FIP AND FEEDCO UNITs

NEW SIMPLIFIED FORM OF GRANT:
FINANCING NOT LINKED TO THE COSTS

CALL FOR PROPOSALS
and guide for applicants

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

Restricted to the list of competent organisations adopted by EFSA Management Board according to Article 36 of European Parliament and Council Regulation (EC) No 178/2002

European Food Safety Authority
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INDICATIVE PROCEDURE TIMETABLE

Milestone	Date[1]	Comments
Launch date	26/07/2022	Date of call publication on EFSA's website.
Deadline for applicants to raise clarification questions to EFSA	~~26/10/2022~~ ~~22/11/2022~~ ~~05/01/2023~~ 23/01/2023	If, after having read this Call for proposals and guide for applicants, you have any questions, you may address them to EFSAProcurement@efsa.europa.eu by indicating the Call reference.
Deadline for EFSA to reply to clarification questions	~~28/10/2022~~ ~~24/11/2022~~ ~~09/01/2023~~ 25/01/2023	Replies will be provided on EFSA's webpage where this Call is published and which the applicants are requested to consult regularly.
Deadline for submission of proposals Any proposal posted after the final deadline will automatically be rejected.	~~03/11/2022~~ ~~30/11/2022~~ ~~13/01/2023~~ **31/01/2023**	Applicants can submit proposals: - either by post (registered mail) or by courier not later than ~~03/11/2022~~ ~~30/11/2022~~ ~~13/01/2023~~ **31/01/2023**, in which case the evidence of the date of dispatch shall be constituted by the postmark or the date of the deposit slip, to the address indicated below. The applicant submitting a proposal by post or by courier is requested to send an informative e-mail to EFSAProcurement@efsa.europa.eu. - or delivered by hand **not later than 12.30 hours (Italian time) on** ~~03/11/2022~~ ~~30/11/2022~~ ~~13/01/2023~~ **31/01/2023** to the address indicated below. In this case, a receipt must be requested from EFSA as proof of submission, signed and dated by the staff member in EFSA Post Office who accepted the delivery. The EFSA Post Office is open from 8.30 to 12.30 Monday to Friday. It is closed on Saturdays, Sundays and EFSA holidays. Submission by post, courier or hand to this address: *European Food Safety Authority - EFSA* *For the attention of – Simone PETTINAU, Finance Unit (Procurement Team)* *Via Carlo Magno 1/A, I – 43126 Parma, Italy* Proposals must be submitted using the double envelope system. The outer envelope should be sealed with adhesive tape, signed across the seal and carry the following information: - *"CALL FOR PROPOSALS GP/EFSA/FIP/2022/01 – NOT TO BE OPENED BY THE INTERNAL MAIL DEPARTMENT".* - name of the applicant - **the posting date should be legible on the outer envelope**
Notification of the evaluation results	~~December 2022~~ ~~January 2023~~ March 2023	Estimated. *Attention: outcome of the present call will be communicated to all applicants to the e-mail address indicated in their proposal. Accordingly, applicants who have submitted proposals under the present call are strongly invited to check regularly the inbox in question.*
Grant agreement(s) signature	~~January 2023~~ ~~February 2023~~ April 2023	Estimated.

[1] All times are in the time zone of the country of EFSA.

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1. GRANT OPPORTUNITY AND CONDITIONS[2]

1.1 LEGAL FRAMEWORK

Article 36 (1) of **the Regulation (EC) 178/2002**[3] **of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety**, stipulates that the Authority shall promote the European networking of organisations operating in the fields within the Authority's mission. The aim of such networking is, in particular, to facilitate a scientific cooperation framework by the coordination of activities, the exchange of information, the development and implementation of joint projects[4], the exchange of expertise and best practices in the fields within the Authority's mission.

The Commission Regulation (EC) 2230/2004[5] **of 23 December 2004 laying down detailed rules for the implementation of the European Parliament and Council Regulation (EC) 178/2002 with regard to the network of organisations operating in the fields within the EFSA's mission** specifies in Article 4 that tasks may be entrusted by the Authority to organisations on the list of competent organisations. **The present call specifically focuses on tasks defined in Article 4(3), 5th point - preparing the Authority's scientific opinions, including preparatory work relating to the assessment of authorisation dossiers.**

Article 5(2) of **the Commission Regulation (EC) 2230/2004** specifies that the financial support to the networking organisations shall take the form of subsidies (grants) awarded in accordance with the EFSA's financial regulation and implementing rules.

The present Call for proposals and guide for applicants (hereinafter referred to as "the Call") is procedurally governed by Title VIII of **Regulation (EU, Euratom) 2018/1046 of the European Parliament and of the Council of 18 July 2018 on the financial rules applicable to the general budget of the Union**.

The present Call is based on **EFSA's 2022 Work Programme for grants and operational procurements** as presented in Annex IX of the Programming Document 2022 – 2024, available on the EFSA's website[6].

On 19 December 2006 the Management Board, acting on a proposal from the Executive Director, drew up a **list of competent organisations designated by the Member States** which may assist EFSA, either individually or in networks, with its mission. This list is regularly updated by EFSA's Management Board.

The Transparency Regulation (EU) No 1381/2019 amending the Regulation (EC) 178/2002 entered into force on 27 March 2021.

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[2] The applicant is reminded that this Call and guide for applicants contains a selection of the most important conditions for the grant implementation. For the full set of conditions, the applicant is invited to consult the draft grant agreement attached to this Call.

[3] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2002:031:0001:0024:EN:PDF

[4] Project is frequently referred to in this Call as "action", in line with EU Financial Regulation terminology.

[5] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2004:379:0064:0067:EN:PDF

[6] https://www.efsa.europa.eu/sites/default/files/corporate_publications/files/amp2224.pdf

Article 28(5e) of the Regulation (EC) 178/2002[7], as amended, states that the Authority shall support the tasks of the Scientific Committee and Scientific Panels by organising their work, in particular the preparatory work to be undertaken by the Authority's staff or by designated national scientific organisations referred to in Article 36, including by organising the possibility for preparing scientific opinions to be peer-reviewed by the scientific Panels before they adopt them.

Ensure preparedness for future risk analysis needs is one of three strategic objectives of EFSA's 2027 Strategy. An expected outcome of this objective is to reach increased risk analysis capabilities in partnership with national scientific organisations to prepare draft scientific opinions that will subsequently be reviewed and adopted by the EFSA scientific Panels.

1.2 BACKGROUND AND OBJECTIVE OF THE CALL

1.2.1 BACKGROUND

EFSA is responsible for EU risk assessments of materials from farm to fork. With this Call for Proposals, EFSA is exploring a new opportunity to involve Article 36 organisations in the preparation of draft opinions (specific sections or in full) for four regulatory domains: food enzymes, food flavourings, food additives and feed additives.

Risk assessments on **food enzymes** are carried out by the Panel on Food Contact Materials, Enzymes and Processing Aids (CEP Panel) and its Enzymes Working Group, coordinated by the food enzymes team of EFSA's FIP unit and following the related EU Regulatory framework. Specific requirements for the preparation and presentation of a dossier for food enzymes are included in a specific guidance document (EFSA CEP Panel, 2021[8]).

Risk assessments on **food flavourings** are carried out by the Panel on Food Additives and Flavourings (FAF Panel) and its Working Groups, coordinated by the food additives and flavourings team of EFSA's FIP unit and following the related EU Regulatory framework. Specific requirements for the preparation and presentation of a dossier for food flavourings and the risk assessment paradigm applied are included in specific guidance documents (EFSA CEF Panel, 2010[9]; EFSA FAF Panel, 2021[10]).

Risk assessments on **food additives** are carried out by the Panel on Food Additives and Flavourings (FAF Panel) and its Working Groups, coordinated by the food additives and flavourings team of EFSA's FIP unit and following the related EU Regulatory framework. Specific requirements for the preparation and presentation of a dossier for food additives and the risk assessment paradigm applied are included in a specific guidance document (EFSA ANS Panel, 2012[11]).

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7 https://eur-lex.europa.eu/eli/reg/2002/178/oj/eng

8 EFSA CEP Panel (EFSA Panel on Food Contact Materials, Enzymes and Processing Aids), 2021. Scientific Guidance for the submission of dossiers on Food Enzymes. EFSA Journal 2021;19(10):6851, 37 pp. https://doi.org/10.2903/j.efsa.2021.6851

9 EFSA CEF Panel (EFSA Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids), 2010. Guidance on the data required for the risk assessment of flavourings to be used in or on foods. EFSA Journal 2010; 8(6):1623. https://doi.org/10.2903/j.efsa.2010.1623. This guidance is currently undergoing revision, please also refer to draft document that underwent public consultation https://connect.efsa.europa.eu/RM/s/publicconsultation2/a0l7U0000011Yej/pc0168.

10 EFSA FAF Panel (EFSA Panel on Food Additives and Flavourings), 2021. Scientific Guidance for the preparation of applications on smoke flavouring primary products. EFSA Journal 2021; 19(3):6435, 40 pp. https://doi.org/10.2903/j.efsa.2021.6435

11 EFSA ANS Panel (Panel on Food Additives and Nutrient Sources added to Food), 2012. Guidance for submission for food additive evaluations. EFSA Journal 2012;10(7):2760, 60 pp. https://doi.org/10.2903/j.efsa.2012.2760

In accordance with Regulation (EC) No 257/2010[12], EFSA is also tasked to re-evaluate **food additives** that were already authorised for use in food as of 20 January 2009. The re-evaluation programme was due to be completed by the end of December 2020. To date, EFSA has a backlog of 80 substances to be re-evaluated in approximately 25-28 scientific opinions (see Appendix 2).

