



TENDER SPECIFICATIONS

Reference: OC/EFSA/NUTRI/2021/01

Subject: updating of Upper Levels for micronutrients

Procurement procedure: Open call (Article 164(1) (a) of the Financial Regulation)

Project/Process code: NUTRI-02 E02.01.09

Budget Line: 3210

Tender specifications purpose:

1. specify what EFSA will buy under the contract resulting from this procurement procedure;
2. announce the criteria which EFSA will use to identify the successful contractor;
3. guide tenderers in the preparation and sending of their offer;
4. form annex 1 of the contract resulting from this procurement procedure and be binding for contract implementation.

Additional guidance:

Please read the [EFSA Guidance for tenderers](#) available on the EFSA website, designed to assist potential tenderers in their understanding of EFSA procurement procedures.

Provide EFSA with feedback:

If you considered applying to this call for tenders but finally decided not to, please provide EFSAProcurement@efsa.europa.eu with your feedback on the call and reasons for not applying. Feedback will be treated confidentially and will only be used for improving future EFSA procurement calls.



PROCEDURE TIMETABLE

Milestone	Date ¹	Comments
Launch date	02/07/2021	Date Contract Notice is sent to Official Journal
Deadline for sending request for clarification to EFSA	05/08/2021 at 14:30 (CEST)	Requests for clarification may only be submitted through the e-Tendering website as described in the Invitation Letter. EFSA is not obliged to reply to clarifications received less than 6 working days before the deadline for submission of offers.
Deadline for EFSA to reply to clarification questions	06/08/2021	
"Receipt Time Limit" - Closing date and time for receipt of offers	13/08/2021 at 14:30 (CEST)	Refer to the Invitation letter and part 3 of these tender specifications regarding how to submit your offer.
Opening session	16/08/2021 at 14:30 (CEST)	Requests to attend the virtual opening session must be made 2 working days in advance of the opening session. Refer to Invitation letter for details.
Notification of evaluation results	Estimated September 2021	The outcome of the procurement procedure will be communicated to all tenderers exclusively using the e-mail address indicated in their offer. Please check regularly the inbox in question.
Contract signature	Estimated September / October 2021	

¹ All times are in the time zone of Italy, the country in which EFSA is based.



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

1.1 BACKGROUND

Article 6 of Regulation (EC) No 1925/2006² on the addition of vitamins and minerals and of certain other substances to foods and Article 5 of Directive 2002/46/EC³ on the approximation of the laws of the Member States relating to food supplements provide that maximum amounts of vitamins and minerals added to foods and to food supplements respectively, shall be set.

To set maximum amounts (MA) of vitamins and minerals in fortified foods and food supplements, the European Commission (EC) requests the European Food Safety Authority (EFSA):

- 1) **To update the guidelines of the SCF for the development of Tolerable Upper Intake Levels (UL) for vitamins and minerals** (adopted on 19 October 2000)⁴ in the light of available recent scientific and methodological developments.
- 2) **To review existing scientific evidence and provide advice on Tolerable Upper Intake Levels** for the following vitamins and minerals:
 - **vitamin A**
 - **folic acid / folate**
 - **vitamin D**
 - **vitamin E**
 - **Vitamin B6**
 - **iron**
 - **manganese**
 - **β-Carotene**

This mandate⁵ is allocated to the EFSA Panel on Nutrition, Novel Foods and Food Allergens (NDA), which deals with questions related to human nutrition in relation to Community legislation at the request of the Commission. The NDA Panel is supported by EFSA NUTRITION Unit and by the Working Group on Upper Levels (UL).

The NDA Panel will deliver the requested work following the steps below:

1. The SCF Guidelines to establish UL for vitamins and minerals will be updated, in the light of the experience gained by EFSA in assessing ULs for nutrients and of relevant scientific developments in the field. As a result, EFSA will publish an updated guidance. The guidance will include a template protocol for the

² <https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:32006R1925>

³ <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32002L0046>

⁴ https://www.efsa.europa.eu/sites/default/files/efsa_rep/blobserver_assets/ndatolerableuil.pdf

⁵ <https://open.efsa.europa.eu/questions/EFSA-Q-2021-00364>, <https://open.efsa.europa.eu/study-inventory/EFSA-Q-2021-00364>



evaluation of the UL of vitamins and minerals, in line with the EFSA methodological framework⁶.

2. For each above-listed micronutrient:
 - a. A tailored 'high level' protocol will be developed, based on the template protocol and taking into account the specificities of the micronutrient; the 'high level' protocol will outline the methods to be applied to prioritise, collect, appraise (i.e. risk of bias assessment) and synthesise the relevant evidence for the scientific assessment, to analyse uncertainties, and to integrate the evidence and draw conclusions;
 - b. The scientific assessment (Hazard identification, Hazard characterisation, Intake assessment, Risk characterisation) will be conducted, supported by systematic reviews of the literature;
 - c. A scientific opinion will be drafted;
 - d. The draft scientific opinion will be released for public consultation;
 - e. The final scientific opinion will be adopted by the NDA Panel and published.

The assessment of the 8 micronutrients will be run in parallel (see Figure 1).

