



CLARIFICATION 1

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:

For the dossiers, are new evaluations foreseen or is it solely re-evaluation of existing dossiers?

ANSWER 1:

Tasks under this call will cover incoming dossiers which could be both new and/or renewal applications (as indicated in Section 1.3.1.1 of the call) and re-evaluation of approved food additives under Reg. (EC) No 257/2010 (as indicated in Section 1.3.1.2 of the call).

QUESTION 2:

Our scientific groups are strong in food additives, but not feed additives. Is it possible to apply for one or more lots in the food additives & food flavourings, except feed additives?

ANSWER 2:

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. From our experience, if the expertise to assess the food additives is available, after a short training, it should be possible to assess also the feed additives.

QUESTION 3:

In case the answer to the above is 'No', is it possible to receive training to handle dossiers related to 'feed additives'?

ANSWER 3:

On the job trainings are foreseen for each lot separately. Some lots cover all regulatory domains, others are specific only to 'feed additives'.

QUESTION 4:

In your guidelines, we came across 'toxicological assessment'. This is a very broad & general area. Would you be able to specify or segregate this topic into specific area to help us identify the type of tasks entrusted within it? Is this something foreseen for the next info session?

ANSWER 4:

Your question refers to Lot 3. The expertise required for this lot covers all the toxicology-related areas that one may encounter in the most complex dossiers. However, dossiers with low and medium complexity will require expertise in only part of the toxicology-related areas. The segregation of those areas can also be found in Appendix 1 of the call which details the type of toxicological studies in dossier for each regulatory domain. EFSA will clarify this point also in the upcoming info session.

QUESTION 5:

The number of foreseen dossiers is projected per year (40 for Y1, 50 for Y2, etc.), but how large would the pool of applicants/experts be? In other words, how can we estimate what amount of dossiers we will receive?

ANSWER 5:

It is the task of a single applicant or a consortium to make an estimation of the number of experts needed to handle up to 40 or more dossiers per year. 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. Rough estimation that takes into consideration also the training needs of successful applicant(s) in the first year may involve up to 40 dossiers in the first year and up to around 70 dossiers in the final year. Furthermore, it is envisaged that EFSA will not task 40 dossiers in the same specific contract, hence it could be possible that a successful applicant would be offered a lower number of dossiers in a specific contract. It also needs to be stressed that this 4-year framework partnership agreement aims at establishing long-term collaboration and as such should be considered.

QUESTION 6:

When dossiers are allocated to MS partners, is it possible to decline (e.g. due to valid reasons of unsuitability/lack of expertise, etc.)?

ANSWER 6:

For the winners of the framework contract, EFSA will launch specific agreements per lot with the selected organisation(s) and/or consortium with specified workload and timeline. It is possible to decline the work at that stage. However, once a specific agreement is signed, the contract is binding.

QUESTION 7:

Regarding consortium formation, could private agencies participate?

ANSWER 7:

As explained in Section 1.2.2 of the call, the overall objective of the call is the identification of several partners among Article 36 organisations, and only Article 36 organisations are eligible to apply to this call either as a single Article 36 organisation or as a consortium of several Article 36 organisations. List of Article 36 organisations can be found [here](#).