CLARIFICATION 3

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

Q1 to Q34 raised during Info session on Tuesday 20 September 2022

Q35 received in writing via EFSAProcurement@efsa.europa.eu

QUESTION 1:

Can the financing amounts predefined by EFSA based on complexity of dossiers be re-negotiated?

ANSWER 1:

The output value based on the complexity of dossiers is already established in the Call and cannot be re-negotiated. The complexity level is decided a priori by EFSA. The output value is predefined on the basis of experience of EFSA's work on similar dossiers.

QUESTION 2:

Would it seem feasible to increase the budgets indicated on page 19 of the call for proposals, which seem to be somewhat undersized in relation to the work to be done?

ANSWER 2:

See reply to Question 1.

QUESTION 3:

Could you please clarify for lot 4 (allergenicity): is it only for enzymes or also for food additives (see the appendix 1 in the call)?

ANSWER 3:

Lot 4 on Allergenicity assessment is envisaged for food enzymes area only.

QUESTION 4:

Does that mean that a partner can finalise the evaluation of one dossier (task) in 5 weeks and continue working with the other dossiers (task) within a lot?

ANSWER 4:

Yes, under one Specific Agreement several dossiers from different regulatory domains may be included and the deadline for the evaluation of one dossier is indicatively 5 weeks (for new/renewal applications) or indicatively 8 weeks (for re-evaluation of food additives) after getting access to the dossier/supporting information. Please bear in mind that before signing the Specific Agreement, partners will be presented and explained the deadlines for the assessment.

QUESTION 5:

Does the conflict of interest analyse done by a MS partner on its team of experts be accepted by EFSA?

ANSWER 5:

No, an applicant applying to this grant is subject to EFSA Policy on Independence and the Decision of the EFSA Executive Director on Competing Interest Management.

QUESTION 6:

Does the delay of 5 weeks applies to the whole lot or to individual dossiers within the lot?

ANSWER 6:

Please see the reply to Question 4.

QUESTION 7:

For a past EFSA call of a similar type (also applied in 2022), we submitted legal entity forms and other supporting docs. These won't change for our organization. Can these be reused by EFSA if we submit an application, and make a reference to the previous proposal?

ANSWER 7:

Yes for the Legal Entity and Financial Identification forms, however, these documents should not be older than one year, and no changes should have occurred in the reported information. When submitting an application to this call, the applicant should indicate from which past application(s) EFSA can retrieve which form.

QUESTION 8:

How is it possible to become a partner in a consortium? Does any institution applying for the grant search for additional partner?

ANSWER 8:

Applicants interested in forming a consortium with another institution(s) are responsible for searching for and contacting other Art. 36 institution(s).

QUESTION 9:

How will this call affect the workload of the current Panel and working groups working on these substances? Is a substantial decrease or increase foreseen?

ANSWER 9:

This 4-year Framework Partnership Agreement aims at establishing a long-term collaboration with Article 36 organisations. A gradual increase in the number of the dossiers to be evaluated in the subsequent years is envisaged. This approach takes into consideration the fact that time is needed to gain experience and fine-tune the preparation of the scientific opinions with the desired quality by the WG/Panel. Therefore, in practice an increased workload of the Panels is foreseen, however unlikely in the first years.

QUESTION 10:

I understood that a consortium can arrange the work within the consortium, as we wish (as long as we meet the deadline set by EFSA)?

ANSWER 10:

Yes, the organisation of the work among partners within the consortium is the sole responsibility of the partners, ensuring that the deadlines are met.

QUESTION 11:

If we identify a data gap and this result in EFSA uses the "stop the clock" function, and the applicant then submit new information/explanation - what then? Will EFSA deal with that or will a new request for performing the task of evaluate the new information?

