



# **“Info session on the Call for proposals Support to EFSA in the Risk Assessment of Food Enzymes, Food Additives, Food Flavourings and Feed Additives”**

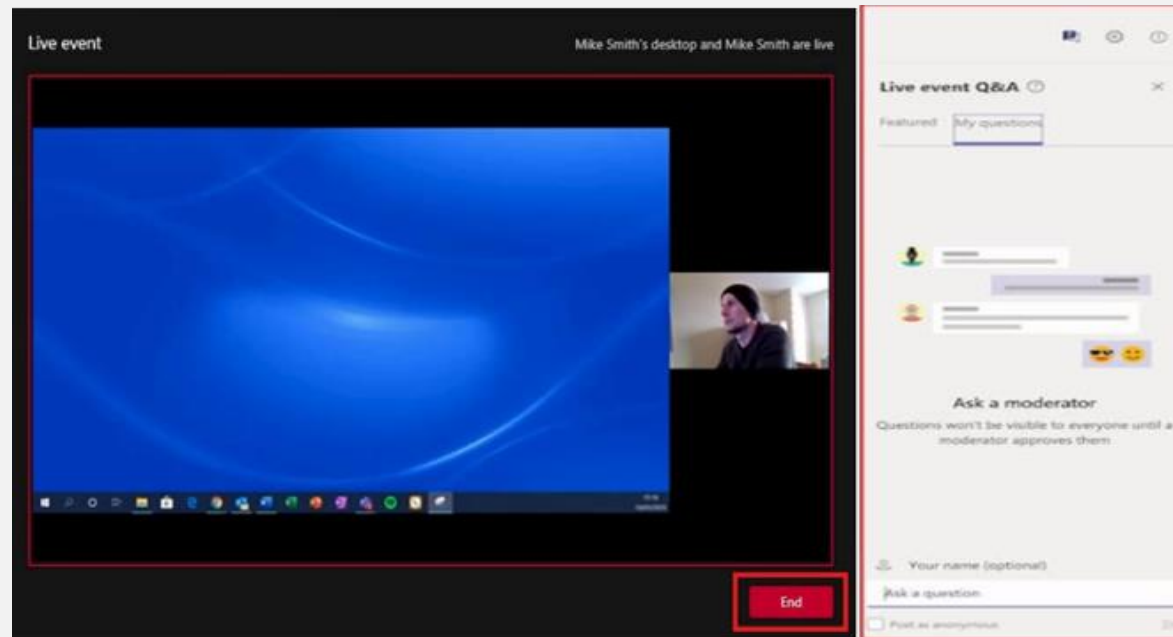
20 September 2022

Trusted science for safe food

# Event guide for attendees

- This event **is being recorded**
- The event **is in English** and questions should be submitted in English through the platform.
- You are automatically connected to the audio broadcast. One-way audio (listen only mode).

