

95<sup>TH</sup> MEETING OF THE EFSA ADVISORY FORUM  
6<sup>TH</sup> March 2025

PROJECT FOR A **SUPPORT**  
**OFFICE FOR PESTICIDE RISK**  
**ASSESSMENT**  
**"SOPRA"**

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# CONTEXT: EU PARTNERSHIP FOR FOOD SAFETY

## Challenge

- The centralisation to EFSA of most EU level RA responsibilities poses two challenges:
- Increasing workload for EFSA, which cannot be sustainably managed by adjusting staff numbers
  - MS authorities may opt to freeze – or even reduce – their investment in their RA expertise (in terms of volume of staff and expertise level), also in strategic domains

## Solution

- Increasing the use of Partnerships, i.e., striving for sustaining distributed EU RA capacity
- Implementation so far: Several cooperation models in operation, e.g. from cooperation via traditional G&P projects to more closely integrated 'partnering' via Framework Partnership Agreements (e.g., supporting Enzymes, Food/Feed Additives; Novel Foods; Pesticides).

**New proposal in the domain of Pesticide RA: the Support Office for Pesticide RA (SOPRA)**



# PILOT – WHY A PESTICIDES SUPPORT OFFICE?

- **Complexity** of assessments
  - Regulatory: dual system for Active substances vs. Products; new biocontrol substances
  - Scientific: e.g. endocrine disruption, mixtures, co-formulants, biodiversity, etc.

- **Missing capacity volume** in MSs and EFSA
- **Missing key expertise** in certain aspects of the risk assessment in some MSs

Delay in the overall RA process (e.g., ca. 250 dossiers pending review)



Potential EU-wide side-effects on innovation rate, competitiveness and sustainability



# SOPRA - ENVISAGED SCOPE AND MISSION

## Establishing a Support Office for Pesticide Risk Assessment (SOPRA) to:

- Support MSs on selected tasks that they have to perform across the pesticides assessment domain, e.g., related to Active Substance assessment and preparation of the corresponding reports
- Support Products' assessment (on request), e.g., Co-formulants' assessment and other tasks of EU-wide benefit
- Provide pre-submission advice, aiming to improve quality of incoming active substance dossiers (with procedures in place for avoiding conflicts of interest)

## Outcome

- Unblock some of the bottlenecks and expand capacity in MSs Competent bodies and applicants



# DRAFT PROPOSAL - FOUNDATIONS

## EFSA Grant

- Art.36 organisations
- Initially 1M or more per year, and growing as needed
- Total of 4 years , potentially longer and renewable
- Initial capacity-building support to be provided by MSs (consortium of organisations) and EFSA

## Main requirements:

- Ideally, create a new entity in the MS (to enhance coordination and visibility)
- Staffing by mobilising NEW experts, with the flexibility needed
- Demonstration of an attractive workplace for EU staff
- Procedures that will enable support to MS competent bodies AND applicants ensuring NO conflicts of interest
- Template to be adopted to support other areas of EFSA work, if proven successful and sustainable



# DRAFT PROPOSAL – OPERATION Q&A 1/2

## Which tasks would SOPRA be mandated with?

- **Active substance assessments**
  - Pre-submission advice to improve quality of incoming active substance dossiers
  - Preparation of active substances assessment reports

## Upon request, support to products' assessment

- Co-formulant assessment and other tasks of EU-wide benefit
- Ad hoc questions to support zonal harmonisation

NOTE: SOPRA will NOT support the national authorisation of PPPs, which is a national task



# DRAFT PROPOSAL – OPERATION Q&A 2/2

## How would the assignment of activities to SOPRA be done?

- Upon request of the MSs on one or more areas of expertise
- Upon preliminary analysis with EC of the delays (e.g., once a year) and possible additional criteria
  - EU/MS priorities
  - Capacity building in MSs
- Planning and prioritisation exercises to be designed in early stages and run as needed

## How can the risk of drawing on resources currently in use in MSs be avoided?

- By finding new experts, e.g., through:
  - Early career experts, with experience in the EU PPP RA processes (e.g. past trainees in EFSA or MS competent bodies)
  - Seasoned experts currently outside of the PPP RA system (e.g., recently retired experts)
- Encouraging participation of consortia with partners typically outside the current RA processes, e.g., consortia with academic partners



## NEXT STEPS

Explore the **interest** of MS competent authorities in the area of pesticides

Prepare an **open call**, aimed for publication **between Q4 2025 and Q1 2026.**

**Refine** the SOPRA proposal, taking into account input and feedback from MS





**THANKS FOR YOUR  
ATTENTION  
QUESTIONS?**



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