

TENDER SPECIFICATIONS

Reference: OC/EFSA/GMO/2017/01

Subject: *In vitro* protein digestibility

Procurement procedure: Open call

Project/Process code: GMO-03

Budget Line: 3210

Tender specifications purpose:

1. specify what EFSA is to buy under the contract resulting from this tender procedure
2. announce the criteria which EFSA will apply to determine the successful contractor among the offers received
3. guide tenderers to establish and dispatch their offer in the required form and time

These tender specifications will form annex 1 of the contract resulting from this tender procedure and will be binding during the contract implementation.

Additional guidance:

The economic operators wishing to submit an offer following this call for tenders are also invited to read the [EFSA Guidance for tenderers](#) available at EFSA website. The general guidance aims to assist the potential tenderers in their understanding of EFSA procurement procedures and to complete the specific information contained in this tender specifications.

Submitting your tender on time:

Follow carefully the guidance in annex 2 "E-Submission application description".
Do not wait until the last day to upload your offer. Responsibility rests with you to ensure that your tender is fully, completely and correctly uploaded before the time limit for receipt. Failure to respect the time limit for receipt will result in the rejection of your offer for non-compliance with the deadline for tenders.

Provide EFSA with feedback:

If you considered applying to this call for tenders but finally decided not to do so, your feedback and reasoning for such a decision would be very much appreciated. You should address your feedback to EFSAProcurement@efsa.europa.eu. Please note that your comments will be kept strictly confidential and will only be used for the purpose of improving future EFSA procurement calls.

INDICATIVE PROCEDURE TIMETABLE

Milestone	Date ¹	Comments
Launch date	14/07/2017	Date of publication being sent to OJ
Deadline for sending a request for clarification to EFSA	20/09/2017 <u>04/10/2017</u>	Attention: <i>Requests for clarification may only be submitted through the eTendering website as described in the Invitation Letter.</i>
"Receipt Time Limit" - Closing date and time for offers reception	28/09/2017 12/10/2017 at 14:30 (CET)²	See details in the Invitation letter. Please also refer to the e-Submission application description attached in annex 2 hereto.
Opening session	29/09/2017 <u>13/10/2017</u>	14:30hr, EFSA premises, Parma
Notification of the evaluation results	NOVEMBER 2017 <u>DECEMBER 2017</u>	Estimated. <i>Attention: outcome of the present procurement procedure will be communicated to all tenderers to the e-mail address indicated in their offer. Accordingly, the tenderers who have submitted offers under the present call are strongly invited to check regularly the inbox in question.</i>
Contract signature	NOVEMBER-JANUARY 2018 <u>7</u>	Estimated

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

² **Do not wait until the last day to upload your offer. Responsibility rests with you to ensure that your tender is fully, completely and correctly uploaded before the time limit for receipt. Failure to respect the time limit for receipt will result in the rejection of your offer for non-compliance with the deadline for tenders.**

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PART 1 TECHNICAL SPECIFICATIONS - WHAT DOES EFSA NEED TO BUY THROUGH THIS PROCUREMENT PROCEDURE?

1.1 BACKGROUND

The objective of this call is to outsource the protocol development and experimental testing of the revised *in vitro* gastrointestinal digestion test proposed in Annex B of the EFSA GMO Panel guidance document recently published³.

The tenderer, consulting with EFSA throughout the project, shall further detail and apply the refined digestion test methodology described by EFSA³. The procurement will involve data production through testing different proteins for their susceptibility to digestion.

Briefly, gastrointestinal digestion can affect the immunological properties of dietary proteins in relation to both IgE- and non-IgE-mediated adverse reactions to food. *In vitro* digestibility tests provide useful data on the susceptibility of a protein to digestion. Consequently, digestibility is considered as relevant information for the allergenicity assessment, which is a mandatory requirement in both Codex Alimentarius⁴ and the EFSA Guidance Document⁵. Limitations of the current implementation of the test have been highlighted by EFSA. EFSA has now developed principles for a refined *in vitro* gastrointestinal digestion test³, and considered necessary to establish an interim phase to experimentally evaluate the proposed revisions and to confirm their practical applicability in the risk assessment context. The interim phase initiates through this EFSA procurement where experimental data will be collected.