Risk assessments on **feed additives** are carried out by the Panel on Additives and Products or Substances used in Animal Feed and its Working groups, coordinated by the feed team of EFSA's FEEDCO unit and following the related EU Regulatory framework. The structure of a dossier on feed additives is described in Annex II of Regulation (EC) No 429/2008 and should follow the guidance documents prepared by the FEEDAP Panel[13].

EFSA has legal deadlines to deliver safety assessments of new and/or renewal applications within the remit of the above-mentioned regulatory domains which range from six months (smoke flavourings, feed additives) to nine months (food enzymes, food additives, food flavourings) from receipt of a valid application for assessment.

Table 1 shows the structure of a scientific opinion per regulatory domain. Different areas of expertise are required to evaluate the data and draft the corresponding parts. Table 1 demonstrates several common areas of expertise to deliver safety assessments across different regulatory domains. To maximise use of resources, EFSA decided to launch a call for a Framework Partnership Agreement covering all regulatory domains with eight (8) lots. Each lot corresponds to a specific areas of expertise.

Table 1. Structure of a scientific opinion across regulatory domains

Food enzymes	Food additives & flavourings	Feed additives
1. Source of the food enzyme a. Characteristics of the parental and recipient microorganisms b. Characteristics of introduced sequences c. Description of the genetic modification process d. Safety aspects of the genetic modification **2. Food enzyme characterisation** a. Properties of the food enzyme b. Compositional data c. Purity d. Manufacturing process	**1. Existing authorisations and risk assessments** **2. Identity and characterisation of the food additive/food flavouring** a. Identity of the food additive/food flavouring b. Specifications of the food additive/food flavouring c. Manufacturing process (including use of production organisms) d. Physico-chemical properties of the food additive/food flavouring e. Methods of analysis in food f. Stability, reaction and fate in food	**1. General aspects** **2. Identity, characterisation and conditions of use of the feed additive** a. Identity of the additive b. Characterisation of the active substance(s)/agent(s) c. Manufacturing process, including any specific processing procedures d. Physico-chemical and technological properties of the additive e. Conditions of use of the additive f. Methods of analysis and reference samples

[12] Commission Regulation (EU) No 257/2010 of 25 March 2010 setting up a programme for the re-evaluation of approved food additives in accordance with Regulation (EC) No 1333/2008 of the European Parliament and of the Council on food additives. Available online at: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A32010R0257

[13] Available online at: https://www.efsa.europa.eu/en/applications/feedadditives/regulationsandguidance (see section on the scientific guidance).

e. Viable cells and DNA of the production strain **3. Toxicological information** a. Genotoxicity b. Sub-chronic toxicity **4. Allergenicity information** a. Homology search with known allergens b. Literature search **5. Dietary exposure** a. Intended use of the food enzyme b. Removal/absence of transfer of Total Organic Solids (TOS) during food manufacturing process c. Calculation of exposure	**3. Use in food and exposure assessment** a. Occurrence data in food b. Natural occurrence data in food c. Dietary exposure assessment **4. Biological and toxicological data** a. Data on ADME (adsorption, distribution, metabolism, excretion) b. Genotoxicity data c. Toxicity data	**3. Studies concerning safety of the additive** a. Safety of use of the additive for the target animals b. Safety of use of the additive for consumers c. Safety of use of the additive for users/workers d. Safety of use of the additive for the environment **4. Studies concerning the efficacy of the additive** a. In vitro studies b. Short term efficacy studies with animals c. Long term efficacy studies with animals

1.2.2 OBJECTIVE OF THE CALL

The overall objective of the present Call is **the identification of several partners among Article 36 organisations** - to which EFSA can entrust at any time during the next 4 years the tasks of contributing to the **preparatory work for the safety assessment of food enzymes, food additives & flavourings and feed additives**. The involvement of the partners in the risk assessment workflow is explained in section 1.3.1.

The Call consists of eight (8) lots, each corresponding to a specific area of expertise shown in Table 2. A detailed explanation for each lot is given in section 1.3.2.

Only Article 36 organisations are eligible to apply to this Call (see section 1.5). Proposals can be submitted by a single Article 36 organisation or by a consortium of several Article 36 organisations. Proposals can be submitted for one or more lot(s). Roles and responsibilities of involved organisations are defined in Section 1.6.

Table 2: Overview of scientific expertise organised in lots

Lot No	Lot title	Envisaged work in regulatory domains
Lot 1	Assessment of the data regarding the identification and characterisation of microorganisms used as such or as production strains	Food enzymes, food additives & flavourings and feed additives
Lot 2	Assessment of the identity and characterisation of a food enzyme, food additive, food flavouring or feed additive	Food enzymes, food additives & flavourings and feed additives
Lot 3	Assessment of toxicological safety	

	ADME(R) studies	Food additives & flavourings and feed additives
	Genotoxicity and toxicological studies (e.g., sub-chronic oral toxicity study, chronic oral toxicity studies)	Food enzymes, food additives & flavourings and feed additives
	QSAR analysis	Food additives & flavourings and feed additives
	Toxicological testing relevant for user safety	Feed additives
Lot 4	Allergenicity assessment	Food enzymes
Lot 5	Dietary exposure	Food enzymes, food additives & flavourings and feed additives
Lot 6	Assessment of efficacy and safety for target animal species	Feed additives
Lot 7	Environmental risk assessment	Feed additives
Lot 8*	Opinion assemblage	Food enzymes, food additives & flavourings and feed additives

*Note: Lot 8 can be applied for only in conjunction with at least one other lot. Colour coding: grey denotes common area of expertise needed to undertake safety assessments across three regulatory domains.

With the partner(s) selected following this Call for proposals, EFSA will sign **with each of them a 4-year Framework Partnership Agreement (FPA)**. Once the FPAs are signed, as soon as a specific need for support arises, EFSA will decide the lot(s) to be entrusted and identify suitable partner(s) for the assignment and sign with that partner(s) a Specific Agreement specifying timeline and the exact work to be carried out. The mechanism of the Specific Agreement is presented in Section 1.3.3.

1.3 TASKS TO BE PERFORMED IN EACH LOT BY THE FPA PARTNER(S) UNDER SPECIFIC AGREEMENTS

For each lot, EFSA will supply the relevant parts of a validated technical dossier, additional data from the 1st clock stop, guidance documents and templates to draft (parts of) scientific opinions. In the case of specific agreements linked to provision of support for the food additive re-evaluation programme, EFSA will provide all available data (e.g. technical, biological, toxicological, food additive occurrence) submitted by interested business operators in response to calls for data and, if applicable, relevant evidence retrieved from the published literature to undertake a safety assessment or part(s) thereof.

1.3.1. Involvement of the FPA partner(s) in the risk assessment workflow and indicative timelines

1.3.1.1 New and/or renewal applications

Based on the current application process described here for food enzymes, food additives & flavourings and feed additives, the workflow foreseen within the frame of this Framework Partnership Agreement is summarised in Figure 1.

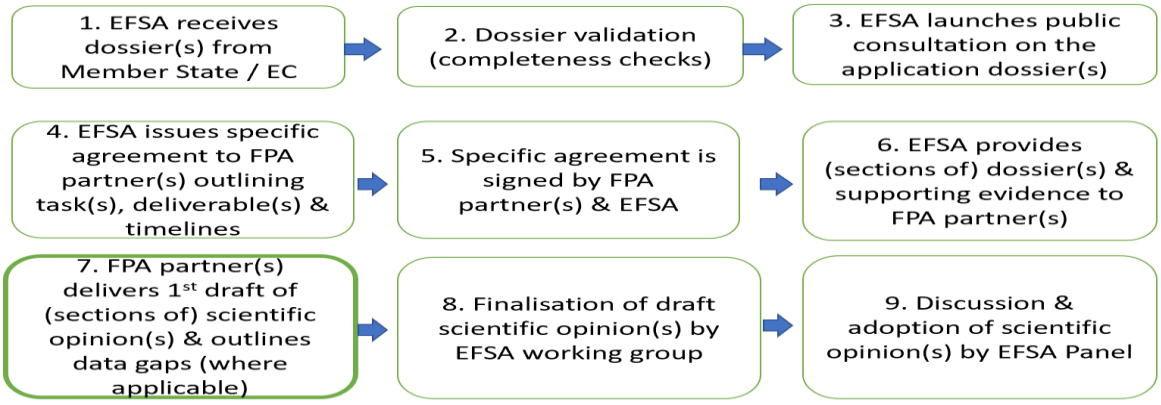

Figure 1. Workflow for scientific assessment of new/renewal applications within the frame of the FPA.

The FPA partner(s) will contribute mainly to step 7 of Figure 1. The following tasks (A-G below) are foreseen. Regular reporting to EFSA counterparts is needed to keep track of progress.