To optimise the process and provide timely advice to the Commission in the MA setting, the EFSA NUTRITION Unit explores the opportunity:

- To **benefit from the scientific and technical capacity in nutritional and safety assessment** which is present at Member State (MS) level, particularly in national/supranational organisations with experience and expertise in deriving national/supranational dietary reference values (DRVs) and/or setting ULs;
- To task **preparatory work for the scientific assessment of the UL for the above-listed micronutrients** to selected tenderers (see Specific Objectives). Awarded Organisations will contribute to step 2.b of the process described above.

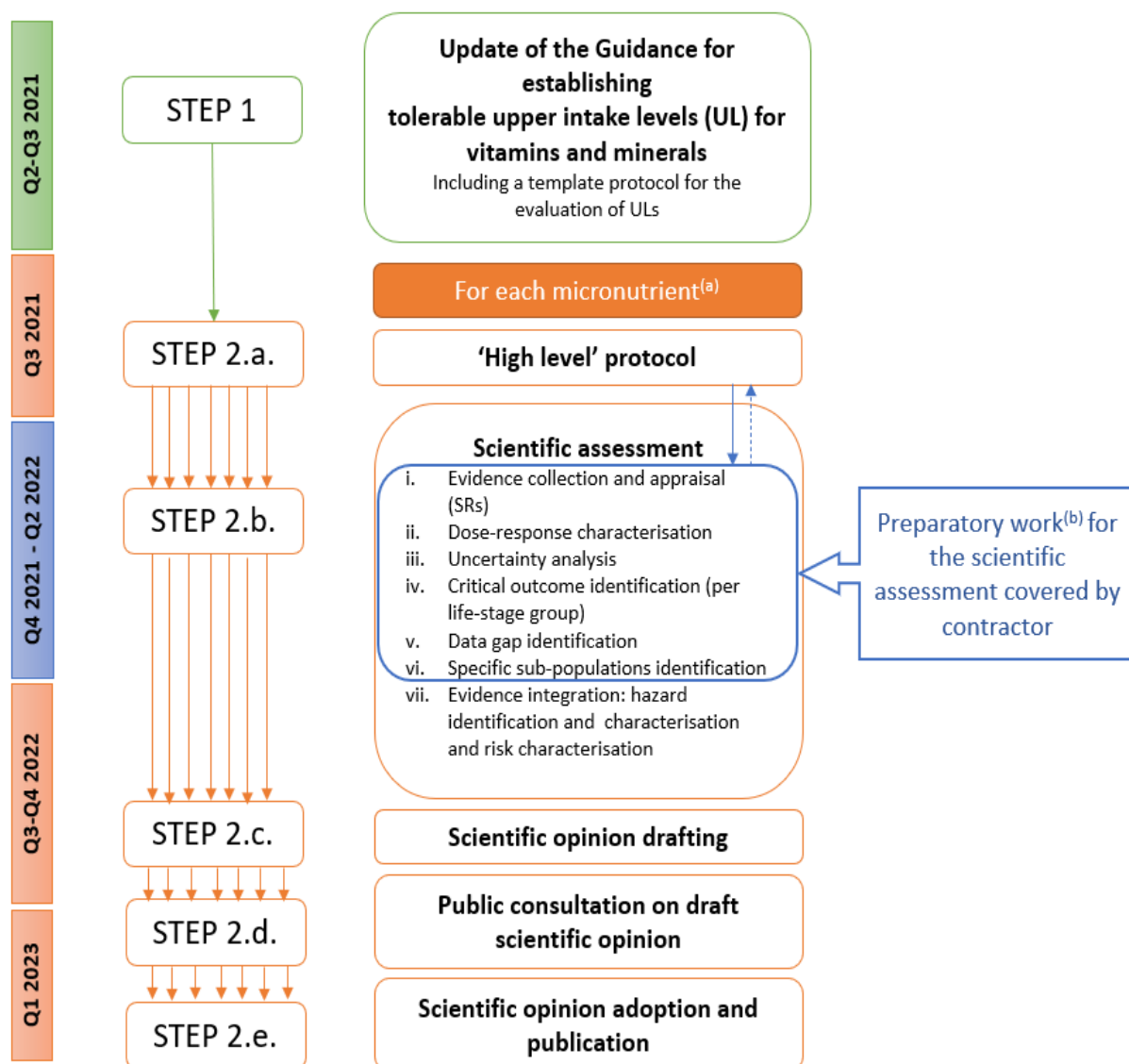
This call is based on EFSA's 2021 Work Programme for grants and operational procurements as presented in Annex XIa of the Programming Document 2021 – 2023, available on the EFSA's website⁷.

⁶ In line with the draft framework for protocol development for EFSA's scientific assessments: <https://www.efsa.europa.eu/en/supporting/pub/en-1843>

⁷ https://www.efsa.europa.eu/sites/default/files/corporate_publications/files/amp2123.pdf



Figure 1. EFSA process and timeline to deliver scientific opinions on UL for vitamins and minerals, including expected contributions from awarded Art. 36 organisations



- (a) Iron, manganese, folic acid/folate, vitamin A, vitamin B6, vitamin D and β -carotene
- (b) Tenderers may apply to conduct the preparatory work for one or several micronutrients, depending on their interest and capacity



1.2 OBJECTIVES AND DIVISION IN LOTS

This call for tenders aims at identifying Organisations which can support EFSA in the preparatory work for the assessment of ULs for vitamins and minerals with a view for EFSA to deliver its scientific opinions to the Commission by March 2023.