Following the completion of this procurement, EFSA will assess whether the proposed test protocol adds the expected value to the allergenicity assessment and, if so, what further steps are needed for its final implementation.

The present Call is based on the Final work programme for grants and operational procurements 2017 as presented in Annex IX of the EFSA Programming Document 2017 – 2019, available on the EFSA's website⁶.

1.2 OBJECTIVE

The aim of this procurement procedure is to conclude a direct contract for the execution of specific tasks over a clearly defined period as defined in these tender specifications.

This procurement aims to outsource the protocol development and the production of experimental data for the improvement of classical *in vitro* protein degradation tests, following the principles described in the EFSA GMO Panel supplementary guidance document³ (2017) and related Annex B. This data will be used by the EFSA GMO Panel to discuss the added value for the allergenicity assessment of the proposed revisions.

³ EFSA GMO Panel (EFSA Panel on Genetically Modified Organisms), Naegeli H, Birch AN, Casacuberta J, De Schrijver A, Gralak MA, Guerche P, Jones H, Manachi ni B, Messean A, Nielsen EE, Nogue F, Robaglia C, Rostoks N, Sweet J, Tebbe C, Visioli F, Wal J-M, Eigenmann P, Epstein M, Hoffmann-Sommergruber K, Koning F, Lovik M, Mills C, Moreno FJ, van Loveren H, Selb R and FernandezDumont A, 2017. Guidance on allergenicity assessment of genetically modified plants. EFSA Journal 2017;15 (5):4862, 49 pp. <https://doi.org/10.2903/j.efsa.2017.4862>

⁴ Codex Alimentarius, 2009. Foods derived from modern biotechnology. Codex Alimentarius Commission, Joint FAO/WHO Food Standards Programme, Rome, Italy. 85 pp.

⁵ EFSA GMO Panel (EFSA Panel on Genetically Modified Organisms), 2011a. EFSA Panel on Genetically Modified Organisms (GMO); Scientific Opinion on Guidance for risk assessment of food and feed from genetically modified plants. EFSA Journal 2011;9(5):2150, 37 pp. doi:10.2903/j.efsa.2011.2150

⁶ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/amp1719.pdf

1.3 TASKS, DELIVERABLES, TIMELINE AND PAYMENTS

No	Tasks	Can be subcontracted? ⁷	Deadline for finalisation
1	Define an <i>in vitro</i> protein digestibility protocol fit-for-purpose, following recommendations described in Annex B of the new EFSA guidance document ³ . In line with this document, at least two digestion conditions should be considered. The interplay between pH, enzyme concentration and duration of digestion should be carefully analysed. A report describing the progress of the project shall be produced (see deliverables Section).	Yes	6 months after the entry into force of the contract.
2	Experimental evaluation of the protocol employing, at least, a highly resistant protein and a labile protein. This step shall be used to adjust the test conditions defined in task 1 before being applied to a larger number of control proteins. A report describing the progress of the project and future work plan shall be produced (see deliverables Section).	Yes	8 months after the entry into force of the contract
3	Apply the final protocol to approximately 8 (preferably 10) control proteins selected, in consultation with EFSA, to represent different degrees of resistance to the action of the digestive enzymes under the test conditions: highly resistant, moderately resistant or labile. A report describing the progress of the project shall be produced (see deliverables Section).	Yes	16 month after the entry into force of the contract
4	A document shall be produced reporting the steps taken throughout the project and the final outcome of the tenderer work. In particular, Annex B of the EFSA document ³ shall be taken into consideration to provide an analysis regarding: <ul style="list-style-type: none"> - definition of transient versus persistent fragments; - comparison of the final read outs of the gastrointestinal digestion and those obtained after the classical pepsin test only; - risk assessment considerations, taking into account Annex B and Figure B.2. The final <i>in vitro</i> protein digestibility protocol in the format of standard operating procedures (in house validation) shall be included as an appendix.	Yes	18 months after the entry into force of the contract
No	Meetings		Deadline for finalisation
1	Kick off meeting at EFSA premises (1 day duration). The aim of the meeting is to have a first discussion between the contractor and EFSA for a clear understanding of the objectives of the project, the tasks to be performed, the structure of the reports, timeframe, scope, etc. This meeting can be also considered as an opportunity to discuss administrative and financial		Within 3-weeks after the entry into force of the contract