(A) Check compliance of the data provided (e.g. quality standards like Good Laboratory Practice (GLP)) in the dossier(s) with EFSA applicable guidance documents and EFSA internal checklists.
(B) Critically analyse the data (e.g. reports of experimental activities conducted) submitted in the dossier(s), and outline (if any) data gaps which are to be requested by EFSA in the 1st clock-stop letter.
(C) Prepare specific section(s) of the first draft opinion(s), based on the extracted information and according to the template provided by EFSA.
(D) When the additional data/studies identified under (B) are requested from the applicant, in these cases, the FPA partner(s) may be requested to analyse those data and update the draft opinion(s) in the light of received information.
(E) If needed, participation of the FPA partner(s) in one or more Working Group(s) in the role of a hearing expert to provide clarifications on the draft opinion(s) (step 8 of Figure 1).
(F) The comments received via public and/or targeted (Member States) consultations (step 3 of Figure 1), if any, need to be considered and the FPA partner(s) might need to update the draft opinion(s) accordingly. For feed additives, where relevant, the report of the European Reference Laboratory (EURL) should also be considered; the impact of the conclusions on the relevant sections of the opinion(s) need to be checked and should be referred to in the draft opinion(s).
(G) Identifying confidential information in the draft opinion.

The tasks A-G are linked to the lifecycle of an application and foreseen to be included in corresponding Specific Agreements. Specific Agreements may relate to one or several dossiers.

In rare cases, a dedicated Specific Agreement may be issued when there is a need for a task not directly linked to the lifecycle of the application i.e., Public Access to Documents (PAD) request.

(H) The FPA partner can be requested to support EFSA in blackening dossier business confidential data in reply to a PAD request.

The FPA partner will be requested to **deliver the intermediate deliverable (for lots 1-7) indicatively within 5 weeks** after getting access to the technical dossier (to complete tasks A-C).

When the FPA partner is requested to provide the deliverable for Lot 8, this shall be delivered within additional 3 weeks after the delivery of the lots 1-7.

The short timeline to deliver the intermediate deliverable is needed to ensure that time is available for the subsequent steps of the risk assessment process and to adopt the corresponding opinion within the legal deadline of 6 or 9 months depending on the regulatory domain.

Tasks D-G may be required to complete the final deliverable. When required, completion of these tasks will be considered as the final deliverable. When tasks D-G are not required, the intermediate deliverable (completion of tasks A-C) will be treated as the final deliverable.

1.3.1.2 Re-evaluation of food additives under Regulation (EC) No 257/2010

EFSA may also request support in the drafting of (sections of) scientific opinions linked to the food additive re-evaluation programme under Regulation (EC) No 257/2010. These scientific assessments are not linked to applications. A scientific opinion may cover one or more substance(s) (see Appendix 2).

As described in Regulation (EC) No 257/2010, when re-evaluating an approved food additive, EFSA shall:

a) Examine the original opinion and the working documents of the former Scientific Committee on Food ('SCF') or EFSA;
a) Examine, where available, the original dossier;
b) Examine the data submitted by the interested business operator(s) and/or any other interested party;
c) Examine any data made available by the Commission and Member States;
d) Identify any relevant literature published since the last evaluation of each food additive.

The FPA partner(s) may be asked to screen all the information and data gathered on the points above for their relevance and summarise them for the preparation of scientific opinions. The foreseen workflow is similar to that described for new and/or renewal applications (Figure 1) from step 4 onwards.

The following tasks (A-F below) are foreseen related to respective area(s) of expertise. Regular reporting to EFSA counterparts is needed to keep track of progress.

(A) Compile the information submitted to EFSA or the European Commission by the interested parties/interested business operators in response to the calls for data and/or relevant literature identified by EFSA into a structured template; check compliance of the data provided with EFSA applicable guidance documents.
(B) Critically analyse and review the data (e.g. reports of experimental activities conducted) submitted to EFSA or the EC or identified by EFSA.
(C) Prepare specific section(s) of the first draft opinion(s), based on the extracted information and according to the template provided by EFSA, and outline data gaps and missing information to be requested to complete the assessment for those specific sections, if any.
(D) When the additional data/studies identified under (C) are requested to the interested business operators, in these cases, the FPA partner(s) may be requested to analyse those data and update the draft opinion(s) in the light of received information.
(E) If needed, participation of the FPA partner(s) in one or more Working Group(s) in the role of a hearing expert to provide clarifications on the draft opinion(s) or sections thereof.

(F) Identifying confidential information in the draft opinion.

The tasks A-F are foreseen by default and will be reflected in the corresponding Specific Agreement.

In rare cases, a dedicated Specific Agreement may be issued when there is a need for a task not directly linked to the lifecycle of the application i.e., Public Access to Documents (PAD) request.

(G) The FPA partner can be requested to support EFSA in blackening confidential data in reply to a PAD request.

As an indicative timeline, the FPA partner will be requested to **deliver the intermediate deliverable (for lots 1-7) indicatively within 8 weeks** after getting access to the data and supporting evidence (to complete tasks A-C). The exact timeline will depend on the volume of information received in response to the calls for data and/or identified in the literature. **When the FPA partner is requested to provide the deliverable for Lot 8 this shall be delivered indicatively within additional 3 weeks after the delivery of the lots 1-7.**

The short timeline to deliver the intermediate deliverable is needed to ensure that time is available for the subsequent steps of the risk assessment process and to adopt the corresponding opinion within the legal deadline of 6 months.

Tasks D-F may be required to complete the final deliverable. When required, completion of these tasks will be considered as the final deliverable. When tasks D-F are not required, the intermediate deliverable (completion of tasks A-C) will be treated as the final deliverable.

1.3.2. Entrusted tasks within lots

Lot 1 – Assessment of the data regarding the identification and characterisation of microorganisms used as such or as production strains

The objective of Lot 1 is to identify data gap and draft the section(s) of a scientific opinion(s) related to the assessment of the data regarding the identification and characterisation of microorganisms used as such or as production strains. This lot is applicable to food enzymes, food additives & flavourings and feed additives.

The assessments need to be performed according to guidance documents indicated in **Appendix 1.**

Below are examples of some tasks (not exhaustive list) that could be requested under this lot:

- To assess the data on the characterisation of the active agent/production strain (which may include the genetic modification) and draft a detailed description (following templates). This may include one or more of the following aspects:
    - Taxonomic identification of the microorganism (mainly bacteria, fungi)
    - Description of the genetic modification, where relevant
    - Identification of genes of potential concern (antimicrobial resistance genes, virulence and genotoxicity)
    - Antimicrobial susceptibility
    - Antimicrobial production

- Toxigenicity testing, where relevant
- Manufacturing process involving the microorganisms (presence of the production strain and its DNA)

Lot 2 – Assessment of the identity and characterisation of a food enzyme, food additive, food flavouring or feed additive

The objective of Lot 2 is to identify data gap and draft the section(s) of a scientific opinion(s) related to the assessment of the identity and characterisation of a food enzyme, food additive, food flavouring and feed additive.

The assessments need to be performed according to guidance documents indicated in **Appendix 1.**

Below are examples of some tasks (not exhaustive list) that could be requested under this lot:

- To assess the data on the identity and characterisation of a food additive, food enzyme, food flavouring, and feed additive (chemical or microbiological) and draft a detailed description (following templates). This may include the following aspects:
  - Manufacturing process including the source of the substance (e.g., extraction, chemical synthesis)
  - Identification and characterisation of the food additive, food flavouring, food enzyme and feed additive (amino acid sequence, molecular mass, protein pattern, ingredient and chemical composition, batch to batch variability, chemical and microbiological purity, active agents), if relevant also their formulations
  - Physico-chemical properties of the food additive, food flavouring, food enzyme and feed additive (solubility and dissolution rate, pH and temperature profiles, (thermal) stability, homogeneity, dusting potential, particle size measurements, interactions and incompatibility with other substances, reaction and fate in food/feed)

Lot 3 – Assessment of toxicological safety

The objective of Lot 3 is to identify data gap and draft the section(s) of a scientific opinion(s) related to the assessment of the toxicological safety. This lot is applicable to food enzymes, food additives & flavourings and feed additives.

The assessments need to be performed according to guidance documents indicated in **Appendix 1.**

Below are examples of some tasks (not exhaustive list) that could be requested under this lot:

- To assess the data on absorption, distribution, metabolism and excretion (ADME) and residue (R) studies, and draft a detailed description
- To assess the data on genotoxicity and toxicological studies (e.g., sub-chronic oral toxicity study, chronic oral toxicity studies), and draft a detailed description (following templates)
- To prepare a toxicological dataset for benchmark dose analysis, perform and report the outcome
- To perform and report a QSAR analysis
- To draft an assessment of toxicological testing relevant for user safety of feed additives
- Appraisal of literature searches related to toxicological safety

Lot 4 – Allergenicity assessment

The objective of Lot 4 is to identify data gap and draft the section(s) of a scientific opinion(s) related to the assessment of allergenicity, which is applicable to food enzymes.

The assessments need to be performed according to guidance documents indicated in **Appendix 1**.

Below are examples of some tasks (not exhaustive list) that could be requested under this lot:

- To assess the data on allergenicity (homology search with known allergens, literature data on potential sensitisation or elicitation reactions caused by food enzymes), and draft a detailed description (following templates)

- To perform literature search for possible allergic reactions caused by food enzymes.

Lot 5 – Dietary exposure

The objective of Lot 5 is to identify data gap and draft the section(s) of a scientific opinion(s) related to the assessment of dietary exposure. This lot is applicable to food enzymes, food additives & flavourings and feed additives.

