Work-programme Scientific Committee cross-cutting guidance revision/development 2025-2027

Stakeholders bureau, 17 Oct 2025

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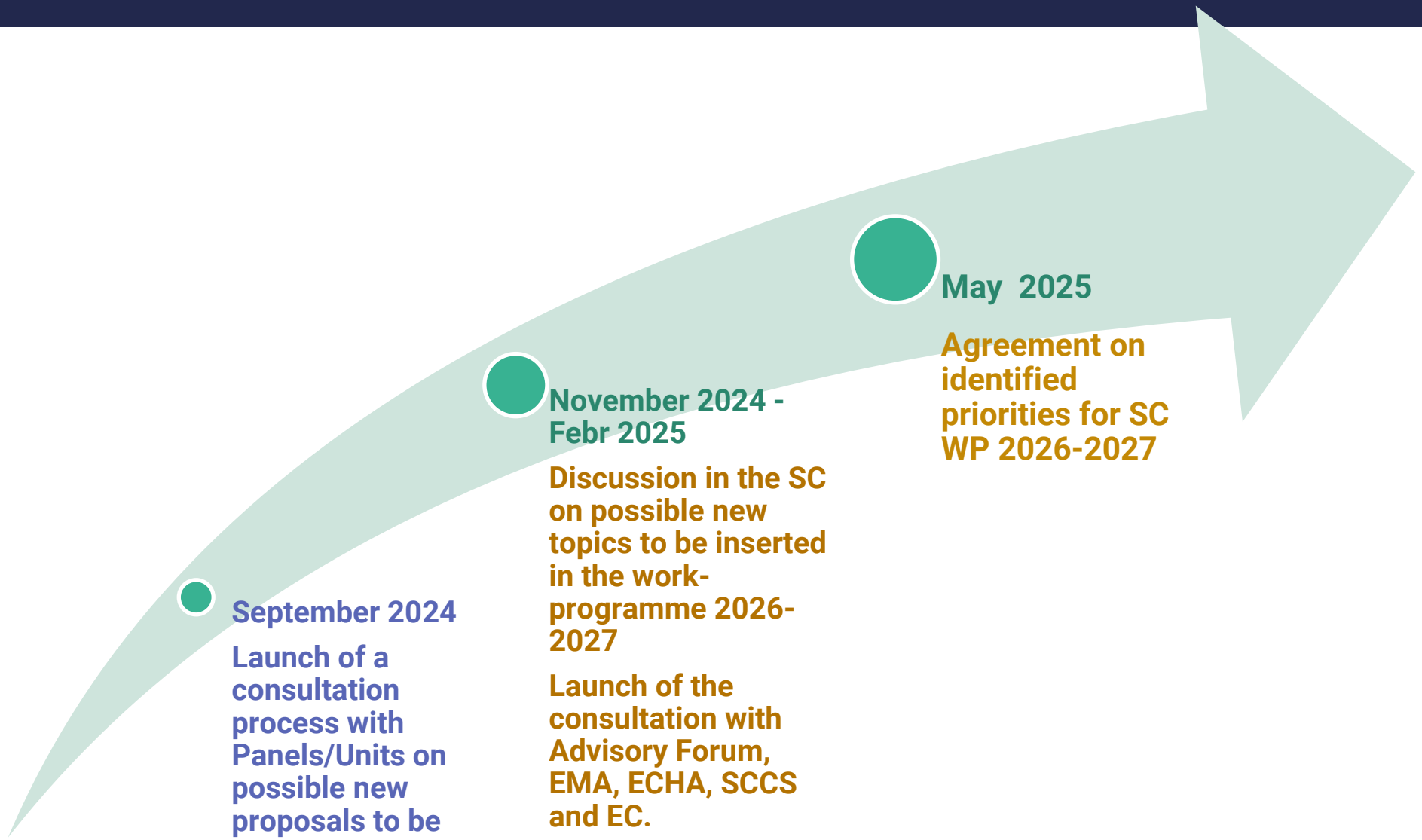
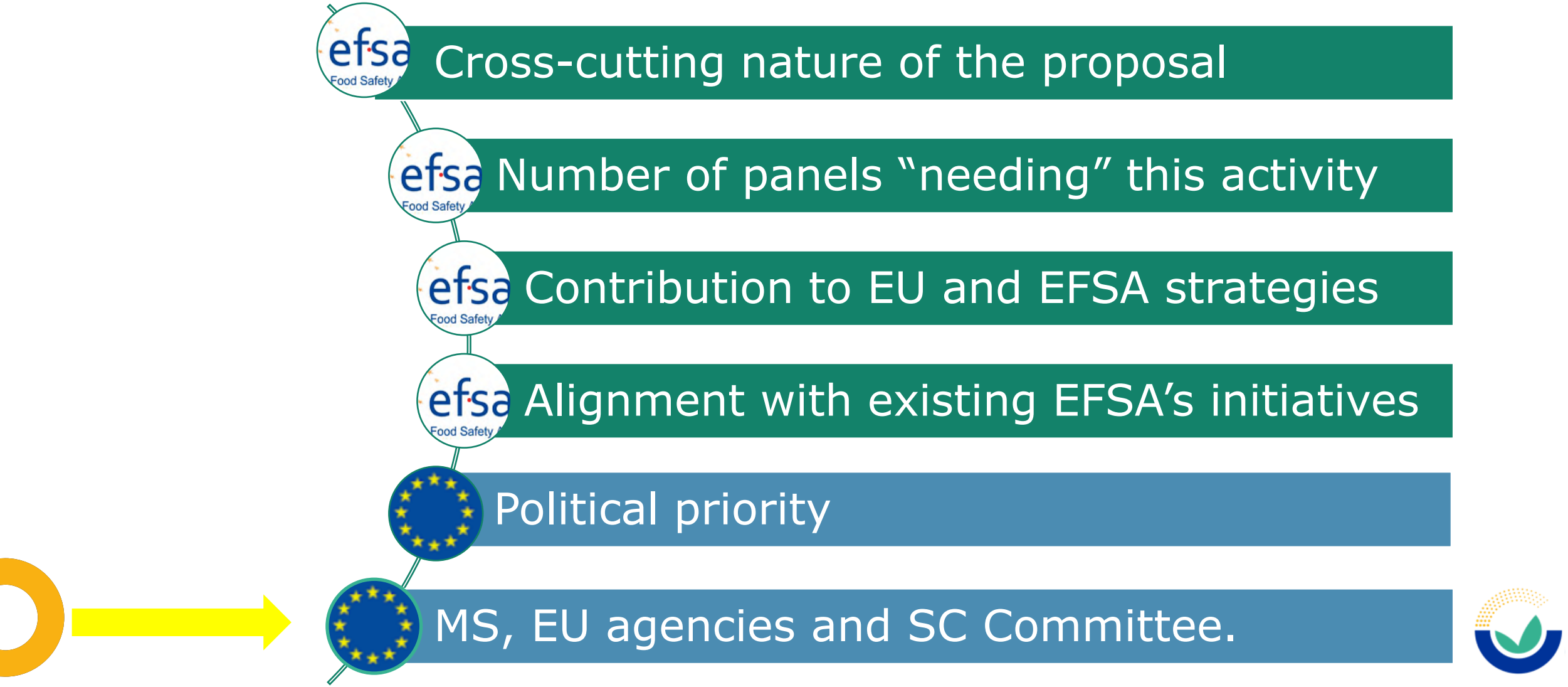
EUROPEAN FOOD SAFETY AUTHORITY

