

**89TH ADVISORY FORUM
VIRTUAL, 4-5 OCTOBER 2023**

PROGRESS UPDATE ON THE DEVELOPMENT OF THE GUIDANCE ON BIOMARKERS OF EFFECT

Lucian Farcal (Scientific Officer, MESE)

BACKGROUND AND PROJECT GOALS

Background

- The project is developed in the context of the **risk assessment processes** at EFSA aiming at supporting the risk assessors in applying a **harmonise approach and integrating additional biological parameters or measurements**, such as the biomarkers of effects that indicate an early biological response due to exposure to a chemical.
- EFSA organised in Sep 2022 a Workshop to collect views and experiences regarding the use of biomarkers of effect in risk assessment and to provide recommendations for future activities. It has been concluded that **a guidance on biomarkers of effect is needed** and that EFSA's Scientific Committee shall start a self-task mandate for its implementation.



Goals

- The goal is to **work towards a harmonised guidance** on the use of biomarkers of effect to derive Reference Points (RPs) for establishing Health Based Guidance Values (HBGVs) or deriving Margins of Exposure (MoEs), as part of the risk assessment process.
- The aim is also to achieve an **internationally agreed guidance** by establishing consultation and co-creation mechanisms with EU and international partners.

The Scientific Committee proposed and requested from EFSA the mandate to work on this topic



PROJECT OBJECTIVES AND DELIVERABLES

Phase 1 Feasibility study

1. **Establishing definitions and descriptors** for biomarkers of effect and the overall scope of the guidance.
2. **Reviewing and mapping** the activities, initiatives, knowledge, approaches relevant to the project goal