The assessments need to be performed according to guidance documents indicated in **Appendix 1.**

The following calculators are available on EFSA's website and shall be used:

- Food Enzyme Intake Model (FEIM)*
- Food Additive Intake Model (FAIM)
- Feed Additives Consumer Exposure (FACE)
- Dietary Exposure (DietEx) tool

*Note that the complete FEIM model is still under development. Therefore, specific agreement for using this model will be signed not earlier than July 2024.

Below are examples of some tasks (not exhaustive list) that could be requested under this lot:

- To evaluate the data related to
  - Conditions of use
  - For modifications of the conditions of use, a comparison of the changes proposed on dietary exposure estimates
  - Occurrence in food
- To perform the dietary exposure assessment using available tools and draft the section on dietary exposure.

Lot 6 - Assessment of efficacy and safety for target animal species

The objective of Lot 6 is to identify data gap and draft the section(s) of a scientific opinion(s) related to the assessment of the safety for the target species and efficacy of feed additives.

The assessments need to be performed according to guidance documents indicated in **Appendix 1.**

Below are examples of some tasks (not exhaustive list) that could be requested under this lot:

- To draft an assessment of the safety for the target animal species. The assessment should include a detailed description (following templates) of the evidence provided in the technical dossier to support the safety for the different target animals. The assessment should include a detailed description and a critical analysis of:
    - Literature review
    - Tolerance studies with target animals, including the use of the Feed Additives maximum safe Concentration in feed for target Species (FACTS)
    - Statistical analysis
    - Compliance with animal welfare and farming practices in the EU
    - Extrapolations across production categories/species
- To draft an assessment of the efficacy of a feed additive The assessment should include a detailed description (following templates) of the evidence provided in the technical dossier to support the efficacy of the feed additive for the different target species. The assessment should include a detailed description and a critical analysis of:
    - Short term efficacy studies
    - Long term efficacy studies
    - In vitro studies (for technological and/or sensory feed additives)
    - Literature review
    - Statistical evaluation
    - Compliance with animal welfare and farming practices in the EU
    - Extrapolations across production categories/species
- To draft an assessment of the data on the deposition/residues in food products derived from animal receiving feed additive

Lot 7 – Environmental risk assessment

The objective of Lot 7 is to identify data gap and draft the section(s) of a scientific opinion(s) related to the environmental risk assessment for feed additives.

The assessments need to be performed according to guidance documents indicated in **Appendix 1**.

Based on the experience from previous evaluations, EFSA does not envisage the need to perform an environmental risk assessment on a regular basis for food additives and food flavourings. However, there may be cases in which some consideration on environmental safety may be appropriate, e.g., if the structural and physical chemical properties of a food additive/food flavouring or its metabolites indicate persistence, bioaccumulation and/or toxicity for the environment.

Below are examples of some tasks (not exhaustive list) that could be requested under this lot:

- To draft an assessment of the safety for the environment. The assessment should include a detailed description (following templates) of the evidence provided in the technical dossier to support the safety of the active substance for the environment. The assessment should include a detailed description and a critical analysis of:
    - Phase I (decision tree, PECsoil, PECgw), including the use of the Feed additives Environmental Risk Assessment (FERA) calculation tool
    - Phase II (Physico-chemical properties studies, environmental fate studies, ecotoxicological studies

- Literature review

Lot 8 – Opinion assemblage

The objective of Lot 8 is to assemble the delivery from all lots into a full draft opinion(s), and to identify mismatch between lots and follow up with the partners responsible for the concerned lots until a final draft is complete. This lot is applicable to food enzymes, food additives & flavourings, and feed additives.

Below are examples of some tasks (not exhaustive list) that could be requested under this lot:

- To provide overall coordination of the deliverables resulting from the Lots 1-7 and ensure the deadlines provided are respected
- Prepare an entire draft opinion(s) (following templates) by merging the deliverables of the Lots 1-7, ensuring the logic flow, drafting the final conclusion(s), and compiling the identified data gaps in the form of questions (following established questions database) on the front page of the draft opinion(s)
- To identify and clarify cross-cutting issues between lots, and to flag to EFSA WGs.
- To communicate with the partners of the Lots 1-7 to ensure on time delivery, and with the relevant EFSA staff to report on progress and risks (quarterly)
- To organise meetings with partners of the Lots 1-7 and/or EFSA units, if needed

1.3.3 SELECTION OF PARTNER TO ENTRUST THE TASKS & RESULTING GRANT AGREEMENT

The applicants applying for this Call **must indicate precisely** in their proposal for which **lot(s) they apply. An applicant can apply for one (1) or more (even all) of the Lots 1-7. An applicant can only apply for Lot 8 if he also applies for at least one (1) of the other lots**. Each lot applied for in the proposal from an applicant will be individually evaluated by EFSA according to the award criteria indicated in part 2.5.

Framework Partnership Agreement:
A framework partnership agreement (FPA), of up to four (4) years, will be proposed by EFSA to the successful organisation(s) that has met the award criteria thresholds (see section 2.5). The proposed framework partnership agreement will indicate precisely for which lot(s) it applies, and the respective ranking(s) obtained by the organisation on the basis of the comparison of the scores obtained by all organisations awarded for the same area(s). The scores in each area for all beneficiaries will be presented in a table; please find an example in Table 3. An FPA sets out the framework conditions and is subsequently implemented through Specific Agreements.

Specific Agreements:
Specific Agreements will be awarded to a FPA beneficiary on the basis of the assignment mechanisms described below. Each Specific Agreement will set out the specific conditions for performing the respective assignment, defining exact timing of deliverables/milestones and the expected quality level of the output.

Assignment mechanism: The points awarded in the evaluation will constitute the ranking in order to establish cascades of FPA beneficiaries for the various lots where EFSA envisages to entrust tasks. The following scenarios are envisaged:

i) When in EFSA the need to entrust tasks (for one or more applications) within one lot arises, EFSA will propose a specific agreement to the beneficiary ranked first in the cascade in question in order to conclude a Specific Agreement for the work to be carried out (see Example 1, Table 3). In case the first ranked beneficiary within that lot does not accept the proposed Specific Agreement or doesn't reply in 5 working days, the beneficiary ranked second will be consulted. In case the second ranked beneficiary does not accept the proposed Specific Agreement or doesn't reply in 5 working days, the beneficiary ranked third will be consulted etc.

ii) When in EFSA the need to entrust tasks (for one or more applications) arises for more than one lot for the same opinion, EFSA will propose a Specific Agreement to the beneficiary with the highest combined total score for the lots required (see Examples 2 and 3, Table 3).

Table 3: The table below illustrates the assignment mechanism via examples, in particular in the cases where several lots are to be covered by one Specific Agreement:

Lot 1	Lot 2	Lot 3	Lot 4	Lot 5	Lot 6	Lot 7	Lot 8
1. Beneficiary A: awarded score = 99 2. Beneficiary B: awarded score = 87 3. Beneficiary C: awarded score = 70	1. Beneficiary D: awarded score = 56	1. Beneficiary E: awarded score = 94 2. Beneficiary C awarded score = 89 3. Beneficiary B: awarded score = 73	1. Beneficiary E: awarded score = 94 2. Beneficiary C: awarded score = 89 3. Beneficiary B: awarded score = 73		1. Beneficiary F: awarded score = 98	1. Beneficiary A: awarded score = 90 2. Beneficiary B: awarded score = 85 3. Beneficiary C: awarded score = 70	1. Beneficiary D: awarded score = 99 2. Beneficiary C: awarded score = 90 3. Beneficiary B: awarded score = 89
Example 1	**EFSA needs to perform assessment of Lot 1 only. The beneficiary who got the highest score in Lot 1 will be contacted (Beneficiary A).**						
Example 2	**EFSA needs to perform assessment of Lots: 1, 3, 7. Beneficiary B will be contacted since he applied for the three lots and has the highest combined total score (87 + 73 + 85 = 245).**						
Example 3	**EFSA needs to perform assessment of Lots: 2, 3, 4, 7. Beneficiary D will be contacted for Lot 2 and Beneficiary C will be contacted for Lot 3, 4 and 7 since he applied for the three lots and has the highest combined total score (89 + 89 + 70 = 248).**						

1.3.4 CONDITIONS FOR THE PERFORMANCE OF ENTRUSTED TASKS:

The tasks entrusted through the Specific Agreements will be conducted by one or more staff members of the FPA partner(s) extra-muros (in the premises of the beneficiary)~~; however some meetings might be requested to be held in person (in EFSA premises)~~.

Should EFSA during implementation of a specific agreement identify that a staff member of the beneficiary working on an entrusted task is not performing according to expectations, EFSA has the right to request a replacement of staff member from the beneficiary. The beneficiary in such a case must ensure there is a smooth handover between the outgoing and new staff member and at the same time the beneficiary shall endeavour to minimise any negative impact from such a change of staff on the execution of the entrusted task.

The ownership of the delivered outputs as a result of these tasks will be vested solely in EFSA and EFSA will be solely responsible of the results of the tasks performed. Only with **EFSA`s prior written permission** the beneficiary will be allowed to use the outputs resulting from the entrusted tasks.