⁷ If a subcontractor provides the whole or a very large part of the financial capacity OR executes the whole or a very large part of the tasks, EFSA may demand that that the subcontractor signs the contract.

	matters related to contract implementation.	
2	Progress meeting 1 , via tele/webconference to discuss the progress made on task 1. EFSA comments or considerations on the several aspects discussed should be integrated in the interim report covering task 1.	4 months after the entry into force of the contract
3	Progress meeting 2 , via tele/webconference to discuss the outcome of task 1. The tenderer shall prepare and submit to EFSA a report at least 1-week in advance of the conference. Following the consultation with EFSA, a first version of the protocol shall be defined and submitted to EFSA for final review.	6 months after the entry into force of the contract
4	Progress meeting 3 , via tele/webconference to discuss the outcome of task 2 and to adjust the first version of the protocol for task 3. The tenderer should prepare and submit to EFSA a report at least 1-week in advance of the conference. Following the consultation with EFSA, a final protocol should be defined and submitted to EFSA for final review. The control proteins to test should also be discussed and agreed with EFSA.	8 months after the entry into force of the contract
5	Progress meeting 4 , via tele/webconference to discuss the outcome of task 3. The tenderer shall prepare and submit to EFSA a report at least 1 week in advance of the conference. EFSA comments or considerations on the draft report should be integrated in the subsequent deliverable.	16 months after the entry into force of the contract
6	Progress meeting 5 , via tele/webconference to discuss the draft final document covering all tasks and including an appendix with the standard operating procedures followed. EFSA comments or considerations on the draft report should be integrated in the subsequent deliverable.	18 months after the entry into force of the contract
7	Final meeting at EFSA premises (1 day duration), the contractor shall present the draft final report to the EFSA GMO Panel.	Within approximately 1 month after the submission of the draft final report
No	Deliverables	Deadline for submission to EFSA
1	Interim report covering task 1. The interim report shall be written in English and shall describe in detail the protocol that will be used in task 2. The tenderer shall also describe levels of uncertainty in the different phases of the protocol development and execution, and how the tenderer is planning to mitigate potential issues that might arise. EFSA comments or considerations on the interim report should be integrated into subsequent deliverables, as appropriate. The tenderer should prepare and submit to EFSA a report at least 1-week in advance of the conference. Following the consultation with EFSA, the protocol to be used in task 2 should be submitted to EFSA for its final review.	6 months after the entry into force of the contract
2	Draft report describing in detail the outcome of task 2. The tenderer should justify the need for adjustment of the initial protocol and should provide appropriate supporting amendments, as needed. It should also describe the levels of uncertainty in the several phases of the protocol proposed and how the tenderer is planning to mitigate them. EFSA comments or considerations on the draft report should be integrated in the subsequent deliverables. Following the consultation with EFSA, the protocol to be used in task 3 should be submitted to EFSA for its final review.	8 months after the entry into force of the contract
3	Draft report describing in detail the outcome of task 3. All EFSA comments raised during the course of the	16 months after the entry into force of the contract

	contract should be taken into consideration in this draft report. The content of the report should be structured as follows: an executive summary (max. 2 pages), introduction, material and method, results, discussion and conclusion. The report should be submitted in electronic format (DOC format). The electronic format used must allow the possibility of editing by EFSA. EFSA intends to publish the final report in an appropriate EFSA format. The standard EFSA template will be provided by EFSA in due time.	
4	Draft Final report addressing all tasks (1, 2, 3, and 4), including the final <i>in vitro</i> protein digestibility protocol in the format of standard operating procedures as an appendix. All EFSA comments raised during the course of the contract should be taken into consideration in this draft final report. The tenderer should provide a finalised report at least 1-week in advance of the EFSA GMO Panel meeting.	18 months after the entry into force of the contract
5	Final report addressing all tasks described above. All EFSA comments raised during the course of the contract should be taken into consideration in this final report, including those of the EFSA GMO Panel. The payment of this deliverable will be linked to the approval by EFSA of the final report.	Within 4 weeks after the report is presented to the EFSA GMO
No	Payments	Linked to approval by EFSA of deliverable No
1	Interim payment 1 of 40%	2
2	Payment of the balance of 60%	5

Important general considerations: before initiating any of the tasks, the tenderer should consult with EFSA and consider any recommendation made. The working language for the contract implementation (execution of tasks, meetings and deliverables) shall be English. The deliverables shall be delivered to EFSA in DOC format using the standard EFSA template format. In case of need and in agreement with the contractor, other issues not detailed in the task list and relevant for this call might be included in the contract and final reports. Finally, EFSA may request additional tele/web-conferences with the tenderer as need arise.

