



## CLARIFICATION 4

**Call reference:** GP/EFSA/FIP/2022/01

**Call title:** Support to EFSA in the Risk Assessment of Food Enzymes, Food Additives, Food Flavourings and Feed Additives

### QUESTION 1:

Based on figure 1, box 6 in the Call – it is correctly understood that once EFSA want to entrust a task, EFSA will contact directly the FPA partner/co-beneficiary holding the needed expertise (and hence need a contact person for every partner?) and forward the dossier/information directly and not via the coordinator of the consortium? In addition, if so, will EFSA make a specific agreement directly with that FPA partner? We ask, as we cannot see that the cost of time/management related to the receiving of the submission from EFSA and further distribution within the consortium can be covered by the way EFSA wants to pay for the tasks?

### ANSWER 1:

To entrust a task, EFSA will initiate a Specific Agreement by communicating with the contact person of the FPA partner/the consortium leader (as indicated in Section 1.5 of the Call). The contact person/consortium leader is the reference point for all communication with EFSA. The cost for coordination tasks is considered already embedded in the output value set in Table 4 of the Call.

### QUESTION 2:

How does EFSA plan to distribute the tasks per lot – will there be a collection of tasks on e.g. Lot 1 covering many submissions from applicants – or will it be one submission equal to one lot 1, lot 2, lot 3 etc. based on what the submission cover of information?

### ANSWER 2:

As explained during the Info session, EFSA will task several dossiers in one Specific Agreement. EFSA plans to gather as many dossiers as possible under one Specific Agreement to reduce administrative burden for all parties involved.

### QUESTION 3:

For Lot 8; To collect from across the lots information/expert evaluations from lot 1-7 into a draft opinion; how to coordinate this? Will EFSA inform experts from the various consortiums to whom and when they should submit their evaluations?

### ANSWER 3:

Coordination of Lot 8 is responsibility of the partner awarded to Lot 8 based on the selection criteria. EFSA will inform other partners who were entrusted these tasks. The partner awarded to Lot 8 will be kept in the communication loop by EFSA since the beginning of the outsourcing activity, e.g. how a specific dossier will be entrusted to which partner and with which deadline.

**QUESTION 4:**

For table 4 in the Call: is it correctly understood that the amount of money estimated for a given task (e.g. lot 1, complexity level 1 = 1,320€ or lot 6, complexity level 3 = 6,600€ ) shall potentially cover:

- all tasks A-G listed on page 10, (or on page 11-12) and
- the time used by the coordinator within a consortium for coordination/distribution of tasks and the following quality check of the experts drafts, and
- potentially a travel to EFSA by an expert, if EFSA request so, as well as
- the time used for (online?) training?

It is foreseen that whether this is economically feasible for a co-beneficiary will depend on the number of tasks (and complexity) that EFSA entrust to the single co-beneficiary. It will also have an influence on the time (money) allocated to the actual work on the draft it-self by the expert.

**ANSWER 4:**

Yes, completion of the work on one single dossier includes above bullet points, and the output value per dossier per lot is indicated in Table 4 in the Call. See also the answer to Question 1. For the training, please consult Answer 26 ([here](#)) to the Clarification 3 related to the questions addressed during the Info session on 20 September 2022.

**QUESTION 5:**

For task (H) on page 10 (and task (G) on page 12) – for which a special agreement will be made; who will be legally responsible for that all relevant confidential data have been blackened? Will EFSA do quality control on what the partner submit of blackened material?

**ANSWER 5:**

The responsibility of the partner is to highlight which text should be redacted. EFSA will do quality control check afterwards.

**QUESTION 6:**

For the training offered (a brilliant idea!) – What type of training is EFSA prepared to give to partners? Has EFSA identified specific lots or regulatory domains to which training is expected (will training be provided if a need is identified within a consortium, and/or will EFSA provide training for all consortia?) And will training be given in how to understand regulations, EFSA guidelines/Guidance/use of data-bases/wordings in the opinions (for the following use by the risk managers)/EFSA templates?

**ANSWER 6:**

Please consult Answer 26 ([here](#)) to the clarification 3 related to the questions addressed during the Info session on 20 September 2022.

**QUESTION 7:**

With the exception of the general information mentioned in article II.25.4 Step 4 - Reduction due to improper implementation, irregularity, fraud or breach of obligations of the draft FPA, there is no

mention in the call for proposals of the possibility of financial penalties in case of delay in the transmission of deliverables. Is this case foreseen for this call, if so what are the precise conditions?

**ANSWER 7:**

Possible payment reductions in connection to delays in the implementation of the action defined in the Specific Agreements will be dealt with under the provisions of Article II.25 of the FPA.

**QUESTION 8:**

Considering the complexity of the topic and the time necessary to build up a consortium, we would kindly ask EFSA if an extension of the current deadline could be considered.

**ANSWER 8**

The deadline for submission of proposals will be postponed from 3<sup>rd</sup> November 2022 to 30<sup>th</sup> November 2022. A corrigendum to the call for proposal will be published shortly.