During the performance of the entrusting tasks, the staff of the FPA partner(s):

- Shall carry out their duties and conduct themselves with the interests of EFSA in mind. They shall neither seek nor take instructions from any government, authority, organisation or person outside EFSA in relation to the execution of the specific tasks entrusted through the specific agreement. They shall carry out the duties assigned to them objectively and impartially.
- Shall be fully subject to the EFSA Policy on Independence [1] and the Decision of the Executive Director on Competing Interest Management [2]. Before signature of the specific agreement, they will submit a Declaration of Interest which will be screened according to the rules applicable to the external experts contributing to the EFSA's work (Articles 6-8) and the rules applicable to screening of Declarations of Interest in the context of procurement and grant awarding procedures (Article 15-16).
- Shall refrain from any unauthorised disclosure of information received in the line of duty, unless that information has already been made public or is accessible to the public. Under specific agreements in this field, EFSA will grant the staff of the partner/beneficiary access to confidential information in order to perform the tasks. They will therefore be required to sign a confidentiality agreement before commencing the performance of tasks (Annex 8).

The working language for performance of tasks will be English.

1.4 EFSA GRANT CONTRIBUTION

The present Call for proposals comes with an innovative and very simplified grant management, where the grant amounts paid to the partner are based on the predefined sums that are not linked to the costs. This means there is no need of co-financing from the partner, and no need of estimated budget or timesheets to record the work. The agreed sums are set at level that is to stimulate the mutually convenient partnership creation. The payment of agreed sums from EFSA will be carried out based on the acceptance by EFSA of the delivered work. If you have questions on this innovative grant form, during the application period, please raise the clarification questions in line with point 3.3.

This Call will result into several FPAs signed. EFSA reserves the right to award Specific Agreements under this group of FPAs up to an indicative maximum of ~~3,100,000~~ 3,536,000 euro in 4 years duration of FPAs. This includes the following estimations per lot: ~~410,000~~ 472,000 euro (Lot 1); ~~470,000~~ 532,000 euro (Lot 2); ~~630,000~~ 718,000 euro (Lot 3); ~~90,000~~ 98,000 euro (Lot 4); ~~150,000~~ 176,000 euro (Lot 5); ~~560,000~~ 640,000 euro (Lot 6); ~~90,000~~ 100,000 euro (Lot 7); ~~700,000~~ 800,000 euro (Lot 8). The breakdown in lots is given as an indication; EFSA reserves the right to shift budget across lots depending on the actual needs. EFSA reserves the right not to award Specific Agreements under the FPA without any compensation to be paid to the applicants/beneficiaries.

The grant amount of each Specific Agreement will be established based on the complexity of the opinion, the number of lots and on the number of opinions within a lot that will be entrusted to the identified FPA partner(s). It implies that many scenarios with different grant amounts can be envisaged, in line with the preestablished mechanism indicated in Table 4.

Table 4: Output value per lot

Lot No	Lot	Output value based on complexity* of the task. No of working days needed [€]		
		complexity level 1	complexity level 2	complexity level 3

1	Assessment of the data regarding the identification and characterisation of microorganisms used as such or as production strains	3 [~~1,320~~ 1,500]	5 [~~2,200~~ 2,500]	12 [~~5,280~~ 6,000]
2	Assessment of the identity and characterisation of a food enzyme, food additive, food flavourings or feed additive	2 [~~880~~ 1,000]	5 [~~2,200~~ 2,500]	12 [~~5,280~~ 6,000]
3	Assessment of toxicological safety	3 [~~1,320~~ 1,500]	7 [~~3,080~~ 3,500]	15 [~~6,600~~ 7,500]
4	Allergenicity assessment	1 [~~440~~ 500]	3 [~~1,320~~ 1,500]	5 [~~2,200~~ 2,500]
5	Dietary exposure	3 [~~1,320~~ 1,500]	5 [~~2,200~~ 2,500]	12 [~~5,280~~ 6,000]
6	Assessment of efficacy and safety for target animal species for feed additives	4 [~~1,760~~ 2,000]	8 [~~3,520~~ 4,000]	15 [~~6,600~~ 7,500]
7	Environmental risk assessment	3 [~~1,320~~ 1,500]	5 [~~2,200~~ 2,500]	12 [~~5,280~~ 6,000]
8	Opinion assemblage	3 [~~1,320~~ 1,500]	5 [~~2,200~~ 2,500]	12 [~~5,280~~ 6,000]

*Complexity is assigned based on EFSA experience, considering the number of working days envisaged to complete the task for one opinion.

The above output value refers to the delivery of tasks (A) to (G) per lot per opinion for new and/or renewal applications, and to delivery of tasks (A) to (F) for re-evaluation of food additives under Regulation (EC) No 257/2010.
Task H for new and/or renewal applications and task G for re-evaluation of food additives are not included in the above output value. If EFSA has the need to entrust these tasks, the output value applied will be ~~880~~ 1,000 EUR [2 working days] per opinion. These tasks will be offered to the beneficiary that has the total highest combined score in all the lots applied for and the cascade mechanism will be applied in case the beneficiary cannot undertake the task.

Examples:

For **Specific Agreement X** Partner is entrusted on new and/or renewal applications:

1. The analysis of Lot 2, judged by EFSA as complexity level 3 (e.g., assessment of product in nanoform) = ~~5,280~~ 6,000 euro
2. The analysis of Lot 3, judged by EFSA as complexity level 2 (e.g., genotoxicity and several toxicological studies) = ~~3,080~~ 3,500 euro
3. The analysis of Lot 4, judged by EFSA as complexity level 1 (e.g., homology search assessment) = ~~440~~ 500 euro
4. The analysis of Lot 7, judged by EFSA as complexity level 3 = ~~5,280~~ 6,000 euro

Specific Agreement amount would be ~~14,080~~ 16,000 euro in this case. Deadline is set 5 weeks after the dossier is made available to the beneficiary.

For **Specific Agreement Y** Partner is entrusted on new and/or renewal applications:

1. The analysis of Lot 3 (e.g. genotoxicity and one 90-d oral toxicity study), judged by EFSA as complexity level 1 = ~~1,320~~ 1,500 euro
2. The analysis of Lot 4, judged by EFSA as complexity level 2 (e.g., homology search and literature search assessment) = ~~1,320~~ 1,500 euro
3. The analysis of Lot 8, judged by EFSA as complexity level 3 = ~~5,280~~ 6,000 euro

Specific Agreement amount would be ~~7,920~~ 9,000 euro in this case. Deadline is set 8 weeks after the dossier is made available to the beneficiary.

For **Specific Agreement Z** Partner is entrusted work on **3** dossiers on new and/or renewal applications:

1. The analysis of Lot 1, judged by EFSA as complexity level 1 (e.g., fermentation product from a non-GM strain) = ~~1,320~~ 1,500 euro **x 3 = ~~3,960~~ 4,500 euro**
2. The analysis of Lot 2, judged by EFSA as complexity level 1 (e.g., additive with multiple formulations) = ~~880~~ 1,000 euro **x 3 = ~~2,640~~ 3,000 euro**
3. The analysis of Lot 3 (e.g., ADME(R), toxicological studies and safety for the user), judged by EFSA as complexity level 3 = ~~6,600~~7,500 euro **x 3 = ~~19,800~~ 22,500 euro**
4. The analysis of Lot 5 (e.g., dietary exposure), judged by EFSA as complexity level 1 = ~~1,320~~ 1,500 euro **x 3 = ~~3,960~~ 4,500 euro**

Specific Agreement amount would be ~~30,360~~ 34,500 euro in this case. Deadline is set 5 weeks after the dossiers are made available to the beneficiary.

EFSA will generally issue 12-months Specific Agreement in order to account for the possible follow-up tasks, if applicable (i.e. tasks D-G in sections 1.3.1.1 and tasks D-F in section 1.3.1.2) which may be required to complete the final deliverable. Upon execution of the work, and approval by EFSA of the final deliverable, EFSA will pay the agreed amount. There will be no verification of actually incurred costs, no statement of the costs to be submitted to EFSA, as the **form of grant awarded under this Call is based on financing not linked to the costs.**

Specific Agreements signed before expiry of FPA will continue until their completion, which could - if necessary - be up to 12 months after Specific Agreement signature.

1.5 ELIGIBLE ORGANISATIONS

To be eligible to submit a proposal under this Call, at the day of the deadline for submission of proposals, the applicant must be on the list of competent organisations designated by the Member States in accordance with Article 36 of Regulation (EC) 178/2002 and Commission Regulation (EC) 2230/2004. This list is regularly updated by EFSA Management Board and is available for consultation using this link https://efsa.force.com/competentorganisations/s/.

An applicant interested in joining the list should contact its national Focal Point, which will explain the procedure. Contact details of the Focal Points are available on the EFSA website here.

In order to achieve the main objective of the call, proposals can be submitted by one eligible organisation or by a consortium. The applicant is responsible for identifying consortium partners. All partners within a consortium should be Article 36 organisations. In case of a consortium, one of the partners must be identified in the proposal as the consortium leader. EFSA communicates with the consortium leader.

1.6. ROLES AND RESPONSIBILITIES

For proper understanding of this Call it is important to have clarity on the terminology regarding involved organisations and their roles.

A) Proposals submitted by consortium:

- **The Applicant** submits the proposal/grant application to EFSA on behalf of the consortium. The applicant is the leading entity of the consortium. There can be only one applicant in project proposal/grant application;

- **The Partner of the applicant** is the other entity in the consortium. There is no limit to number of partners of the applicant.

Applicant with its partners need to be Article 36 organisations.

Once the grant is awarded, the framework partnership agreement (FPA) is signed between EFSA and the applicant. Partner/s of applicant do not sign the FPA directly but instead sign a mandate (template provided by EFSA) to authorise the applicant to sign the FPA, any future amendments of FPA, and specific agreements on their behalf.

