

95th Advisory Forum
Warsaw, 6-7 March 2025



ADVISORY GROUP ON BIOMARKERS OF EFFECT - PROPOSAL

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BACKGROUND INFORMATION

- **Context:** co-development of EU guidance on the use of biomarkers of effect by EFSA, EMA and ECHA (mandate under discussion)
- **Scientific Report:** basis for guidance development
- **Guidance:** address health hazards assessment related to food/feed compounds or contaminants, the use of chemicals and pharmaceutical products
- **Aim:** set up an **Advisory Group on biomarkers of effect** to support in developing the guidance



MANDATE OF THE ADVISORY GROUP

- Act in an **advisory** capacity
- Aim to **anticipate and avoid the duplication of** activities and divergence of opinions
- **Harmonise** the methodology and **streamline** future risk assessment outputs
- **Knowledge** sharing



OBJECTIVES

Facilitate a constructive dialogue and jointly address scientific & technical challenges related to biomarkers of effect:

- Address critical aspects and main components of the guidance
- Input and recommendations on the scope and context of use
- Identify biomarkers of effect in use
- Define criteria for the selection and validation of biomarkers of effect
- Demonstration of the methodology
- Recommendations for the guidance implementation and further adaptation
- Provide access to knowledge and expertise in MSs
- Recommendations on further activities in this area



MEMBERS OF THE ADVISORY GROUP

- Advisory Forum members
- Governmental experts nominated by Advisory Forum members as representatives
- Observers: EC representatives and Switzerland
- EFSA representatives

Scientific background: biomarkers, human or animal physiology/pathology, toxicology, adverse outcome pathways, new approach methodologies, risk assessment of chemicals, biomonitoring

One representative for each Member State

Other experts can be invited to the meetings on an ad hoc basis

Chaired by one Member State nominated by the Advisory Forum

→ List of nominees to be completed / confirmed



TIMELINES AND DELIVERABLES

Timeline:

- The mandate will be set until **31 Dec 2027**
- The AF can extend the timeline of the Advisory Group for a longer period

Deliverables:

- **Input** provided to EFSA on documents, the process and other actions related to the development of guidance on biomarkers of effect
- **Meeting's minutes**
- **Progress updates** at Advisory Forum meetings





Thank you



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