ANSWER 11:

Once EFSA requests a partner to update a draft opinion with the additional data received from an applicant, the partner will receive a specific deadline to fulfil this task (namely task D in Sections 1.3.1.1 and 1.3.1.2 in the text of the Call). This task is already covered by the same Specific Agreement as tasks A-C for the same dossier, only the completion of task D is prolonged in time due to the need to await receipt of additional data.

QUESTION 12:

If you apply to just one lot and are highly ranked, whether or not you will be invited to sign a specific agreement will depend on the aspects (lots) of relevance for the particular lot?

ANSWER 12:

According to the mechanism described in Table 3 Section 1.3.3 of the Call, there are two options.

Option 1: if the applicant applies only to one lot and EFSA needs to task the work of the concerned dossiers only in this specific lot, then the beneficiary who received the highest score in this lot will be contacted.

Option 2: if EFSA needs to task the work of the concerned dossiers in several lots, the applicant who applied to those lots and has the highest combined total score will be contacted.

In addition, the cascade mechanism provides that in case the first ranked beneficiary does not accept the proposed Specific Agreement or does not reply within 5 working days, the beneficiary ranked second will be consulted. In case the second ranked beneficiary does not accept the proposed Specific Agreement or does not reply within 5 working days, the beneficiary ranked third will be consulted etc.

QUESTION 13:

In case of a proposal presented by a consortium, is it possible that two or more partners justify competency on the same lot?

ANSWER 13:

Yes it is possible.

QUESTION 14:

In case of traveling to EFSA premises for meetings, how will the expenses be covered?

ANSWER 14:

As indicated in Section 1.3.4 of the Call, the tasks entrusted through the Specific Agreements will be conducted by the partners in the premises of beneficiary. However, some meetings might be requested to be held in EFSA premises, and if this necessity arises, all related expenses are considered already covered by the all-inclusive pre-defined output values set in the Specific Agreement.

QUESTION 15:

In our scientific groups, we have expertise in food additives but not feed additives. Can we submit our interests across several Lots for only food additives?

ANSWER 15:

As indicated in Table 2, Section 1.2.2 of the Call, the lots are organised according to scientific expertise envisaged across all regulatory domains. This means that the successful applicant may be tasked in all domains to the same extent. In the application, please indicate the domain where your technical strength lies. Based on the experience of EFSA, if expertise to assess food additives is available, after a short training on the legal frameworks and sectorial guidance documents, the same expertise can become also applicable to evaluate feed additives. This was also explained in Clarification 1 available at: https://www.efsa.europa.eu/sites/default/files/documents/art36/gpefsafip202201/clarification-1-risk-assessment-fip.pdf

QUESTION 16:

In the Call document it is said that the applicant should provide a team of experts (page 26) with evidence of CVs. Does that mean that EFSA will finally decide which experts can be gathered by a partner?

ANSWER 16:

The CVs of the experts submitted with the proposal will be evaluated by EFSA as evidence that the applicant's team possesses the required expertise to meet the selection criteria of this Call for proposals. When the actual needs arise during implementation of the Framework Partnership Agreement, EFSA will request the CVs of the proposed experts for the specific assignment and will assess them, together with their Declaration of Interest, before the Specific Agreement is signed.

QUESTION 17:

Is it correct to assume that there's no page or word limit for the technical proposal?

ANSWER 17:

Yes, there is no word and page limit for the technical proposal.

QUESTION 18:

What should be included in a proposal for this call? Is there a template for proposal? Is there a word limit?

ANSWER 18:

The proposal must be submitted using the EFSA application form (annex 2). The application form provides a checklist with the list of documents to be included in the application. There is no word limit.

Please also refer to Answer 1 in Clarification 2 previously published and available athttps://www.efsa.europa.eu/sites/default/files/documents/art36/gpefsafip202201/clarification-2-risk-assessment-fip.pdf

QUESTION 19:

Is it possible to submit the hardcopy of the application with electronic signatures?

ANSWER 19:

Yes, electronic signatures are acceptable.