As soon as the FPA is signed, the applicant becomes the Coordinator and partner/s become co-beneficiary(ies). The coordinator and co-beneficiary(ies) are referred to together as the beneficiaries. The beneficiaries are jointly and severally liable for the technical implementation of the project/tasks as described in the proposal / the call which becomes annex 1 of the FPA. If a beneficiary fails to implement its part of the project/tasks, the other beneficiaries become responsible for implementing that part.

The coordinator has the following important roles:

- Takes part in implementing the project/tasks;
- Monitors the action/task is implemented properly;
- Acts as intermediary for communication between the consortium and EFSA;
- Receives and answers all claims EFSA might have in relation to implementation of the project/tasks;
- Requests and reviews any documents or information required by EFSA and verifies their completeness and correctness before passing them to EFSA;
- Informs EFSA and its partner(s) of any event that is likely to substantially affect implementation of the project/tasks;
- Submits the deliverables and reports to EFSA;
- Requests and receives payments from EFSA and distributes the funds to its partner(s) without unjustified delays.

The coordinator may not delegate the above-mentioned tasks to the co-beneficiary(ies).

The co-beneficiary(ies):
- Take part in implementing the project/tasks;
- Forward to the coordinator the data needed to draw up reports, financial statements and other documents required under the FPA;
- Inform the coordinator of any event or circumstances likely to substantially affect or delay the implementation of the project/tasks.

B) Proposals submitted by a sole applicant:

- **The Applicant** submits the proposal/grant application to EFSA. There can be only one applicant in the proposal/grant application.

As soon as the FPA is signed, the applicant becomes the beneficiary. The beneficiary is liable for the technical implementation of the project/tasks as described in the proposal/the call which becomes annex 1 of the FPA.

The beneficiary:

- Takes part in implementing the project/tasks;
- Monitors the action/task is implemented properly;
- Communicates with EFSA;
- Receives and answers all claims EFSA might have in relation to the implementation of the project/tasks;
- Requests and reviews any documents or information required by EFSA and verifies their completeness and correctness before passing them to EFSA;
- Informs EFSA of any event that is likely to substantially affect the implementation of the project/tasks;
- Submits the deliverables and reports to EFSA;
- Requests and receives payments from EFSA;

1.7. POSSIBILITY OF SUBCONTRACTING

Subcontracting is not permitted.

1.8 PAYMENTS

Final payment after approval by EFSA of the final deliverable. With the final payment, the Specific Agreement is concluded.

In case the partner cannot finalise the work due to stop the clock-time by EFSA, if such event continues for a period estimated to be > 6 months according to the indicative timelines as specified in the Annex A of the Administrative guidance[14], EFSA, taking into account the grant amount of the Specific Agreement, exceptionally can agree to a request for an **interim payment** of 70% of the grant amount specified in the Specific Agreement, after approval by EFSA of the draft deliverable.

1.9 GRANT PRINCIPLES

The form of grant awarded under this Call is based on financing not linked to the costs of the relevant operations in accordance with Article 125 (1)(a) of the EU Financial Regulation. Grants financed in this way require the fulfilment of conditions set out in sector specific rules of Commission decisions or the achievement of results measured by reference to previously set milestones or through performance indicators.

The financial support provided by EFSA under this Call is a grant governed by the EU Financial Regulation referred to in part 1.1. Accordingly, the grant awarded following this Call must comply with certain grant principles established in the EU Financial Regulation, specifically:

[14] https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/sp.efsa.2021.EN-6471

- **Non-retroactivity**: A grant may be awarded for a project which has already begun only where the applicant can demonstrate in the grant application the need to start the action before the grant agreement is signed. In accordance with Article 193 of the Financial Regulation. The tasks entrusted by EFSA should not be performed before the signature of the FPA and Specific Agreement.

Article 180(3) of the EU Financial Regulation specifically states that the **following grant principles are NOT applicable where the grant takes the form of financing not linked to the costs** pursuant to article 125(1)(a):

- **Co-financing**: In accordance with Article 190 of the Financial Regulation, grants shall involve co-financing.
- **No-profit**: In accordance with Article 192(3)(d) of the Financial Regulation, grants shall not have the purpose or effect of producing a profit within the framework of the project for the applicant or partner.
- **Non-cumulative**: In accordance with Article 191(3) of the Financial Regulation, in no circumstances shall the same costs be financed twice from the EU budget.

1.10 PUBLICITY

According to Article 38 of the EU Financial Regulation EFSA is bound to publish information on recipients of its grants at its website. Such publication shall take place no later than 30 June of the year following the financial year in which the grants were awarded and shall cover these data of the beneficiaries:

- name of the beneficiary,
- address of the beneficiary,
- subject of the grant,
- amount awarded.

1.11 PROTECTION OF PERSONAL DATA IN RELATION TO GRANT PROCEDURES

Processing of personal data by EFSA

Information on the processing of personal data by EFSA in the context of this grant procedure is available in the Privacy Statement on the EFSA website as well as in Article II.7 of the draft grant agreement. Any personal data included in the Agreement must be processed by EFSA in accordance with Regulation (EU) No 2018/1725.[15]

Applicants should note that personal data as applicant or selected beneficiary may be registered in the Early Detection and Exclusion System (EDES) if you are in one of the situations mentioned in Article 136 of the Financial Regulation. For more information see the Privacy Statement on: http://ec.europa.eu/budget/explained/management/protecting/protect_en.cfm#BDCE).

Processing of personal data by the beneficiary

[15] Regulation (EU) 2018/1725 of the European Parliament and of the Council of 23 October 2018 on the protection of natural persons with regard to the processing of personal data by the Union institutions, bodies, offices and agencies and on the free movement of such data, and repealing Regulation (EC) No 45/2001 and Decision No 1247/2002/EC

In case the implementation of activities under this FPA or subsequent specific agreements entails the processing of personal data, the beneficiary shall comply with the relevant rules in Article II.7.2 of the Grant Agreement (Annex 1) as a data processor of EFSA.

1.12 PUBLIC ACCESS TO DOCUMENTS

In the general implementation of its activities and for the processing of grant procedures in particular, EFSA observes Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents.

2. SELECTING PROPOSALS

The Evaluation Committee established by EFSA specifically for this call will evaluate the submitted proposals in five steps:

1. Verification of submission requirements (2.1)
2. Eligibility criteria (2.2)
3. Exclusion criteria (2.3)
4. Selection criteria (2.4)
5. Award criteria (2.5)

If the proposal fails at any step, it is automatically excluded from further evaluation. EFSA may contact the applicant during the evaluation process if there is a need to clarify certain aspects or for the correction of clerical mistakes.

2.1 VERIFICATION OF SUBMISSION REQUIREMENTS

The following will be verified:

- proposal was submitted within the deadline for submission of proposals;
- proposal is submitted on the EFSA application form (Annex 2);
- proposal is duly signed by the authorised representative of the applicant;
- proposal is complete and includes all the supporting documents.

2.2 ELIGIBILITY CRITERIA

The following will be verified:

- At the day of deadline for submission of proposals, the applicant and in case of consortium also its partner/s are on the list of competent organisations designated by the Member States in accordance with Art 36 of Regulation (EC) 178/2002 and Commission Regulation (EC) 2230/2004;
- Applicant and in case of consortium also its partner/s are involved in the execution of the project, with no subcontracting involved

Documents to be provided:

- **LEGAL ENTITY FORM (Annex 3)** (download template here)
  to be completed and signed by the applicant and in case of consortium also by its partner/s. For a public body the legal entity form should be provided together with a copy of the resolution or decision establishing the public body, or other official document establishing that public body. For a private body an extract from the official journal, copy of articles of association, extract of trade or association register, certificate of liability to VAT (if, as in certain countries, the trade register number and VAT number are identical only one of these documents is required).

- **FINANCIAL IDENTIFICATION FORM (Annex 4)** (download template here)
  to be completed only by the applicant and in case of consortium only by the coordinator.

There is no need to submit these forms if they have already been submitted under another EFSA procurement or grant procedure and provided that these forms are still valid. In this case simply indicate in the application form the reference of the call under which the form/s were submitted to EFSA.

Only applicable if the applicant is a consortium:

- **PARTNERSHIP STATEMENT**:
  The applicant and partner/s must provide EFSA with a signed statement indicating their involvement. No template is provided by EFSA.

2.3 EXCLUSION CRITERIA

The applicant and partner/s must sign a declaration on their honour certifying they are not in one of the exclusion situations referred to in the Articles 136 of EU Financial Regulation.

Documents to be provided:

- **THE DECLARATION ON HONOUR FOR EXCLUSION CRITERIA (Annex 5)**: template is published with this Call; to be completed/signed individually by the applicant and in case of consortium by each partner.

2.4 SELECTION CRITERIA

The purpose of the selection criteria is to verify the financial and operational capacity of the applicant and in case of consortium also of its partner/s.

Financial capacity:
The applicant and in case of consortium also its partner/s must have stable and sufficient financial resources to:

- maintain their activity throughout the period during which the project is being carried out, and
- participate in its funding.

Operational capacity:
The applicant or the organisation must have the professional resources, competencies and qualifications necessary to complete the proposed project:

Requirement 1:
The applicant should have expertise pertaining to one or more of the eight (8) lots listed in the table below and provide the respective evidence as indicated.