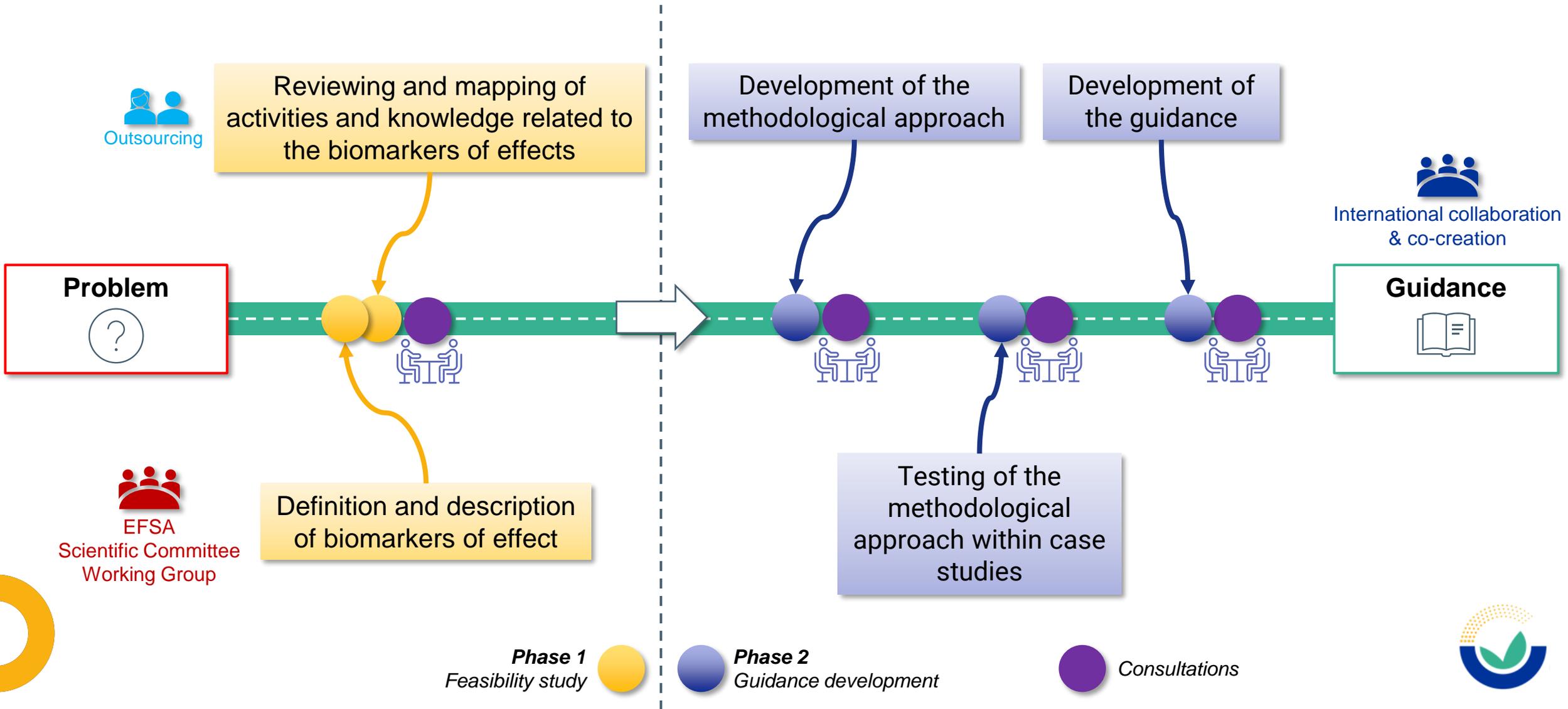


Phase 2 Guidance development

3. **Developing the methodology**, including a stepwise approach, criteria and workflows for the use of biomarkers of effects to derive Reference Points.
4. **Demonstrating the applicability** of the established methodology within case studies.
5. **Developing a guidance** on the use of biomarkers of effect in regulatory risk assessment of chemicals.

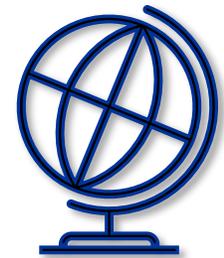


PROJECT WORKFLOW & ACTIVITIES



MECHANISMS PROPOSED FOR THE COLLABORATION AND CO-CREATION

- Establish collaboration and co-creation mechanisms for the development of the guidance with EU (e.g. Member States, EU Agencies, EC) and international organisations (e.g. OECD, WHO):
 - *Establishment of a Working Group of experts for the implementation of the project*
 - *Consultations with international organisations on specific outcomes of the project (e.g. ILMERAC - International Liaison Group On Methods For Risk Assessment Of Chemicals In Food)*
 - *Establishment of a Scientific Network of EU MS organisations to follow the development of the guidance and provide advice on the content*
 - *Public consultations to be organised on major milestones*
 - *Workshops to present and discuss major achievements*
- Advice from MS on the collaboration and co-creation mechanism
- Recommendations regarding the development of the guidance expected after the implementation of Phase 1 (feasibility) and further consultations



**International collaboration
& co-creation of guidance**



WORKING GROUP OF THE SCIENTIFIC COMMITTEE

- Nominations from MS and EFSA's Panels
 - *Eight (8) countries sent nominations and expressed interest following EFSA's invitation to join the initiative*
 - *Three (3) Panels sent nominations for the WG*
- In a first step, a core WG of experts is being established
 - *Expertise includes human pathology, physiology, biomonitoring, toxicology, AOPs, risk assessment*
 - *Other experts may be invited later to join the WG*



**Scientific Committee
Working Group**





Thank you!



STAY CONNECTED

SUBSCRIBE TO

efsa.europa.eu/en/news/newsletters
efsa.europa.eu/en/rss
[Careers.efsa.europa.eu](https://careers.efsa.europa.eu) – job alerts



LISTEN TO OUR PODCAST

Science on the Menu – Spotify, Apple Podcast and YouTube



FOLLOW US ON TWITTER

[@efsa_eu](https://twitter.com/efsa_eu) [@methods_efsa](https://twitter.com/methods_efsa)
[@plants_efsa](https://twitter.com/plants_efsa) [@animals_efsa](https://twitter.com/animals_efsa)



FOLLOW US ON LINKEDIN

[Linkedin.com/company/efsa](https://linkedin.com/company/efsa)



FOLLOW US ON INSTAGRAM

[@one_healthenv_eu](https://instagram.com/one_healthenv_eu)



CONTACT US

efsa.europa.eu/en/contact/askefsa