BUILDING THE WORK-PROGRAMME OF THE SCIENTIFIC COMMITTEE



IDENTIFICATION OF PRIORITIES



HOW EFSA WORKS ON METHODOLOGIES GUIDANCE DEVELOPMENT

- Cross-cutting guidance documents developed by EFSA Scientific Committee (SC)

- **Scoping document:** background, reasoning to start the activities, draft term of reference, engagement plan. Published for public consultation and targeted consultation (e.g. EFSA's Advisory Forum (MS), EU sister agencies)
- Comments are addressed, terms of reference refined (if needed). Explore interest and possible participation of EMA, ECHA and JRC
- WG with EFSA staff and panel/external experts is set up to develop guidance.
- Draft guidance endorsed by SC for public consultation, including targeted consultation (e.g. EFSA Scientific Panels, EU agencies etc). Comments are addressed and final draft guidance adopted by the SC and published.

- Organisation of **different types of engagement activities**, e.g. workshops, technical hearings during the development of the guidance.
- Dissemination activities and trainings after publication to ensure full implementation. Support to the implementation is also given via EFSA cross-cutting WGs.

- SC work-programme for guidance update/development has been published: https://www.efsa.europa.eu/en/science/scientific-committee-and-panels/scientific-committee

ONGOING ACTIVITIES SC GUIDANCE – STATUS OCTOBER 2025

Collaboration; Co-creation; Co-design

Activity
1 **Revision of the Guidance on default values** in the absence of actual data: **ONGOING** (DL summer 2026)
2 Guidance on **critical appraisal of evidence** as part of the systematic review methodology: **ONGOING** (EC mandate - DL spring 2026)
3 Revision of the Guidance on **Margin of Exposure** (MoE): **ONGOING** (DL end 2026)
4 Revision Guidance **on risk assessment of nanomaterials and Guidance on technical requirements:** **ONGOING** (DL summer 2026)
5 Revision guidance on the genotoxicity strategy: **ONGOING** (DL 2027)
6 Guidance on the use of **biomarkers of effect** in regulatory risk assessment of chemicals: **ONGOING** (DL self task beg 2027). **Cocreation** with ECHA and EMA. Joint mandate to be finalised

NEW TOPICS FOR THE WORK-PROGRAMME 2026-2027

	Timelines
Guidance on the establishment/application of relative potency factors (RPFs).	Included in SC WP 2026-2027
Guidance defining a tiered approach for an ADME testing strategy and on the use of kinetic data and qualification/validation of Physiologically based kinetic (PBK) models in human and environmental risk assessment	Included in SC WP 2026-2027
Revision of the Guidance on the safety assessment of botanicals and botanical preparations for use as ingredient in food supplements (2009)	Preparatory work to be initiated in autumn 2025 - To start activity in 2026
Guidance on the Safety assessment for the use of mixtures of natural origin.	Preparatory work to be initiated in autumn 2025 - To start activity in 2026
Merge Guidance on the use of weight of evidence and guidance on the assessment of biological relevance into a single one on Evidence based RA guidance.	Work initiated in September 2025. Ongoing public consultation of scoping paper: https://connect.efsa.europa.eu/RM/s/consultations/publicconsultation2/a0lTk000005oHIv/pc1654


THANKS

Back up slide

FINAL ELABORATED PROPOSALS AFTER PANEL CONSULTATION:

1. Consideration of phasing out the 90-day repeated toxicity study (TG 408) for food enzymes, and use of NAMs ensuring the appropriate level of safety for consumers is maintained.
2. Consideration of studies in domestic animal for assessing mammalian toxicity.
3. Use of probabilistic risk assessment techniques
4. Possible application of approaches developed for assessing combination toxicity in the area of human risk assessment to environmental risk assessments
5. Guidance on the establishment/application of relative potency factors (RPFs).
6. Guidance on harmonised approach for tiered toxicity studies for regulated product an development of testing strategies for biological and toxicological endpoints
7. Guidance on the effects of the microbiome
8. Guidance defining a tiered approach for an ADME testing strategy and on the use of kinetic data and qualification/validation of Physiologically based kinetic (PBK) models in human and environmental risk assessment.
9. Development of criteria for decision on Maximum Tolerated Dose in toxicity studies with experimental animals.