- To ensure a harmonised approach and in line with the EFSA's principles for evidence use in scientific assessments (EFSA PROMoting METHods for Evidence Use in Scientific assessments)^{8, 9}, EFSA will develop a 'high level' protocol to be applied for the scientific assessments of the UL for each micronutrient¹⁰. The 'high level' protocol will guide the Awarded Organisations in conducting preparatory work which fits the specific objectives of the call (Section 1.3). The 'high level' protocol will cover the whole scientific assessment process. It is foreseen that the Awarded Organisations, in consultation with EFSA, may further specify the specific parts of the protocol that they will implement (Figure 1).
- Micronutrient(s) of interest shall be specified in the technical offer (hereinafter referred to as "selected micronutrient(s)"). EFSA may award the contract for preparatory work to the Awarded Organisations for one or several micronutrient(s) among the listed micronutrients (hereinafter referred to as "awarded micronutrient(s)").
- Vitamin E is excluded from this call for tenders owing to ongoing re-evaluation by EFSA Panel on Food Additives and Flavourings (FAF).

The objectives of the contract resulting from this procurement procedure for each of the micro-nutrients are as follows:

- **objective 1 for each micro-nutrient** Where needed, to further specify the parts of the protocol that will be implemented, in consultation with EFSA. This may include, for instance, further specification of the literature search strategy(ies), specification of data extraction processes, specification of the analytical plan for the statistical synthesis of the evidence, tailoring of risk of bias tools.
- **objective 2 for each micro-nutrient** To collect and appraise scientific evidence that could be used to derive an UL for each micronutrient. The data collection and appraisal process should follow the requirements of the "high-level" protocol agreed with EFSA. It will include systematic review(s) of the literature (SR) on the relationship between the dietary intake of the awarded micronutrient and health outcomes identified in the protocol. This entails literature screening, data extraction, evidence appraisal (i.e. risk of bias assessment) and evidence (statistical) synthesis (e.g. meta-analysis, dose-

⁸ <https://www.efsa.europa.eu/en/methodology/evidence>

⁹ Draft framework for protocol development for EFSA's scientific assessments: <https://efsa.onlinelibrary.wiley.com/doi/10.2903/sp.efsa.2020.EN-1843>

¹⁰ For illustration, see the Protocol for the scientific opinion on the Tolerable Upper Intake Level of dietary sugars (<https://www.efsa.europa.eu/en/efsajournal/pub/5393>); Protocol for sodium DRVs (<https://zenodo.org/record/1116290#.YMumSGgzbd5>)



response modelling, where appropriate) (EFSA, 2010)¹¹. Narrative reviews may be required to gather contextual evidence relevant to the interpretation of the main body of evidence (e.g. absorption, distribution, metabolism, elimination, of the micronutrient; mechanistic data and modes of action).

- **Objective 3 for each micro-nutrient** Preparatory work for Hazard identification & for Hazard characterisation using the scientific evidence retrieved from (ii) and in accordance with EFSA's updated Guidance for establishing UL for vitamins and minerals. In particular:
 - i. To critically summarise the evidence concerning the capacity of the micronutrient to cause one or more types of adverse effects in humans. This includes an analysis of the uncertainties in the body of evidence according to the framework that will be provided by EFSA. Critical outcomes, for various life-stage groups within the population, that could be used to derive UL for the micronutrient should be identified as the result of this step.
 - ii. To characterise the dose–response relationship between micronutrient intake (dose) and identified adverse effects, where applicable.
- **Objective 4 for each micro-nutrient** To characterise sub-groups of the general populations having distinct and exceptional sensitivities to the adverse effects of the micronutrient, where relevant.
- **Objective 5 for each micro-nutrient** To identify data gaps

This call for tenders is divided into the following 7 lots covering the following micro-nutrients:

- Lot 1 – Vitamin A
- Lot 2 – Folic acid / folate
- Lot 3 – Vitamin D
- Lot 4 – Vitamin B6
- Lot 5 – Iron
- Lot 6 – Manganese
- Lot 7 – β -Carotene

You may submit an offer for one or more lots but your offer should indicate clearly for which lot you are applying. In case you decide to apply for several lots, your technical and financial offer must explicitly state for which lots are applied for.

The tasks carried out to fulfil the specific objectives shall comply with the requirements of the 'high level' protocol mentioned above. The awarded organisation will be participating to the drafting of the 'high level' protocol for the awarded micronutrient (3Q2021) and will further specify the parts of the protocols that they will implement, as appropriate (4Q2021).

EFSA's methodological framework should be applied when performing the tasks related to specific objectives, including:

¹¹ Application of systematic review methodology to food and feed safety assessments to support decision making: <https://doi.org/10.2903/j.efsa.2010.1637>



- The Updated Guidance for establishing tolerable upper intake levels (UL) for vitamins and minerals (to be provided once available - 3Q2021)
- Relevant EFSA cross-cutting guidance¹², including, where relevant:
 - Application of systematic review methodology to food and feed safety assessments to support decision making (EFSA, 2010)¹³
 - Draft for internal testing Scientific Committee guidance on appraising and integrating evidence from epidemiological studies for use in EFSA's scientific assessments (EFSA Scientific Committee, 2020)¹⁴
 - Guidance on Uncertainty Analysis in Scientific Assessments (EFSA Scientific Committee, 2018)¹⁵
 - Guidance on the use of the weight of evidence approach in scientific assessments (EFSA Scientific Committee, 2017)¹⁶
 - Guidance on the assessment of the biological relevance of data in scientific assessments (EFSA Scientific Committee, 2017)¹⁷
 - Guidance on Statistical Reporting (EFSA, 2014)¹⁸
 - Draft framework for protocol development for EFSA's scientific assessments (EFSA, 2020)¹⁹
- The deliverables should comply with EFSA Templates (*to be provided in due course*).