Lot	Lots (Scientific and technical areas of expertise)	Evidence to be provided for all lots
1	Assessment of the data regarding the identification and characterisation of microorganisms used as such or as production strains Required expertise: - The applicant should provide a team of experts, ensuring that the team covers and demonstrates extensive experience in the assessment of microorganisms regarding the following aspects: - Expertise in assessing data to characterise the microorganism which may be based on molecular techniques (including whole genome sequence data), phenotype-based techniques and literature - The expertise in microorganisms of at least 2 of the experts should be related to those used in the food/feed chain - At least 1 of the experts should have expertise in technologies used for (whole genome) sequencing of microorganisms - At least 1 person should ensure the coordination of the tasks with EFSA and ensure consistency across different domains.	- An applicant may apply for 1 or more lot. For each lot applied for (1 to 8), evidence with CVs that the proposed experts possess the 'required expertise'. Each expert must have at least 3 years of post-graduate work experience in that area and fulfil the English language requirement specified below. - For each lot applied for (1 to 8), evidence of at least one main activity (e.g., characterisation of the production strains used in food/feed production) performed in the past 7 years that your organisation possesses the required capacity in the area applied for. In addition, please also provide for each lot the details on/references to reports/publications/ patents produced (PDF or hyperlink to the document) by your organisation in the course of the past 7 years.
2	Assessment of the identity and characterisation of a food enzyme, food additive, food flavourings or feed additive Required expertise: - The applicant should provide a team of experts, ensuring that the	

	team covers extensive and demonstrable expertise in the assessment of chemical products used in the food/feed chain, in particular: ○ Physico-chemical analysis of chemicals used in the food/feed chain ○ Characterisation of impurities ○ Characterisation of small particles, including nanoparticles with the methodologies required by the EFSA guidance ○ Analysis of formulations - At least 1 person should ensure the coordination of the tasks with EFSA and ensure consistency across different domains.	
3	Assessment of toxicological safety <u>Required expertise:</u> - The applicant should provide a team of experts, ensuring that the team covers extensive and demonstrable experience with substances used in the food/feed chain, in particular: ○ Expertise in the conduct of toxicological studies in laboratory animals and other animal species ○ Genotoxicity ○ Pharmacology, toxicology (reproductive and developmental, neurotoxicology, immunotoxicology) ○ Occupational health ○ QSAR/read across ○ Appraisal of literature searches - At least 1 person should ensure the coordination of the tasks with EFSA and ensure consistency across different domains.	
4	Allergenicity assessment <u>Required expertise:</u>	

	- The applicant should provide a team of experts, ensuring that the team covers extensive and demonstrable experience with substances used in the food/feed chain, in particular: ○ Expertise in immune toxicology on food allergy or food intolerance ○ Expertise in bioinformatics in allergen databases ○ Appraisal of literature searches - At least 1 person should ensure the coordination of the tasks with EFSA and ensure consistency across different domains.	
5	Dietary exposure <u>Required expertise:</u> - The applicant should provide a team of experts who can demonstrate extensive experience in the exposure assessment of products used in the food/feed chain. - At least 1 person should ensure the coordination of the tasks with EFSA and ensure consistency across different domains.	
6	Assessment of efficacy and safety for target animal species for feed additives <u>Required expertise:</u> - The applicant should provide a team of experts, ensuring that the team covers extensive and demonstrable experience with substances used in the food/feed chain, in particular: ○ Animal nutrition ○ Animal physiology ○ Animal husbandry ○ Feed technology ○ Microbiology ○ Appraisal of literature searches ○ Design, conduct and reporting of animal trials, preferably in the	

	area of animal nutrition, animal production and related areas. - At least 1 person should ensure the coordination of the tasks with EFSA and ensure consistency across different domains.	
7	Environmental risk assessment <u>Required expertise:</u> - The applicant should provide a team of experts, ensuring that the team covers extensive and demonstrable experience with substances used in the food/feed chain, in particular: o Expertise in the conduct of fate and behaviour studies o Expertise in the conduct of ecotoxicological studies (terrestrial and aquatic compartments, including marine environment) o QSAR/read across o Expertise in using the FOCUS model o Appraisal of literature searches - At least 1 person should ensure the coordination of the tasks with EFSA and ensure consistency across different domains.	
8	Opinion assemblage <u>Required expertise:</u> The applicant should provide a team of experts, ensuring that the team covers extensive and demonstrable experience in the assessment of substances used in the food chain, together with: o Proven experience in project management related to the risk assessment of chemicals	

	○ Knowledge of regulatory frameworks governing food domains ○ Proven experience in collaborating with EU institutions and MS competent authorities or academia.	

The area(s) of expertise of interest for Requirement 1 shall be clearly specified in the CV and in the list of relevant activities performed by the organisation.

Requirement 2:

Mastering ENGLISH language. All experts proposed to work on EFSA assignments need to have an very good level of spoken and written English. For non-native speakers, this should be evidenced by either:
- having worked in at least one international project where English is used for meetings
- having published at least one scientific publication or made at least one oral presentation in conferences in English
- certification B2 level.

In addition, all experts must be skilled users of the IT Office applications, e.g., Microsoft Office package.

This requirement is inferred from the information included in the CVs and list of activities.

ADDITIONAL documents to be provided by the applicant:

- **DECLARATION ON HONOUR ON SELECTION CRITERIA (Annex 6);**
- **SIMPLIFIED FINANCIAL STATEMENT (Annex 7)**
  only required for private bodies if the grant requested from EFSA is >60.000 €. The template published with the Call should be completed for at least the last two closed financial years;
- **INSTITUTIONAL AND INDIVIDUALS DECLARATION OF INTERESTS**
  Template available here. EFSA will request **Institutional** DoI only from the awarded beneficiary, prior to the signature of FPA. EFSA will request **Individual** DoI only from the awarded beneficiary, prior to the signature of each specific grant agreement. The requirement to submit institutional DOIs will be specified in the event of proposal for grant award in the award letter and they will have to be provided and assessed by the EFSA authorising officer before FPA signature. **Institutional and Individual DoIs do not need to be provided with your proposal.** In case of a consortium, such declarations will need to be completed separately and submitted for each partner (institutional DoIs) and for each individual member of the project team (individual DoIs) coming from consortium partners.

  Please refer to EFSA's policy on independence and the Decision of the Executive Director on Competing Interest Management for more detailed information.

2.5 AWARD CRITERIA

The award criteria serve to assess the quality of the proposals in relation to the objectives of the Call. The following award criteria are applicable in this call:

For each lot, the proposals which have satisfied the below indicated quality thresholds will be ranked according to the award criteria obtained in order to form the cascade of beneficiaries to whom an FPA will be awarded.

AWARD CRITERIA (Max. 100 points for each Lot applied for).

For each Lot you apply for (1 to 8) please provide:

1. Quality of resources: Describe the resources, both in terms of quantity (number of proposed experts), and quality (years of experience, quality of experience) that you have available for tasks to be entrusted from EFSA, and how you intend to make it quickly (in terms of days) available after the task is entrusted via signed specific agreement. Provide also a list of activities, publications and/or reports performed in the past 7 years demonstrating the quality in appraising study reports in accordance with the principles and of the methodologies (e.g., applicable OECD TGs, analytical techniques, etc.) in the area that you apply for. **(max. 40 points, pass-mark 28 points)**

2. Timeliness of delivery: Describe how the resources will ensure delivery of the tasks received for each domain relevant for a given lot (i.e., food enzymes; food additives & flavourings; feed additives) within 5 weeks for Lots 1-7; and within additional 3 weeks in case Lot 8 applies. **(max. 20 points, pass-mark 14 points)**

3. Quality of coordination: Describe how the assigned task is to be distributed among experts involved in a given lot, how it is coordinated and how you will ensure the quality control of the executed work (including keeping consistency of the assessments across different Specific Agreements). In case you apply for more than one lot, please describe also the interactions and possible synergies across experts in the different lots. **(max. 20 points, pass-mark 14 points)**

4. Quality of continuity: Describe how you will guarantee that the experts will be available at the time of need during FPA 4 years life, and which measures you will take in the case there will be fluctuation changes to the proposed pool of experts. In particular, explaining how the newly assigned experts will guarantee the same level of quality of expertise throughout the life of FPA. **(max. 20 points, pass-mark 14 points)**

Based on the above scoring, for each Lot there will be a ranking of proposals. In case there is a specific assignment to be entrusted by EFSA, the ranking resulting from the above scoring will be respected.

3. SUBMITTING PROPOSALS

3.1 APPLICATION FORM & CHECKLIST

The proposal must be submitted using the **EFSA APPLICATION FORM (Annex 2).** The application form is published together with this call. The application form must be:

- duly completed and

- supported with all the requested annexes;
- signed by a duly authorised legal representative of the applicant.

By submitting a proposal, the applicant and in case of consortium also partner/s accept/s the procedures and conditions described in this Call and in the documents referred to in it.

In addition to a full paper version of the application, the applicant must submit the application also in electronic form (USB). The electronic version must be identical to the paper version and is searchable. In case of any discrepancies between the electronic and paper version, the latter will prevail. All documents presented by the applicant become the property of EFSA and are deemed confidential.

3.2 LANGUAGE OF THE PROPOSAL AND THE SUPPORTING DOCUMENTS

Proposals may be submitted in any official language of the European Union. However, as EFSA`s working language is English, the submission of proposals in English would speed up the evaluation process.