1.4 INFORMATION ON THE CONTRACT

Type of contract: direct contract

Nature of expense: services

Duration of tasks in

direct contracts: 20 months after the entry into force of the contract

Budget information: The maximum budget EFSA has available is 225.000 €. Any offer exceeding this maximum will not be retained for contract award.

1.5 OWNERSHIP AND INTELLECTUAL PROPERTY RIGHTS

SPECIFIC INFORMATION ON INTELLECTUAL PROPERTY RIGHTS:

As regards any product or delivery commissioned by EFSA and developed by the contractor in the context of the contract resulting from this call for tenders as well as source codes of IT applications and models and protocols developed for EFSA, the intellectual property rights will be owned by EFSA only, in its capacity as financial source of the contract. The contractor cannot file a trademark, patent, copyright or other IPR protection scheme in relation to any of the results or rights obtained by EFSA in performance of the contract, unless the contractor requests EFSA ex-ante authorisation and obtains from EFSA a written consent in this regard.

In addition, the contractor selected as a result of the present procurement procedure shall be solely responsible and liable for the following:

- To ensure that terms and conditions asserted by any copyright holder of publications or information referred to in the final deliverable for EFSA are fully satisfied;
- To make the necessary arrangements enabling EFSA to reproduce and make non-commercial use of publications and information referred to in the final deliverable it commissioned. As needed, the contractor shall consult with copyright licensing authorities (i.e. at national level) for guidance on purchasing copyright licenses to reproduce any publications provided to EFSA. The contractor remains solely responsible and liable for obtaining all necessary authorizations and rights to use, reproduce and share the publications provided to EFSA

PARTS OF RESULTS PRE-EXISTING THE CONTRACT

If the results are not fully created for the purpose of the contract this should be clearly pointed out in the tender. Information should be provided about the scope of pre-existing materials, their source and when and how the rights to these materials have been or will be acquired.

The draft contract attached in **Annex 3** contains further provisions on ownership of intellectual property rights. All quotations or information the tenderer provides in the technical and financial offer for EFSA which originates from other sources to which third parties may claim rights, have to be clearly marked in the offer in a way allowing easy identification (source publications, including date & place, creator, number, full title etc.). The tenderer shall take account of the above specification on ownership and copyrights in their technical and financial offer.

PART 2 EVALUATION - HOW WILL YOUR OFFER BE ASSESSED?

In case you apply as a group of economic operators in a joint offer or if your offer envisages the use of subcontractors, please also refer to the [EFSA Guidance for tenderers](#).

2.1 OPENING OF OFFERS

The main aim of the public opening session is to check whether the offer received was dispatched within the closing date for tender receipt⁸ and that the tenders are electronically protected until the official opening.

2.2 ORDER OF EVALUATION

Tenderers should note that the content of their offers will be assessed in the following pre-defined order: Exclusion criteria (Access to EU Market); Selection criteria (Technical & Professional capacity); Compliance with tender specifications; Award Criteria (Quality and Price).

Following the above assessment and identification of the winning tender, the following will be assessed only for the tenderer proposed for contract award: Selection criteria (Professional Conflict of Interest – Institutional and Individual Declarations of Interest); Exclusion criteria (Declaration on Honour on exclusion criteria); Selection criteria (Declaration on Honour on selection criteria).

2.3 GROUNDS FOR EXCLUSION

The offers declared admissible during the opening session will be further verified against the eligibility and the exclusion criteria.

As regards the eligibility of the tenderers to submit an offer following this call please refer to the [EFSA Guidance for tenderers](#) available at EFSA website. Only offers from tenderers established in eligible countries will be allowed to the next step of the evaluation – exclusion criteria verification.

Tenderers must not be in one of the exclusion situations listed in the [EFSA Guidance for tenderers](#) available at EFSA website.