1.3 TASKS, DELIVERABLES, TIMELINE AND PAYMENTS

No.	Tasks & deliverables for each lot awarded	Can be subcontracted? ²⁰	Deadline
1	<p>Task: Revision of the parts of the 'high level' protocol that will be implemented by the awarded tenderer, if applicable. The parts requiring revisions will be identified with EFSA during the kick-off meeting and may include, for instance, further specification of the literature search strategy(ies), specification of data extraction processes, specification of the analytical plan for the statistical synthesis of the evidence, tailoring of risk of bias tools.</p> <p>Deliverable 1: Revised version of the protocol</p>	No	Indicatively 1 month from kick-off meeting [at the latest by 30 NOVEMBER 2021]
2	<p>Task: Literature screening and selection and data extraction</p>	Yes	Indicatively 4 months from kick-off meeting

¹² [https://efsa.onlinelibrary.wiley.com/doi/toc/10.1002/\(ISSN\)1831-4732.GUIDANCE](https://efsa.onlinelibrary.wiley.com/doi/toc/10.1002/(ISSN)1831-4732.GUIDANCE)

¹³ <https://efsa.onlinelibrary.wiley.com/doi/10.2903/j.efsa.2010.1637>

¹⁴ <https://efsa.onlinelibrary.wiley.com/doi/10.2903/j.efsa.2020.6221>

¹⁵ <https://efsa.onlinelibrary.wiley.com/doi/10.2903/j.efsa.2018.5123>

¹⁶ <https://efsa.onlinelibrary.wiley.com/doi/10.2903/j.efsa.2017.4971>

¹⁷ <https://efsa.onlinelibrary.wiley.com/doi/10.2903/j.efsa.2017.4970>

¹⁸ <https://efsa.onlinelibrary.wiley.com/doi/10.2903/j.efsa.2014.3908>

¹⁹ <https://efsa.onlinelibrary.wiley.com/doi/10.2903/sp.efsa.2020.EN-1843>

²⁰ 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 the subcontractor to sign the contract.



	Deliverable 2: Written interim report N.1, which will describe the literature screening process and outcome and will include evidence tables and/or data extraction tables, according to EFSA's templates.		[at the latest by 1 MARCH 2022]
3	Task: Evidence appraisal and synthesis Deliverable 3: Written interim report N.2, which will report on the evidence synthesis (including risk of bias appraisal, meta-analysis, dose-response modelling, where appropriate)	Yes	Indicatively 7 months from kick-off meeting [at the latest by 1 JUNE 2022]
4	Task: Critical summary of the evidence and analysis of uncertainties Deliverable 4: Written interim report N.3, which will provide a critical summary of the evidence concerning the capacity of the nutrient to cause one or more types of adverse effects in humans, including an analysis of the uncertainties in the body of evidence according to EFSA's framework.	Yes	Indicatively 8 months from kick-off meeting [at the latest by 1 JULY 2022]
5	Task: Preparation of the final technical report as described below. Deliverable 5: Final technical report, which will comprise the integration of the interim reports N.1, 2, 3 and i) conclusions on the identification of critical outcomes that could be used to derive UL for the micronutrient, for various life-stage group; ii) a characterisation of the dose-response relationships between micronutrient intake (dose) and the critical outcomes; iii) a characterization of sub-groups of the general populations having distinct and exceptional sensitivities to the adverse effects of the micronutrient, where relevant; iv) the identification of data gaps; v) a description of the contextual evidence relevant to the interpretation of the main body of evidence.	No	Indicatively 9 months from kick-off meeting [at the latest by 31 JULY 2022]
No.	Meetings for each lot awarded		Deadline for finalisation
1	Kick-off meeting , one day ²¹ teleconference ²² . At this meeting, details of the tasks will be discussed, the objectives, the deliverables and their structure for presentation and also the timeframe will be clarified. Minutes of the meeting shall be taken and provided to EFSA by the contractor. During this meeting, in addition to operational implementation the		No later than two weeks from entry into force of contract

²¹ One day = 8 hours, half day = 4 hours

²² In the event of the award of several lots to one contractor, for the first lot awarded the kick-off meeting will be one day duration, however, for additional lots awarded the kick-off meeting may be reduced to a half-day.