Please note that supporting documents are required. These supporting documents are an integral part of the proposal. For more information on the relevant supporting documents to be submitted, please refer to Section 2 of this Call. If these supporting documents are in a language other than English, in order to facilitate and speed up the evaluation, it would be appreciated if a reliable translation of the relevant parts of the documents into English is provided with the proposal.

3.3 SUBMISSION MODALITIES

Proposals are to be submitted as indicated in the second page of this document in the Indicative procedure timetable.

If, after having read this Call for proposals and guide for applicants, you have any questions, you may address them to EFSAProcurement@efsa.europa.eu by indicating the Call reference.

3.4 EXPECTED DURATION OF PROCEDURE

In accordance with Article 194(2) of the Financial Regulation, the maximum time-limits for the procedure are as follows:

- All applicants will be informed of the decision regarding their application within 6 months of the deadline for submission of proposals;
- Signature of the grant agreement will take place within 3 months from the date the successful applicant/s has/have been informed of the decision on their application.

Appendix 1 - Main guidances/relevant documents that are applicable for the different lots

Lot number	**Food enzymes** Guidance on food enzymes (GFE)	**Food additives** Guidance for food additive evaluations (GFA) Guidance on the characterisation of microorganisms	**Food flavourings** Guidance for food flavourings (GFF, under public consultation) Guidance for smoke flavourings (GSF)	**Feed additives** List of main Scientific guidances applicable HERE	**Other EFSA guidance documents or information used in the assessments (non-exhaustive list)**
Lot 1	GFE See Section 1.1	Guidance on the characterisation of microorganisms +GFE	Guidance on the characterisation of microorganisms +GFE	Guidance on the characterisation of microorganisms Requirements for whole genome sequence analysis of microorganisms Guidance on the renewal of the authorisation of feed additives See Section 2.2	Zenodo for QPS
Lot 2	GFE See Sections 1.2, 1.3, 2 and 3	GFA See **Section 1**	GFF See Section 1 GSF See section 1	Guidance on the identity, characterisation and conditions of use of feed additives Guidance on the renewal See Section 2.2	EFSA Scientific Committee Guidance on technical requirements for regulated food and feed product applications to establish the presence of small particles including nanoparticles
Lot 3					Scientific opinion on genotoxicity testing strategies applicable to food and feed safety assessment (EFSA SC, 2011) Clarification of some aspects related to genotoxicity assessment (EFSA SC, 2017) Genotoxicity assessment of chemical mixtures (EFSA SC, 2019) Guidance on aneugenicity assessment (EFSA SC, 2021) Guidance on the use of the Benchmark Dose approach in risk assessment (draft, EFSA SC 2022) Guidance on risk assessment of nanomaterials to be applied in the food and feed chain: human and animal health
ADME(R) studies	-	GFA See **Section 4.1**	GFF See Section 4 GSF See section 3.3.2	Guidance safety for the consumer See Section 2.1 Guidance on the renewal See Section 2.3	
Genotoxicity and toxicological studies (e.g., sub-chronic oral toxicity study, chronic oral toxicity studies)	GFE See Sections 4.1 to 4.4	GFA See Sections 4.2- 4.5	GFF See Section 4.1, 4.4 and 4.5 GSF See section 3	Guidance safety for the consumer See Section 2.2 Guidance on the renewal See Section 2.3	
QSAR analysis			GFF See Section 4.3 GSF See section 3.2		
Toxicological testing relevant for user safety	-	-	-	Guidance safety for users/workers See Section 2.3	
Lot 4	GFE See Section 4.5	GFA See Section 4.5	--	Not applicable	Scientific opinion on the assessment of allergenicity of GM plants and microorganisms and derived food and feed of the Scientific Panel on Genetically Modified Organisms" (EFSA GMO Panel, 2010)
Lot 5	GFE See Section 5 and Food Enzyme Intake Model (FEIM)	GFA See Section 3 and Food Additive Intake Model (FAIM)	GFF See Section 3 GSF See section 2 Food Additive Intake Model (FAIM)	Guidance safety for the consumer See Section 4.3 Feed Additives Consumer Exposure (FACE)	
Lot 6	-	-	-	Guidance on the assessment of the safety of feed additives for the target species Guidance on the assessment of the efficacy of feed additives Criteria for the assessment of hygiene condition enhancers Guidance on the renewal of the authorisation of feed additives See Sections 2.3 and 2.4	

Lot 7	-	-	-	Guidance on the safety of feed additives for the environment Guidance on the renewal of the authorisation of feed additives See Section 2.3	

Appendix 2 – List of food additives to be re-evaluated under Regulation (EC) No 257/2010 and tentative grouping into scientific opinions

No	Scientific opinion	Substances to be re-evaluated
1	Re-evaluation of citric acid and citrates (E 330-333; E 380)	Citric acid (E 330)
		Monosodium citrate (E 331(i))
		Disodium citrate (E 331(ii))
		Trisodium citrate (E 331(iii))
		Monopotassium citrate (E 332(i))
		Tripotassium citrate (E 332(ii))
		Monocalcium citrate (E 333(i))
		Dicalcium citrate (E 333(ii))
		Tricalcium citrate (E 333(iii))
		Triammonium citrate (E 380)
2	Re-evaluation of hydroxides (E 524-528)	Sodium hydroxide (E 524)
		Potassium hydroxide (E 525)
		Calcium hydroxide (E 526)
		Ammonium hydroxide (E 527)
		Magnesium hydroxide (E 528)
3	Re-evaluation of oxides (E 529-530)	Calcium oxide (E 529)
		Magnesium oxide (E 530)
4	Re-evaluation of gluconic acid and gluconates (E 574-579)	Gluconic acid (E 574)
		Glucono-delta-lactone (E 575)
		Sodium gluconate (E 576)
		Potassium gluconate (E 577)
		Calcium gluconate (E 578)
		Ferrous gluconate (E 579)
5	Re-evaluation of guanylic acid and guanylates (E 626-629)	Guanylic acid (E 626)
		Disodium guanylate (E 627)
		Dipotassium guanylate (E 628)

		Calcium guanylate (E 629)
6	Re-evaluation of inosinic acid and inosinates (E 630-633)	Inosinic acid (E 630)
		Disodium inosinate (E 631)
		Dipotassium inosinate (E 632)
		Calcium inosinate (E 633)
7	Re-evaluation of ribonucleutides (E 634-635)	Calcium 5'-ribonucleotides (E 634)
		Disodium 5'-ribonucleotides (E 635)
8	Re-evaluation of glycin (E 640)	Glycine (E 640)
9	Re-evaluation of triethyl citrate (E 1505)	Triethyl citrate (E 1505)
10	Re-evaluation of acetic acid and acetates (E 260-263; E 650)	Acetic acid, ethanoic acid (E 260)
		Potassium acetate (E 261)
		Sodium acetate (E 262(i))
		Sodium diacetate (E 262(ii))
		Calcium acetate (E 263)
		Zinc acetate (E 650)
11	Re-evaluation of lactic acid and lactates (E 270; 325-327; E 585)	Lactic acid (E 270)
		Sodium lactate (E 325)
		Potassium lactate (E 326)
		Calcium lactate (E 327)
		Ferrous lactate (E 585)
12	Re-evaluation of malic acid and malates (E 296; 350-352)	Malic acid (E 296)
		Sodium malate (E 350(i)
		Sodium hydrogen malate (E 350(ii))
		Potassium malate (E 351)
		Calcium malate (E 352(i))
		Calcium hydrogen malate (E 352(ii))
13	Re-evaluation of fumaric acid (E 297)	Fumaric acid (E 297)
14	Re-evaluation of succinic acid (E 363)	Succinic acid (E 363)
15	Re-evaluation of adipic acid and adipates (E 355-357)	Adipic acid (E 355)
		Sodium adipate (E 356)

		Potassium adipate (E 357)
16	Re-evaluation of calcium disodium EDTA (E 385)	Calcium disodium ethylenediaminetetra acetate (E 385)
17	Re-evaluation of carbon dioxide and carbonates (E 290; E 500-501; 503-504)	Carbon dioxide (E 290)
		Sodium carbonate (E 500(i))
		Sodium hydrogen carbonate (E 500(ii))
		Sodium monohydrogen dicarbonate (E 500(iii))
		Potassium carbonate (E 501(i))
		Potassium hydrogen carbonate (E 501(ii))
		Ammonium carbonate (E 501(i))
		Ammonium hydrogen carbonate (E 503(ii))
		Magnesium carbonate (E 504(i))
		Magnesium hydroxide carbonate (E 504(ii))
18	Re-evaluation of L-Cysteine (E 920)	L-Cysteine (E 920)
19	Re-evaluation of carbamide (E 927b)	Carbamide (E 927b)
20	Re-evaluation of argon (E 938)	Argon (E 938)
21	Re-evaluation of helium (E 939)	Helium (E 939)
22	Re-evaluation of nitrogen (E 941)	Nitrogen (E 941)
23	Re-evaluation of nitrous oxide (E 942)	Nitrous oxide (E 942)
24	Re-evaluation of butane and isobutane (E 943a,b)	Butane (E 943a)
		Isobutane (E 943b)
25	Re-evaluation of propane (E 944)	Propane (E 944)
26	Re-evaluation of oxygen (E 948)	Oxygen (E 948)
27	Re-evaluation of hydrogen (E 949)	Hydrogen (E 949)
28	Re-evaluation of glyceryl acetates (E 1517-1518)	Glyceryl diacetate (diacetin) (E 1517)
		Glyceryl triacetate (triacetin) (E 1518)