Evidence requested in the offer:

- Tenderers must declare that they are not in one of the exclusion situations by providing a signed and dated Declaration on Honour on exclusion criteria, available in **Annex 4**. In case of a joint offer from a group of economic operators, such declaration should be submitted for each member of the group. Evidence may be requested in support of this declaration to the successful tenderer.

For info: EFSA will request further supporting evidence, from the awarded tenderers, prior to the signature of the contract. Such requested evidence will be specified in the award letter and will have to be provided to EFSA before the contract is signed.

⁸ **Do not wait until the last day to upload your offer. Responsibility rests with you to ensure that your tender is fully, completely and correctly uploaded before the time limit for receipt. Failure to respect the time limit for receipt will result in the rejection of your offer for non-compliance with the deadline for tenders.**

2.4 SELECTION CRITERIA

The offers from tenderers declared eligible and not in one of the exclusion situations will be further verified against the selection criteria.

A) ECONOMIC AND FINANCIAL CAPACITY:

The tenderer must have the following economic and financial capacity to perform the contract. In particular, the tenderer must have generated an overall annual turnover of at least 300.000 in each of the last 2 closed financial years (2016, 2015).

Evidence requested in the offer:

Tenderers must declare that they fulfil the economic and financial criteria indicated above by providing a signed and dated Declaration on Honour on selection criteria, available in **Annex 5**. In case of a joint offer from a group of economic operators, such declaration should be completed by the leading partner.

EFSA will request further supporting evidence (proof of annual turnover), from the awarded tenderer, prior to the signature of the framework contract. Such requested evidence will be specified in the award letter and will have to be provided to EFSA before the framework contract is signed.

B) PROFESSIONAL AND TECHNICAL:

The tenderer must have the professional and technical capacity to perform the contract in accordance with the specifications below. In accordance with article 148(6) RAP, if EFSA, based on the assessment of the professional and technical capacity evidence, concludes that the tenderer has a professional conflicting interest and therefore does not possess the professional capacity to perform the contract to an appropriate quality standard, the tenderer may be rejected.

The tenderer must have the following **minimum professional and technical capacity** to perform the contract:

A. The **minimum professional** to perform the contract is the following:

Ability to provide a team of experts compliant with these specific expertise requirements:

- a) at least two experts in the area of *in vitro* digestion, in particular with experience and competence in protein digestion, one of them being a senior research-scientist with at least 10 years of experience. The senior research-scientist (Project Leader) should have experience in the coordination of international scientific projects in the field;
- b) at least two laboratory specialists with expertise in *in vitro* protein digestion and in the qualitative and quantitative analysis of peptide profiles, with at least two years of experience;
- c) the team of experts must have overall an excellent level of spoken and written standard English.

B. The **minimum technical capacity** to perform the contract is the following:

- a) the tenderer must have extensive and demonstrable experience in the field of *in vitro* protein digestibility and in the provision of services described in the technical specifications;
- b) the tenderer must have demonstrable experience in enzyme kinetics, mainly in proteases;

c) the tenderer must demonstrate laboratory access and ISO 17025 certification or any other quality assurance system in place.

Although it might be important that the experimental phase is taken at one single laboratory, collaborations among research institutes, Universities, etc, that can provide advice throughout the project will be considered an asset. In addition, certification for coordination of validation studies is also an asset.

Specific Evidence requested for professional and technical capacity:

For requirements Aa, Ab and Ac):	Detailed CVs of all team members proposed for the assignment, taking into account the minimum expertise requirements detailed above; EFSA strongly recommends submitting the CVs in the EU CV format which can be accessed here .
For requirement Ba and Bb):	A list of 3 major relevant projects and publications related to the subject of this assignment carried out in the course of the past 5 years.
For requirement Bc):	A Statement confirming that the tenderer will have laboratory access and ISO 17025 certification <u>or any other quality assurance system in place</u> .
	Institutional declaration of interests available here <i>In case of a group of economic operators and/or in case of subcontracting, such declaration should be completed separately and submitted for each partner and for each identified subcontractor.</i>
	Individual declarations of interests available here <i>A separate form to be completed by each member of the proposed team.</i>

With the exception of declarations of interest, evidence must be included in the offer for partners in a joint offer and/or subcontractors only if the capacity of those entities is necessary to satisfy the minimum technical and professional capacity requirements.