	administrative and financial matters related to contract implementation will be discussed.	
2	Interim meetings half day ²³ teleconference Organised between the Project Leader of the awarded tenderer & the Scientific Co-ordinator of EFSA. The purpose of these meetings is to inform on the progress as well as any problems or difficulties encountered. Minutes of the meeting shall be taken and provided to EFSA by the contractor.	Indicatively every 6 weeks from kick off meeting
3	Attendance to EFSA Working Group on UL/NDA Panel meetings , via teleconference (max. 4 half day attendances foreseen): The appointed Project Leader, or a delegate member of the project team, will be invited to attend the meetings of the EFSA Working Group on UL/NDA Panel to update on the progress of the tasks; to seek feedback and solve issues that may arise during tasks implementation; to take strategic decisions and refine approaches when necessary; and, ultimately, to present the draft Technical Report.	<i>Ad-hoc</i> attendance upon request of EFSA.
4	Final meeting: one day teleconference The purpose of this meeting is to present and discuss the final technical report as well as any problems or difficulties encountered.	9 months from kick off meeting
No.	Payments for each lot awarded	Linked to EFSA approval of deliverable No.
1	Interim payment of 30 %	2
2	Payment of the balance of 100% - 50% of the interim payment	5

Tenderers should note that all reports, minutes, outcomes of discussions could be submitted at EFSA’s discretion to EFSA’s NDA Panel and members of the working group (WG) on upper levels.

The working language for contract implementation including execution of tasks, meetings and deliverables shall be English. Any written deliverables must be to a high standard of English which does not require proof reading.

It should also be noted that whilst deliverable no.5 for each lot is due no later than July 2022, indicatively nine months from contract signature date, the precise contract signature date is not yet known. The total duration of the contract is set at 12 months to allow time for any necessary revisions and/or completion of the final technical report if need be. This includes addressing EFSA’s feedback on the final technical report provided during the final meeting.

1.4 INFORMATION ON THE CONTRACT

Nature of expense services

Type of contract direct

²³ One day = 8 hours, half day = 4 hours



Maximum number of contractors for each lot = 1

Place of performance: contractor's premises

Duration of tasks in direct contract

12 months from kick-off meeting

Budget information

The maximum budget EFSA has available for each lot (each micro-nutrient) is 230,000 €. Any offer exceeding this maximum for each micro-nutrient will be excluded from further assessment during evaluation.

1.5 OWNERSHIP, INTELLECTUAL PROPERTY RIGHTS, USE OF RESULTS

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 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

In the specific case of **literature reviews**, should the entirety or partial texts covered by pre-existing rights be used in the final deliverables for EFSA 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".

In practical terms in the context of systematic reviews, EFSA requires a list of references to be provided as part of the deliverables that does not entail any copyright issues. In addition in case of systematic reviews full texts may be shared with EFSA for the sole purpose of assessing the completeness of deliverables. Full texts will not be part of final deliverables.



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.

EFSA does not acquire ownership or any license of pre-existing rights not incorporated in the deliverables. The full ownership is limited to the deliverables, which might include licensed pre-existing rights on excerpts, parts, texts etc., if fully or partially incorporated in the final deliverables.

The draft contract in Annex 2 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.

Use of results

EFSA is committed to the publication of contract deliverables - such as supporting evidence in the form of datasets, raw data, protocols etc. in the Knowledge Junction in order to improve transparency, reproducibility and evidence reuse. The [Knowledge Junction²⁴](#) repository of EFSA runs on the EU-funded Zenodo research-sharing platform where uploaded items receive a unique Digital Object Identifier to make them citable. Any part of the output resulting from this contract may be published (at EFSA's discretion) on the Knowledge Junction repository, with attribution to the contractor, and several deliverables can be cross-linked among them and to the published final Report on Wiley Online Library.

1.6 PERSONAL DATA AND CONFIDENTIALITY

Processing of personal data by EFSA as contracting authority

Information on the processing of personal data by EFSA as contracting authority in charge of the present procurement procedure is available in the [Privacy Statement](#) on the EFSA website as well as in Article II.9.1 of the draft contract in Annex 2.

Please note that your personal data as a tenderer or selected contractor 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. The relevant Privacy Statement is available on the European Commission's website, here:

http://ec.europa.eu/budget/explained/management/protecting/protect_en.cfm#BDCE.

Processing of personal data by the selected contractor

In case tasks and activities under this call relate to the processing of personal data, Article II.9.2 of the draft contract in Annex 2 shall be observed.

²⁴ <http://www.efsa.europa.eu/en/press/news/190117> and <https://zenodo.org/communities/efsa-kj/?page=1&size=20>



For further information on data protection, please refer to the [EFSA guidance for tenderers](#) on the EFSA website, page 13.

Confidentiality

Tender bids will be treated confidentially in accordance with the case law of the European Courts, which confirms the existence of a presumption of non-disclosure in case of a request for public access to documents in accordance with Regulation (EC) No 1049/2001. This does not prevent that specific parts of the submitted tender may be subject to disclosure when applicable law so requires. Unless there is an overriding public interest in disclosure, EFSA will refuse full access to the submitted tender, redacting the parts that contain confidential information, the disclosure of which would undermine the protection of commercial interests and intellectual property of the tenderer.

Accordingly, EFSA will disregard general statements that the whole tender or substantial parts thereof are confidential information. Tenderers need to mark clearly the specific parts of their tender bid they consider confidential providing an explanation why the information should not be disclosed, which may be subject to EFSA's further assessment in accordance with applicable law.



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 refer to the [EFSA Guidance for tenderers](#).

2.1 OPENING OFFERS

The aim of the public opening session is to check whether the offer received was dispatched by the deadline for tender receipt 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 for each lot applied for 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 for each lot, the following will be assessed only for the tenderer proposed for contract award of each lot: 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); Selection criteria (Economic & Financial capacity).