Presentation  
window



**Q&A box:**  
For any  
questions  
related to  
the topic or  
unexpected  
IT issues

20/09/2022

**GP/EFSA/FIP/2022/01**

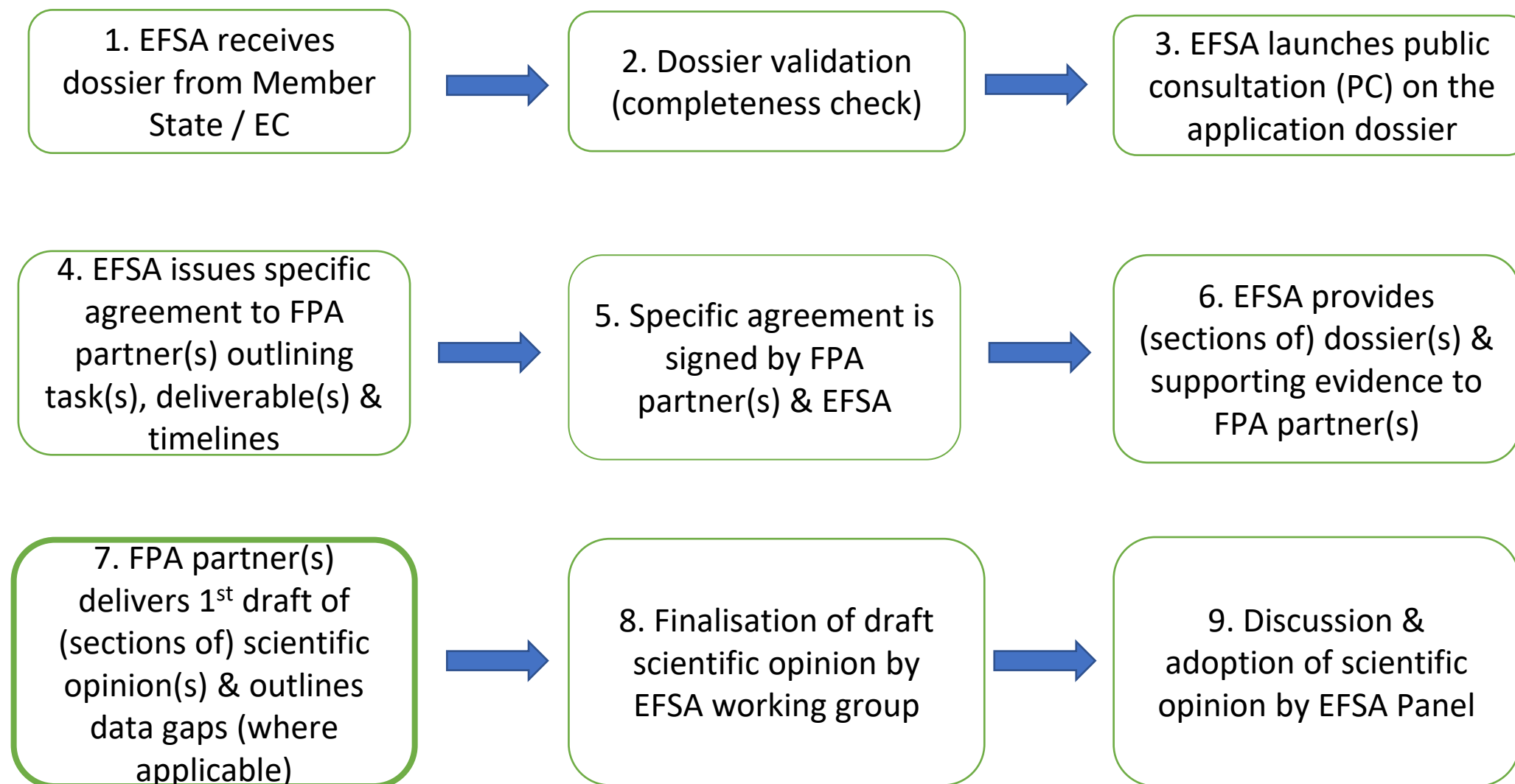
## **General overview**

**Magdalena Andryszkiewicz**

FIP Unit

- Transparency Regulation (EU) No 1381/2019 sets objective for EFSA to reach increased risk analysis capabilities in partnership with national scientific organisations **to draft preparatory scientific opinions** to be peer-reviewed and adopted by the EFSA scientific Panels
- Reg. (EC) No 2230/2004 – Art. 4 specifies which tasks may be entrusted by EFSA to organisations on the list of competent organisations (Art. 36 organisations)

# Workflow for scientific assessment of applications



## Area of work:

- **Food enzymes** *(9 months)*
- **Food additives & flavourings** *(6/9 months)*
- **Feed additives** *(6 months)*

*All dossiers with legal deadlines for EFSA safety assessment*

# Scientific expertise needed

Lot No	Lot title	Area of work		
		Food enzymes	Food additives & food flavourings	Feed additives
<b>Lot 1</b>	Assessment of the data regarding the identification and characterisation of microorganisms used as such or as production strains	✓	✓	✓
<b>Lot 2</b>	Assessment of the identity and characterisation of a food enzyme, food additive, food flavouring or feed additive	✓	✓	✓
<b>Lot 3</b>	Assessment of toxicological safety			
	ADME(R) studies		✓	✓
	Genotoxicity and toxicological studies (e.g., sub- chronic oral toxicity study, chronic oral toxicity studies)	✓	✓	✓
	QSAR analysis		✓	✓
	Toxicological testing relevant for user safety			✓
<b>Lot 4</b>	Allergenicity assessment	✓		
<b>Lot 5</b>	Dietary exposure	✓	✓	✓
<b>Lot 6</b>	Assessment of efficacy and safety for target animal species			✓
<b>Lot 7</b>	Environmental risk assessment		✓	✓
<b>Lot 8</b>	Opinion assemblage	✓	✓	✓