GENERIC EVIDENCE COMMON FOR ALL SELECTION CRITERIA:

1	Declaration on Honour on selection criteria available in Annex 5 <i>To be completed by the tenderer or by the leading partner in case of a joint offer.</i>
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Please note that you do not have to submit any of the above-mentioned evidence if already submitted to EFSA in response to any previous EFSA call, provided the evidence is exactly the same as requested in these tender specifications. If you avail yourself of this possibility, you have to specify the reference of the EFSA call for tenders under which you have already submitted the evidence to EFSA.

EFSA has the right, during the evaluation process, to request further evidence on the tenderer's compliance with the economic, financial, technical and professional capacity requirements.

2.5 COMPLIANCE WITH TENDER SPECIFICATION AND MINIMUM REQUIREMENTS

Your offer will be assessed for compliance with the tender specifications before its assessment against the award criteria.

Tenders are considered not to comply with the tender specifications and are therefore to be rejected if they:

- do not comply with minimum requirements laid down in the tender specifications (non-compliance);
- propose a solution different from the one that is imposed;
- propose a price above the fixed maximum set in the specifications;
- are submitted as variants, when the specifications do not authorise them;
- do not comply with applicable obligations under environmental, social and labour law established by Union law, national law and collective agreements or by the international environmental, social and labour law provisions listed in Annex X to Directive 2014/24/EU⁹.

In all these cases, the grounds for rejection are not linked to the award criteria so there is no evaluation as such. The tenderer will be informed of the ground for rejection without being given feedback on the content of the tender other than on the non-compliant elements.

2.6 AWARD CRITERIA

Tenders will be evaluated against the below defined award criteria. The award criteria serve to identify the **most economically advantageous offer**.

A) QUALITY AWARD CRITERIA

The quality of retained offers will be evaluated according to the following award criteria:

<p>1. Understanding of the assignment This criterion is intended to assess if candidates have taken into consideration all the aspects of the technical specifications.</p>	<p>Max 20</p>
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⁹ OJ L 94 of 28.03.2014, p. 65

<p>2. Methodology proposed for implementation, in conformity with the tender specifications</p> <p>The degree to which the methodology shows the capacity to address the tasks underlined in the tender specifications in a realistic and well-structured way, as well as to whether the methods proposed are in conformity with the needs of EFSA.</p>	<p>Max 40</p>
<p>3. Project management, including organisation of the tasks within the project team and respect of timelines</p> <p>The extent to which the organisational set up is suitable for the implementation of the assignment. Attention will be drawn to project management aspects such as the distribution of responsibilities within the proposed expert team (including partners in a joint offer and subcontractor partner(s), if applicable), the internal communication and the interaction with EFSA. Respect of timelines and the availability of the contractor throughout the duration of the contract will be taken into account.</p>	<p>Max 30</p>
<p>4. Quality control measures</p> <p>Methods and procedures implemented to ensure that data are collected, managed, and utilised with coherence and accuracy in order to provide the highest quality of deliverables as possible respecting the deadlines defined by EFSA.</p>	<p>Max 10</p>

The sum of all quality award criteria gives a maximum possible total of 100 points.

Tenderer shall elaborate in the technical offer on all points addressed in the technical specifications, bearing also in mind the above indicated award criteria, in order to score as many points against the quality award criteria as possible. The mere repetition of mandatory requirements set out in the technical specifications, without going into detail or without giving any added value in the technical offer, will only result in a very low score.

Offers must score at least 70 of maximum possible total points against the quality award criteria.

Tenders that do not reach this minimum quality threshold will be eliminated from the subsequent stages of the evaluation process.

B) PRICE AWARD CRITERION:

Tenders which passed the above quality threshold will be retained for the further assessment of the following:

- I. the price offer is made within the the maximum budget for financial offers indicated in the tender specifications and;
- II. the financial offer satisfies the formal requirements of the tender specifications.

