CLARIFICATION N°2

Call reference: EUBA-EFSA-2024-NIF-01
Call title: Contribution to the Risk Assessment of Novel Foods and Nutrient Sources in the EU.

Question 1: Our organization has signed an ongoing framework partnership agreement with EFSA under the call : GP/EFSA/NUTRI/2021/01 "Support to EFSA in the Safety Assessment of Novel Foods and Nutrient Sources ". This agreement will expire in November 2026. We would like to ask if the activities of the previous call may overlap with those of this new agreement.

Answer 1: The new call (EUBA-EFSA-2024-NIF-01) is an evolution of the previous call (GP/EFSA/NUTRI/2021/01) and is more comprehensive. It will be more favorable for both EFSA and the beneficiaries. The previous call will be phased out once the new agreements have been signed. During the transition EFSA will minimize the risk of overlap between the two calls.

Question 2: The experts involved in specific agreements of the present call will be among the authors of the final opinion issued by EFSA? In other words, does EFSA recognize any kind of authorship to the agreement participants?

Answer 2: Internal discussions are ongoing on how to acknowledge the beneficiaries, when they draft entire sections/draft opinions in accordance with the applicable legal framework.

Question 3: We wonder if the scientific statement on novel foods is solely on written opinion, i.e. no practical procedures shall be applied (e.g. Laboratory analyses).

Answer 3: The deliverable to be provided to EFSA will solely be based on a Novel Food dossier, which consists of studies/reports/certificates of analyses/various types of documentation/published/unpublished literature etc. No practical work, like laboratory analyses, will have to be performed. The provision of all the reports/data/analyses is the responsibility of the applicant of a Novel Food application.

Question 4: In the call, there is mentioned term "risk assessment". Does it mean that a specific procedure according to risk assessment standard (ISO or specific methodology) shall be applied for all fields of the evaluation process? We suppose that there is a great difference between "management of risk assessment" and "scientific opinion". This is not clearly specified in the call.

Answer 4: EFSA is a risk assessment body. Risk management is outside the remit of EFSA. Further information/clarification on the principles of risk assessment vs risk management and EFSA's role can be found in the General Food Law, i.e., Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002.

Question 5: What do you mean with Centralised scientific coordination?

Answer 5: As specified in section 2.4.B.1 of the call for proposals, the applicant should provide evidence of expertise (at least 3 years) in Centralised scientific coordination to be proved by a recently finalised research project (within the last 3 years) and a new or ongoing research project relevant to the topics of this grant. This should be interpreted as coordinating the whole exercise from a scientific point of view, e.g. distributing tasks among members of the team of experts and collating all the information into a single draft.

Question 6: Can we find somewhere an example of dossier template for scientific opinion?

Answer 6: The structure of a scientific opinion dealing with the safety assessment of a Novel Food can best be seen in already finalised and published Novel Food opinions, which contain all the relevant sections. Numerous examples can be found on the EFSA website here: https://www.efsa.europa.eu/en/publications choosing under Topic "Novel food" and under Type "Scientific Opinion".

Question 7: Can we get an example of the particular dossier that will be in the project evaluated?

Answer 7: Novel Food dossiers cannot be shared, owing to confidentiality. However, the names and types of Novel Foods which are under assessment and/or are about to enter the risk assessment process can be found on OpenEfsa here https://open.efsa.europa.eu/questions .