Evidence under sections 2.3 and 2.4 does not have to be submitted to EFSA if it has already been submitted in response to a previous EFSA call. In such case the evidence must be exactly the same as requested in these tender specifications and not older than 12 months. Please specify the reference of the EFSA call for tenders under which you have already submitted the evidence to EFSA if you chose to rely on such evidence.

2.3 GROUNDS FOR EXCLUSION

Eligibility – access to EU Market

Only offers from tenderers established in eligible countries will be allowed to the next step of the evaluation. Please refer to the [EFSA Guidance for tenderers](#) for further details.

Evidence requested in your offer:

Tenderers must submit the Administrative data forms (including LEF and BAF) available [here](#). **If applying for more than one lot, only one Administrative data form is required.**

Exclusion

Tenderers must not be in one of the exclusion situations listed in article 136 of the Financial Regulation, explained in the [EFSA Guidance for tenderers](#).

Evidence requested in your 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 [here](#). In case of a joint offer from a group of economic operators, such declaration should be submitted for each member of the group. **If applying for more than one lot, only one Declaration on Honour on exclusion criteria is required.**



Further supporting evidence in support of this declaration may be requested from the successful tenderer prior to signature of the contract for each lot awarded. Such requested evidence will be specified in the award letter and may have to be provided to EFSA before the contract is signed.

2.4 SELECTION CRITERIA FOR EACH LOT

In addition to the evidence requested below, 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.

A) Economic and financial capacity for each lot

The tenderer must have generated an overall annual turnover of at least 200,000 € in each of the last 2 closed financial years (2019 and 2020).

Evidence requested in the offer:

Tenderers must declare they fulfil the economic and financial capacity by providing a signed and dated Declaration on Honour on selection criteria, available [here](#). In case of a joint offer from a group of economic operators, such declaration should be completed by the leading partner only. **If applying for more than one lot, only one Declaration on Honour on selection criteria is required.**

EFSA will request proof of annual turnover from the successful tenderer prior to signature of the contract(s) for each lot awarded. Such requested evidence will be specified in the award letter and must be provided to EFSA before the contract is signed. This evidence will be evaluated on a consolidated basis.

During contract implementation, in case of request for the addition of new subcontracting or assignment of the contract to a new legal entity, the economic and financial capacity will be checked for the last 2 most recent closed financial years and not necessarily the financial years published with the call.

B) Technical and professional capacity applicable for each lot

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

- a) Extensive and demonstrable experience in:
 - 1) Conducting safety assessment of (micro)nutrients or nutrient sources. This expertise includes experience with the implementation of nutrient risk assessment methodologies, using human data, and expertise in human metabolism and physiology of nutrients; AND
 - 2) Implementing or supervising Systematic Review stepwise process in Lifesciences context. This includes literature screening, data extraction, evidence appraisal (i.e. risk of bias assessment) and evidence (statistical) synthesis (e.g. meta-analysis, dose-response modelling; AND
 - 3) Setting of Upper Levels and/or Dietary reference values for (micro)nutrient(s) at national or supranational level.
- b) Ability to provide a team of experts compliant with these specific expertise requirements:
 - 1) University degree, in any of the following areas: human nutrition, public health nutrition, human medicine, epidemiology, intake



- data/exposure assessment, biochemistry, toxicology, biostatistics, information and data management, or related/similar areas (NB: for related/similar areas, the applicant should explain their relevance for the tasks); AND
- 2) Demonstrable work experience (e.g. evidenced by scientific publications, description of the relevant projects) in one of the following fields:
 - experience with the implementation of nutrient risk assessment methodologies, using human data
 - expertise in human metabolism and physiology of nutrients
 - experience in the setting of Upper Levels and/or Dietary reference values;
 - experience in performing or supervising the Systematic Review stepwise process in Lifesciences context
- c) The Project leader must have:
- 1) demonstrable experience in project coordination of assessments in the area of Human Nutrition or in the area of Setting of Upper Levels and/or Dietary reference values; AND
 - 2) an excellent level of spoken and written English.
 - 3) Tenderer must also propose a back-up project leader meeting the same requirements as described in c.1) and c.2).

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

- d) The tenderer must have access to relevant bibliographic platforms and databases for contract execution.

Evidence requested in the offer:

- Requirement a)
 - At least 2 scientific publications in the last 10 years should be provided (PDF or hyperlink to the document). These publications should demonstrate experience in a.1) and a.3);
 - At least 1 systematic review report produced or supervised by the tenderer in the last 10 years (PDF or hyperlink to the document). This report should demonstrate experience in a.2);
- Requirement b):
 - Detailed CVs of the Project team members proposed for the assignment (relevant work experience should be evidenced in the CVs by a description of the relevant projects or scientific publications accompanied by hyperlinks). EFSA recommends submitting the CVs in the EU CV format which can be accessed [here](#);
 - Tenderers should also provide a one-page summary of the names of the individual Project team members.
- Requirements c):
 - Detailed CV of the Project Leader and back-up Project Leader demonstrating:
 - experience in project coordination of assessments in the area of Human Nutrition or in the area of Setting of Upper Levels and/or Dietary reference values (this should be evidenced by a