C) THE BEST PRICE-QUALITY RATIO:

- I. The tenders for which the financial offers were made within the maximum budget for financial offers and satisfied the formal requirements indicated in the tender specification will be retained for the identification of the tender with the best price-quality ratio based on the formula:

$$\begin{aligned} \text{TOTAL SCORE OF THE EVALUATED OFFER (C) =} \\ \text{TOTAL QUALITY SCORE (OUT OF 100) FOR ALL QUALITY AWARD CRITERIA OF} \\ \text{TENDER (X)/100 *(70)} \\ + \\ \text{CHEAPEST PRICE OFFER/PRICE OF TENDER (X)*(30)} \end{aligned}$$

PART 3 HOW TO SUBMIT YOUR OFFER – e-SUBMISSION APPLICATION GUIDE

You must submit your tender electronically via the e-Submission application available from the e-Tendering website before the time limit for receipt of tenders.

The e-Submission application allows economic operators to respond to call for tenders by preparing their tenders electronically in a structured and secured way, and submitting their tenders electronically. The e-Tendering is the starting point for launching the e-Submission application.

Make sure you submit your tender on time: you are advised to start completing your tender early. To avoid any complications with regard to late receipt/non receipt of tenders within the deadline, please ensure that you submit your tender several hours before the deadline. A tender received after the deadline indicated in the procurement documents will be rejected.

How to Submit your Tender in e-Submission

You can access the e-Submission application via the corresponding call for tender in TED e-Tendering, as specified in the Invitation Letter.

In order to have access to e-Submission, you will need to "Subscribe to call for tenders" on TED e-Tendering first. To subscribe, you will need to login with your an [EU Login](#)¹⁰. In case you don't have an [EU Login](#), you can [create an account](#) at any moment. For more information see the [EU login help](#). After logging in with your EU Login password, the e-Tendering will then display a button 'submit your tender' and you will be able to access the e-Submission.

Information to be filled in

In the e-Submission application, fill in and upload all necessary fields and documents as appropriate. All tenders must be clear, complete and consistent with all the requirements laid down in the tender specifications, including:

- **Signed declaration on Honour(s).** All members of a joint tender, including subcontractors – if applicable – must upload the signed and dated declaration on honour(s) using the templates available in Annex 4 and Annex 5,
- **Exclusion criteria.** If requested in the tender specifications, the tenderer and all members of a joint tender including subcontractors – if applicable – must provide the documentary evidence for exclusion criteria,
- **Selection criteria.** If requested in the tender specifications, the tenderer and all members of a joint tender including subcontractors – if applicable –, must provide the documentary evidence for selection criteria
- **Technical tender.** It must address all the requirements laid down in the tender specifications
- **Financial tender** The complete financial tender, including the breakdown of the price as provided in the tender specifications

¹⁰ Previously called European Commission authentication system (ECAS)

For detailed instructions on how to submit your tender, consult the Quick Reference Guide for Economic Operators available in the [e-Submission help page](#), under the section "Quick Guide", where you will find:

- Technical requirements to use e-Submission
- Step-by-step guide to help you submit your tender
- Important advices and information on how to get technical support

Please make sure all required documents and evidence are submitted with your tender.

Documents to be signed and dated while creating your Tender

The following documents must be signed and dated during the creation of your tender in e-Submission:

- **Declaration on honour(s).** All members of a joint tender, including subcontractors must sign and date the declaration on Exclusion criteria. Only the leader in a joint tender must sign and date the declaration on Selection criteria. The declaration on honour(s) must be converted to PDF format and then signed by the authorised representatives with advanced electronic signature based on qualified certificates or by hand. For technical details on the electronic Signatures, please consult the e-Submission [signature policy](#).
- **Tender Report.** This report is generated by e-Submission while you are completing your tender and it contains the list of documents that you submit. The sole tenderer's or leader's authorised representative(s) must sign the report.

You **must send** the signed Tender Report to the email address indicated in the paragraph below (Contact), stating the reference to the call for tenders and the Tender ID.

Re-submission or alternative tender

After submitting a tender, but within the time limit for receipt of tenders, you may still submit a new version of your tender.

You must formally notify EFSA that the previous tender is withdrawn. You are also entitled to send several tenders to one call for tenders.

The notification must be sent to the e-mail address indicated in the paragraph below (Contact), stating the reference to the call for tenders and the Tender ID you wish to withdraw.

If you submit a new Tender you must include all your Tender documents, including the Qualification and Tender documents.