QUESTION 20:

Is step 8 of the process (finalisation of draft scientific opinion by EFSA working group) compulsory or is it envisaged that eventually the product delivered by the beneficiary could be presented directly to the Panel, and that the beneficiary could thus have more time to deliver his work?

ANSWER 20:

Finalisation of the draft opinion in the WG (step 8) indicated on Figure 1 Section 1.3.1.1 of the Call is an integral part of the workflow for scientific risk assessment of new/renewal applications. Step 8 provides another quality check before presenting the opinions to the Panels for adoption. In the first years, step 8 is unavoidable. EFSA will monitor the performance of the beneficiaries and the quality of the deliverables. Should this happens that entire draft opinions prepared by a beneficiary reach constantly the level of an EFSA WG, it can be envisioned that those draft opinions could be presented directly to the Panels.

QUESTION 21:

Is there any restriction in relation to experts involved in EFSA WGs or Panels to be involved in a consortium for this grant?

ANSWER 21:

The involvement of an expert of the EFSA Panel/WG in the grant does not constitute per se a CoI (conflict of interest). To note that the respective expert will have to refrain from discussing in the WG or Panel the applications to which he/she participated in the context of the grant, should such applications be put for discussion in the respective WG. This was also explained in Clarification 2 available at: https://www.efsa.europa.eu/sites/default/files/documents/art36/gpefsafip202201/clarification-2-risk-assessment-fip.pdf

QUESTION 22:

Will there be different deadlines for the tasks within a SA? Otherwise it could be difficult to take on a SA with many tasks?

ANSWER 22:

Yes, there may be different deadlines for the tasks within one Specific Agreement because the specific task may relate to more than one regulatory domain with different deadlines for safety assessment, and this will be outlined in the Specific Agreement. It should also be stressed that EFSA will present and explain the content of the work, the workload and the timelines before signing a Specific Agreement.

QUESTION 23:

Specific question on exposure assessment food additives. FAIM is now used for new/extension of uses. Applicant is requested to complete the FAIM template. For re-evaluation EFSA?

ANSWER 23:

As specified in the text of the call, the activities to be covered in the area of food additives evaluations may fall either under the scope of new applications submitted under the Common Authorisation Procedure, i.e. Regulation (EC) No 1331/2008, or under the re-evaluation programme set in Regulation (EC) No 257/2010. Indeed, the use of the FAIM online tool to estimate dietary exposure is usually applied to new applications but we cannot exclude that in the future there could be cases in which the tool could be used also for other evaluations (e.g. re-evaluation of food additives or evaluations of new flavourings substances).

QUESTION 24:

The analysis of some parts of the dossier maybe not be necessary depending on the evaluation of some sections (e.g. toxicity not needed if not exposure). How will it be?

ANSWER 24:

The partners will be entrusted the preparation of the section(s) of the opinion(s) relevant to the lot(s) they applied for. EFSA will take care to provide the partners with the relevant parts of the dossier(s) that are needed for the evaluation.

QUESTION 25:

The partners for consortium must be institutions or can it be individuals experts?

ANSWER 25:

The partners in the consortium must all be Article 36 organisations. Individual experts cannot be partners.

QUESTION 26:

There was a mention of training. Could you provide some details on how this is foreseen? Will trainings be provided before dossiers are allocated?

ANSWER 26:

The training we referred in the presentation is related to the training particularly in regulatory domains as the scientific expertise needed to assess the lots should already be reached in the submitted application to this call and assessed in the selection criteria. For successful candidates, EFSA will provide a training, covering an explanation of the relevant EFSA procedures and tools needed to perform the entrusted tasks. EFSA envisages that this training will be provided before issuing any Specific Agreement either in the virtual or physical form depending on the pandemic situation.

QUESTION 27:

There will be any seminars with the selected organizations at the beginning of the process to harmonize the drafting and criteria?