## **INTERMEDIATE DELIVERABLE**

- A) Compliance check of the data provided in the dossier against EFSA GDs/checklists
- B) Analysis of the data & identification of data gaps
- C) Preparation of the specific section(s) of the first draft opinion

## **FINAL DELIVERABLE (optional)**

- D) Analysis of additional data & update of draft opinion
- E) Participation to WG meetings (*if needed*)
- F) Update of the draft opinion in the light of comments received from PC (*if needed*)
- G) Identification of confidential information in the draft opinion

## **Deliverables for lots 1-7** - to be delivered within:

- **5 weeks (indicatively)** after getting access to the dossier  
**(new/renewal applications)**
- **8 weeks (indicatively)** after getting access to  
data/supporting evidence **(re-evaluation of FA)**

## **Deliverable for lot 8** - to be delivered within:

- **additional 3 weeks** after the delivery of the lots 1-7

## 4-years Framework Partnership Agreement

- **1<sup>st</sup> year:** around 40 dossiers
- **2<sup>nd</sup> year:** around 50 dossiers, gradual increase
- **3<sup>rd</sup> year:** around 65 dossiers, full speed
- **4<sup>th</sup> year:** around 70 dossiers, full speed

**\*Disclaimer:** this is only estimated workload. EFSA is not in the position to anticipate at present the exact number of dossiers that will be tasked in the coming years, as EFSA receives mandates for performing specific safety assessments from EC and depends on the number of submissions by food and feed industry. See clarification 1 at: <https://www.efsa.europa.eu/en/art36grants/article36/gpefsafip202201-support-efsa-risk-assessment-food-enzymes-food-additives-food>

- As many dossiers as possible will be included in the same SA
- Dossiers from different regulatory domains (food enzymes, food additives/flavourings, feed additives) will be included in the same SA



Thank you for your attention  
and future fruitful  
collaboration!

20/09/2022



# GP/EFSA/FIP/2022/01

## Grant related aspects

**Marco Cortopassi**

EFSA Procurement Team

Trusted science for safe food

- 8 lots: proposals for multiple lots
- Ranking per lot above min quality threshold
- Multiple FPAs based on ranking
- 4 years duration
- 3.1 M EUR total call budget (break-down per Lot)
- Financing not linked to cost: simplified method

- Specific Agreements (SA)
- Assignment of SAs based on lots ranking: mechanism  
1.3.3 call for proposal
- Cascade mechanism
- Consortium creation encouraged
- 12-months duration of SA, indicative

- Financing not linked to costs i.e. result-based grant
- Output value per lot: defined in section 1.4 of call for proposals
- Payment on acceptance of final deliverable
- Possibility of interim payment (70%)
- In consortium, beneficiaries decides how to share the grant amount

# How to apply

Deadline  
03.11.2022

Eligibility &  
Exclusion

Selection  
criteria p.25

Award criteria  
p.31

## Modalities

Hard copy submission by post/courier

Use application form (annex 2) + evidence/docs requested call

## Art. 36 organisations

Legal entity form

Financial identification form (*coordinator only*)

Partnership statement (*consortium*)

Declaration on honour on exclusion criteria

## Experience/Expertise

Requirements 1: required expertise per lot

Requirements 2: required English Language

Declaration on honour on selection criteria (*coordinator only*)

## Proposal

Resources, Timeliness, Coordination, Continuity

Scoring and thresholds per lot

Ranking per lot

# Information and clarifications



<https://www.efsa.europa.eu/it/art36grants/article36/gpefsafip202201-support-efsa-risk-assessment-food-enzymes-food-additives-food>



[EFSAprocurement@efsa.europa.eu](mailto:EFSAprocurement@efsa.europa.eu)

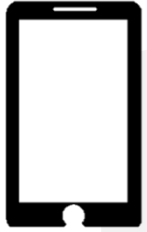
# Questions & answers session

# Thank you for attending our event

In case we did not manage to answer all your questions, you will find them published on EFSA's website few days after the event ([here](#))

The recording of today's event will be available on the EFSA website in few days

Please take few minutes to fill out the [evaluation form](#) that you will receive shortly in your inbox. Your feedback is essential to improve our future events



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