- description of the relevant projects or scientific publications accompanied by hyperlinks), and
- an excellent level of spoken and written English (for non-native speakers, this should be evidenced by either having worked in a working environment where English is used for meetings OR having published scientific publications and made oral presentations in conferences in English OR teaching in English AND/OR Certificate B2 level).
- Requirement d):**
 - A signed statement indicating the relevant bibliographic platforms and databases to which the tenderer will have access to conduct the literature searches.
 - Declaration on Honour on selection criteria** available [here](#). To be signed by the tenderer (in case of joint offer signed by the leading partner only);
 - Confirmatory statement of resources** (*only applicable for joint offers or offers with subcontracting*): a statement signed by each partner/subcontractor confirming they will provide the necessary resources for the performance of the contract;

C) Professional conflicting interest

In accordance with article 167(1)(c) of the Financial Regulation and paragraph 104 of the recitals, if EFSA, based on the assessment of the technical and professional 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.

Evidence requested:

The tenderer proposed for contract award for each lot will be requested, prior to and as a condition of contract signature for each lot, to provide:

Institutional declaration of interests available [here](#) In case of a group of economic operators and/or in case of subcontracting, such declaration will need to be completed separately and submitted for each partner and for each identified subcontractor and;

Individual declarations of interests available [here](#) for each member of the proposed project team.

Institutional and Individual DoIs do not need to be provided with your offer. The requirement to submit Institutional and Individual DoIs will be specified in the award letter and will have to be provided and assessed by the EFSA Authorising Officer before and as a condition of contract signature. Please refer to [EFSA's policy on independence](#) and the [Decision of the Executive Director on Competing Interest Management](#) for detailed information.

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 economic, financial, technical and professional capacity requirements.



If any of the declarations or information provided proves to be false, EFSA may impose administrative sanctions (exclusion or financial penalties) on the entity providing the false declarations/information.

For the purposes of the evaluation related to exclusion and selection criteria EFSA may also refer to publicly available information, in particular evidence that it can access on a national database free of charge.

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 do not comply with the tender specifications and will be rejected if they:

- do not comply with minimum requirements laid down in the tender specifications;
- propose a solution different from the one 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/EU²⁵ and compliance with data protection obligations resulting from Regulation (EU) 2016/679 and Regulation (EU) 2018/1725²⁶.

The grounds for rejection is not linked to the award criteria so there is no evaluation. The tenderer will be informed of the grounds for rejection without being given feedback on the content of the tender other than on the non-compliant elements.

2.6 AWARD CRITERIA APPLICABLE FOR EACH LOT

Tenders will be evaluated against the below award criteria. The award criteria serve to identify the **most economically advantageous offer for each lot applied for**.

A) QUALITY AWARD CRITERIA FOR EACH LOT

1. METHODOLOGY PROPOSED FOR IMPLEMENTATION (50 points)

Tenderers should provide a logical and structured step by step explanation of how they intend to approach the tasks from the scientific perspective, giving a clear explanation of their approach to each task described in section 1.3 and demonstrating acceptance of the methodological conditions to be applied by EFSA.

²⁵ OJ L 94 of 28.03.2014, p. 65

²⁶ Regulation (EU) 2018/1725 of the European Parliament and of the Council of 23 October 2018 on the protection of individuals 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, OJ L 295/39 21.11.2018, <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32018R1725&from=EN>



2. MICRO-NUTRIENT SPECIFICS (10 points)

Tenderers should make clear in their technical offer which micronutrient they apply for. Tenderers may apply for one or more lots (one micronutrient per lot). Considering the specificities of the micronutrient(s) to which they apply, tenderers should explain the specific technical aspects for the performance of tasks in section 1.3 and outline potential key issues relevant to these nutrient(s).

3. PROJECT ORGANISATION (40 points)

Tenderers should provide clear and detailed information on:

- the distribution of tasks among the project team; in case of joint offer and/or subcontractors, clarity on who does what, when and why (justify why the partner/subcontractor is proposed to do the particular task/work-package); **(20 points)**
- the role of team leader / leading partner in quality assurance and additional measures for quality assurance proposed; **(10 points)**
- the proposed measures to ensure the meeting of the deadlines, including measures to ensure availability of proposed team members and mitigation strategies to cover absences; **(10 points)**

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

Tenderers must provide a detailed technical offer addressing all points in the technical specifications and each of the quality award criteria. Repetition of mandatory requirements in the technical specifications without providing detail in the technical offer will only result in a very low score.

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

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

B) PRICE AWARD CRITERION FOR EACH LOT

Tenders which passed the quality threshold will be further assessed to ensure:

- I. the price offer is made within 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 FOR EACH LOT

Tenders for which financial offers were made within the maximum budget 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 following formula:



TOTAL SCORE OF THE EVALUATED OFFER (C) =

30 * Cheapest price offer/price of tender X

+

70 * Total quality score (out of 100) for all quality award criteria of tender X/100



PART 3 - HOW TO SUBMIT YOUR OFFER USING e-SUBMISSION

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. It is not possible to submit a tender through eSubmission after the time-limit for receipt of tenders indicated in the contract notice and/or the TED eTendering website.

Registration in the Participant Register

Any economic operator willing to submit a tender must be registered in the [Participant Register](#) - an online register of organisations and natural persons participating in European Commission's calls for tenders or proposals.