ANSWER 27:

After the framework contract is signed, a dedicated introductory meeting will be organised bringing all the partners together and explaining what needs to be done and how to harmonise the drafting opinions.

QUESTION 28:

What if a partner is busy with 1 dossier (is in week 3) and then receives another dossier (in week 3), will the partner get additional time for the overlapping period?

ANSWER 28:

If this situation happens it will be defined upfront in the Specific Agreement, so the partner will know in advance the schedule of the tasks before accepting the Specific Agreement. Moreover, if a partner is busy with completion of the tasks under one Specific Agreement, (s)he is not obliged to take up new dossiers as there is a cascade mechanism applied to this Call and the next partner in the cascade can be asked to take up the subsequent dossiers.

QUESTION 29:

What is a final deliverable? E.g., a deliverable conditioned to stop the clock response, would not be financed until the applicant completed it?

ANSWER 29:

If a partner cannot finalise the work due to stop-the-clock being applied by EFSA for a period longer than 6 months, EFSA can agree to a request for an **interim payment** of 70% of the grant amount specified in the Specific Agreement. For more details, please consult Section 1.8 of the Call for proposals.

QUESTION 30:

What is the proportion of single level (or 2 or 3) for enzymes folders?

ANSWER 30:

The level of complexity in a lot can be seen also by the number of days required for completion of the work. In general, food enzyme' dossiers are of medium complexity. However, exception exists. One example is an animal rennet dossier which is considered of low complexity, whilst a dossier with multiple *in vivo* toxicity tests is considered of high complexity.

QUESTION 31:

Will a (tox) literature search also be part of the Specific Agreements or will all information to be evaluated be provided via EFSA?

ANSWER 31:

The thorough literature search is not envisaged. The information to be evaluated will be provided by EFSA.

QUESTION 32:

Will the partners be able to choose the lots depending on the nature and number of dossiers?

ANSWER 32:

EFSA will offer the work in lots and dossiers in a Specific Agreement by following the cascade mechanism. The beneficiary ranked higher can accept or reject the offer. In case of consortium, it is up to the consortium's partners to agree on the distribution of work and workload.

QUESTION 33:

Will the questions being addressed now be published as clarifications on the website?

ANSWER 33:

Yes, the questions and answers provided during the Info session will be published on the EFSA website.

QUESTION 34:

Will you know in advance the composition of lots regarding the nature and number of dossiers?

ANSWER 34:

The precise number of dossiers is not known at present. However, in Section 1.4 of the Call for proposals, EFSA has provided an estimate of the budget break-down between lots of the 4-year duration of the Framework Partnership Agreements.

QUESTION 35: Regarding lot 5 and 6, we are wondering whether as "target species" the call refers to species strictly related to food production or "model species" are also of interest within the call? Secondly, the enzymes, additives, and flavourings you are interested in, are only products already "registered" or they can also be "candidates"?

ANSWER 35:

The studies to be evaluated in lot 5 and lot 6 can be done in target species or in species allowing for conclusions in the target species for which authorisation is sought. Target species in feed dossiers include food-producing and non-food-producing animals. Zebra fish could be a potential target species and consequently studies carried out with zebra fish be present in dossiers for feed additives to address the safety (e.g., tolerance studies) and the efficacy of the additive. However, such studies may be seldom seen in the assessments because the data may not be needed in case data are available from other relevant species (e.g., salmonids). The use of studies conducted with the zebra fish as a model for other species in the context of lot 5 and 6, is limited due to the requirements established in the guidances (See in Appendix 1 the links to the guidance on the safety for the consumers (lot 5) and the guidance on the safety for the target species and efficacy (lot 6)). It is noted that zebra fish may be used in the context of toxicological studies which may be present in lot 3.

Regarding food enzymes, food additives and flavourings, please consult Section 1.3.1.1. (for new/renewal applications) and Section 1.3.1.2 (for re-evaluation of food additives) of the Call for proposals (here).