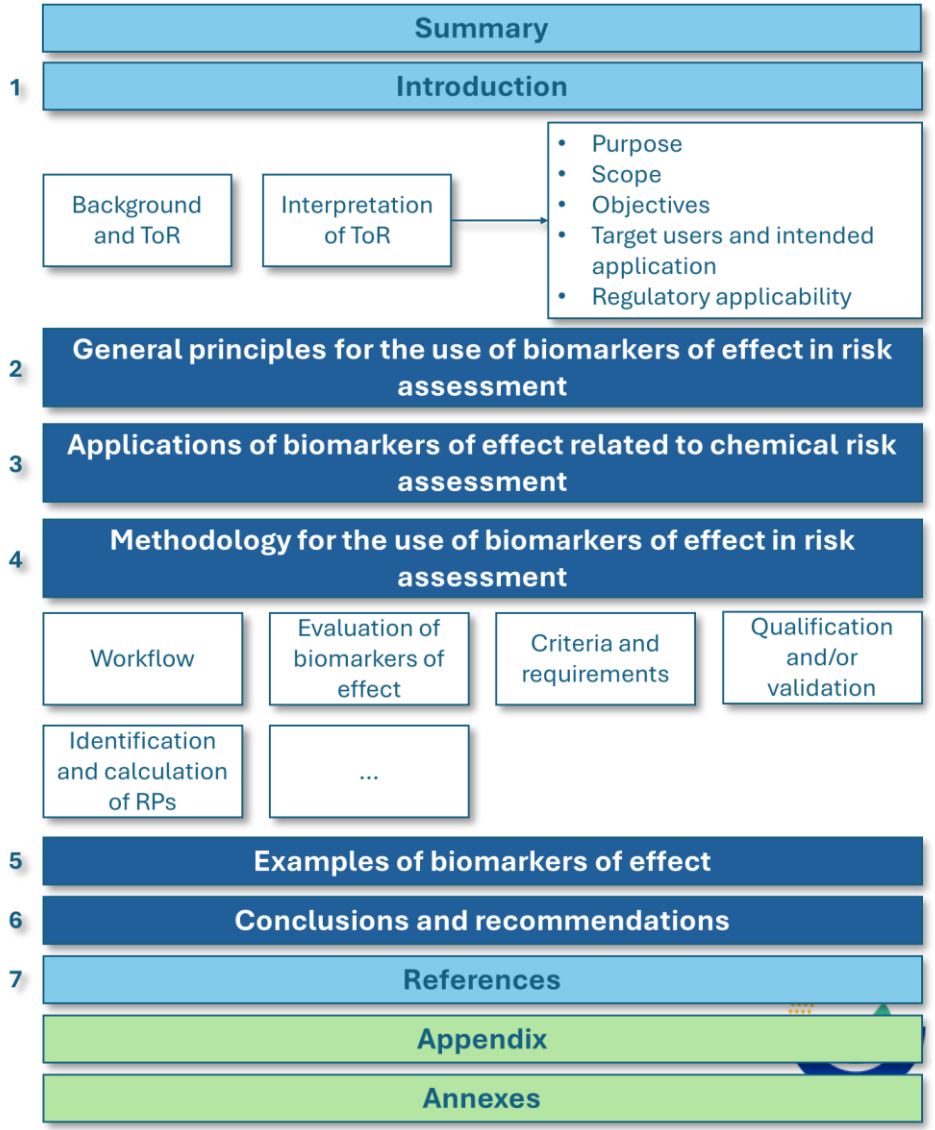
AGOB STRUCTURE

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

- **Expression of interest for the AGoB Chair**: Dimosthenis Sarigiannis (GR)
  - *Director and President of the Board, National Hellenic Research Foundation*
  - *Professor of Environmental Engineering, School of Chemical Engineering, Aristotle University of Thessaloniki*
  - *Member of the Management Board of PARC (EU Partnership for the Assessment of Risks from Chemicals)*
  - *Experience in regulatory risk assessment*

GUIDANCE DEVELOPMENT | OUTLINE

- Provides a harmonised framework for using biomarkers of effect in risk assessment, aligned with current scientific and regulatory consensus
- Promotes their integration into regulatory processes, and the use of New Approach Methodologies (NAMs) as the field evolves
- Focused on measurable biological changes (key events) occurring before the manifestation of adverse outcomes.
- Supports risk assessors in evaluating chemical hazard/risk
- Guides business operators in preparing regulatory dossiers
- Assists method developers in designing and applying tools for biomarker integration



GUIDANCE DEVELOPMENT | AGOB FEEDBACK

- **AGoB discussion:** toxicological considerations, application in hazard and risk assessment, regulatory and innovation interface
- **Integration of knowledge** from ongoing initiatives (OECD, PARC, etc.)
- **Objectives and tasks** aligned with the guidance development process
- **AGoB members** acknowledged the promising potential of the field and the need for guidance
- **Continuous collaboration and input** from the group are essential for the successful development of the guidance

NEXT STEPS

Meetings:

- **3rd AGoB meeting** - in-person, 2 Dec 2025, (Copenhagen, Denmark), prior to the AF meeting
- The meeting will include also other participants: EFSA's SC WG members and representatives from EMA and ECHA

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**

Thank you

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