Withdrawal of tenders

If after submitting a tender, you wish to completely withdraw your tender, you must formally notify that you wish to withdraw your submitted Tender(s). This notification must be signed by the same authorised legal representative(s) who previously signed the tender(s) in question.

The notification must be sent to address indicated in the paragraph below (Contact), stating the reference to the call for tenders and the Tender ID(s) you wish to withdraw.

Deadline for receipt of tenders

The tender (including all documents) must be fully uploaded and received before the deadline for receipt of tenders indicated in the invitation to tender.

Please note that you are responsible to ensure that your full tender reaches the destination in due time.

In case of problems with the submission of the electronic tender, we recommend that you call the helpdesk in reasonable time before the time limit for receipt. The time it takes to submit the tender and upload all your documents may vary considerably depending on the number of concurrent submissions by other economic operators, the size of your tender and the type of internet service you are using. We recommend that you upload the documents the day before the deadline.

If the contracting authority detects technical faults in the functioning of the electronic equipment used for submitting and receiving tenders due to which it is impossible to electronically submit and receive tenders, you will be informed of the extension of the time limit by the contracting authority at the e-Tendering link.

For more information or technical support on e-Submission, please visit the [e-Submission help site](#).

CONTACT

- The original hand signed tender report must be scanned and sent by email immediately after submission, to the following address: EFSAProcurement@efsa.europa.eu.
- Notifications for re-submission or withdrawal of tenders must be sent to: EFSAProcurement@efsa.europa.eu

When communicating state the reference to the call for tenders and, if applicable, the Tender ID.

- For technical support on e-Submission, please contact support as described in the help page:
https://webgate.ec.europa.eu/supplier_portal_toolbox/esubmissionFileProject/files/BT3/spotsHelpPage_en.html

ANNEX 1 - FINANCIAL OFFER TEMPLATE

FINANCIAL OFFER

Tenderers are requested to use the following model for drawing up their financial offer. In doing so tenderers confirm they are aware of the following facts:

- As referred to in part 1.4, the maximum budget EFSA has available for this assignment is **225.000 €**. Any offer exceeding this maximum will not be retained for contract award.
- Prices must be quoted in Euro using the conversion rates published in the C series of the Official Journal of the European Union on the day when the invitation to tender was issued. This information is also available on the website of the European Central Bank at the following URL: <http://www.ecb.int/stats/eurofxref/>.
- Pursuant to the provisions of Article 9 of the Italian Law n. 17 dated 10/01/2006 and under Article 151 of Council Directive 2006/112/EC, EFSA is exempt from all duties, taxes and other charges, including VAT. For this reason, all prices given in the financial breakdown should be free of VAT and other taxes or duties.
- The price offered below is understood to be all inclusive. For example any additional costs which can be incurred by the contractor in performing the contract, such as overheads, travelling and subsistence/accommodation expenses, etc. should also be factored in to the all-inclusive price. In addition, if the deliverables incorporate pre-existing rights, the tenderer should factor into their total price the cost of licensing those pre-existing rights to EFSA.

<p>ALL INCLUSIVE TOTAL PRICE</p> <p>to be used for the evaluation and for the contract in the case of award.</p> <p>(Please provide attached to the Financial Offer, for information purposes only, a breakdown of costs using your own template – the submission of this breakdown is not compulsory)</p>	<p>..... €</p>
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Tenderer name:

Date:

Name of person signing the financial offer:

His/her position in the company:

His/her signature:

ANNEX 2 - E-SUBMISSION QUICK REFERENCE GUIDE FOR ECONOMIC OPERATORS

The guide can be viewed [here](#).

ANNEX 3 - DRAFT CONTRACT

Tenderers should note that in the event that their offer is successful, the resulting contract will be based on the model annexed to these tender specifications.

ANNEX 4 - DECLARATION ON HONOUR ON EXCLUSION CRITERIA

ANNEX 5 - DECLARATION ON HONOUR ON SELECTION CRITERIA

ANNEX 6 – ADMINISTRATIVE DATA FORM

ANNEX 7 – INSTITUTIONAL DECLARATION OF INTERESTS

ANNEX 8 – INDIVIDUAL DECLARATION OF INTERESTS

The templates are uploaded in e-Tendering with all other procurement documents.