On registering each participant obtains a Participant Identification Code (PIC, 9 - digit number) which acts as its unique identifier in the Participant Register. A participant needs to register only once – the information provided can be further updated or re-used by the participant in other European Commission's calls for tenders or calls for proposals.

At any moment during the procurement procedure the Research Executive Agency Validation Services (hereafter *the EU Validation Services*) may contact the participant and ask for supporting documents on legal existence and status [and financial capacity].

The requests will be made through the register's messaging system to the e-mail address of the participant's contact person indicated in the register. It is the responsibility of the participant to provide a valid e-mail address and to check it regularly.

The documents that may be requested by *the EU Validation Services* are listed in the [EU Grants and Tenders Rules on Legal Entity Validation, LEAR appointment and Financial Capacity assessment](#).

Please note that a request for supporting documents by the *EU Validation Services* in no way implies that the tenderer has been successful.

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](#)²⁷. 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.

The e-Submission "[quick guide for economic operators](#)" is available after logging in with your EU Login password.

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 on Exclusion criteria.** All members of a joint tender, including subcontractors – if applicable – must upload the signed and dated declaration on honour on exclusion criteria using the template available [here](#).
- **Signed declaration on Honour on Selection criteria.** In case of a joint offer from a group of economic operators, such declaration should be completed by the leading partner using the template available [here](#).
- **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.

For detailed instructions on how to submit your tender, consult the Quick Reference Guide for Economic Operators 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:

²⁷ Previously called European Commission authentication system (ECAS)



- **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.

Re-submission of a tender

After submitting a tender, but within the time limit for receipt of tenders, you may still submit a new version of your tender. **If you submit a new Tender you must include all your Tender documents, including the Qualification and Tender documents.**

You must formally notify EFSA that the previous tender is withdrawn. The notification letter must be signed by the legal representative who signed the original tender stating the call reference and the Tender ID you wish to withdraw. The notification must be uploaded in e-submission together with the new version of all tender documents. You are kindly requested to also e-mail the notification letter to EFSAProcurement@efsa.europa.eu.

Withdrawal of tenders

If after submitting a tender, you wish to completely withdraw your tender, you must formally notify EFSA that you wish to withdraw your submitted Tender(s) as indicated above.

Alternative tender

You are entitled to send several tenders to one call for tenders.

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. It is not possible to submit a tender through eSubmission after the time-limit for receipt of tenders indicated in the contract notice and/or the TED eTendering website.

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

- 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.



ANNEX 1 - FINANCIAL OFFER TEMPLATE FOR EACH LOT APPLIED FOR

Tenderers are requested to use this template for preparing their financial offer. **Tenderers should indicate their financial offer ONLY FOR THE LOT OR LOTS APPLIED FOR.** 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 each lot (each micronutrient) is 230,000 €.** Any offer exceeding this maximum for each lot will not be retained for contract award.
- Prices must be quoted in Euro. Tenderers from countries outside the euro zone have to quote their prices in euro. The price quoted may not be revised in line with exchange rate movements. It is for the tenderer to bear the risks or the benefits deriving from any variation.
- 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, travel, subsistence/accommodation expenses, etc. should also be factored into 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.
- It is the responsibility of each tenderer to ensure that the total amount of the tender inserted in the relevant field of the e-Submission application corresponds to the amount indicated in the uploaded financial offer. In case of discrepancies, only the amount indicated in the financial offer will be taken into account.

<p style="text-align: center;">ALL INCLUSIVE TOTAL PRICE FOR LOT 1 – VITAMIN A</p> <p>to be used for the evaluation and for contract implementation in the case of award.</p>	<p>..... €</p>
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<p style="text-align: center;">ALL INCLUSIVE TOTAL PRICE FOR LOT 2 – FOLIC ACID / FOLATE</p> <p>to be used for the evaluation and for contract implementation in the case of award.</p>	<p>..... €</p>
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<p style="text-align: center;">ALL INCLUSIVE TOTAL PRICE FOR LOT 3 – VITAMIN D</p> <p>to be used for the evaluation and for contract implementation in the case of award.</p>	<p>..... €</p>
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<p style="text-align: center;">ALL INCLUSIVE TOTAL PRICE FOR LOT 4 – VITAMIN B6</p> <p>to be used for the evaluation and for contract implementation in the case of award.</p>	<p style="text-align: center;">..... €</p>
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<p style="text-align: center;">ALL INCLUSIVE TOTAL PRICE FOR LOT 5 – IRON</p> <p>to be used for the evaluation and for contract implementation in the case of award.</p>	<p style="text-align: center;">..... €</p>
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<p style="text-align: center;">ALL INCLUSIVE TOTAL PRICE FOR LOT 6 - MANGANESE</p> <p>to be used for the evaluation and for contract implementation in the case of award.</p>	<p style="text-align: center;">..... €</p>
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<p style="text-align: center;">ALL INCLUSIVE TOTAL PRICE FOR LOT 7 - β-CAROTENE</p> <p>to be used for the evaluation and for contract implementation in the case of award.</p>	<p style="text-align: center;">..... €</p>
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Tenderer name:

Name of person signing the financial offer:

His/her position in the company:

His/her signature:

Date:



ANNEX 2 - DRAFT CONTRACT

The contract which results from this procurement procedure will be based on the model annexed to these tender specifications.