



## TENDER SPECIFICATIONS

**Reference:** OC/EFSA/SCER/2020/02

**Subject: Screening for emerging chemical risks in the food chain**

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

**Project/Process code:** D01.01-SCER-03.18

**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](mailto: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 <sup>1</sup>	Comments
Launch date	30/06/2020	Date Contract Notice is sent to Official Journal
Deadline for sending request for clarification to EFSA	22/09/2020 at 14:30	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	24/09/2020	
"Receipt Time Limit" - Closing date and time for receipt of offers	<b>30/09/2020 at 14:30 (CEST)</b>	Refer to the Invitation letter and part 3 of these tender specifications regarding how to submit your offer.
Opening session	01/10/2020 at 14:30	Due to COVID-19 related restrictions on access to EFSA's premises, the public opening session will be held as a virtual online meeting.  Requests to attend the virtual online 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 October 2020	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 November 2020	

<sup>1</sup> 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**

The European Food Safety Authority's (EFSA) Founding Regulation (EC) No 178/2002 (Article 34), requires EFSA to establish monitoring procedures for systematically searching for, collecting, collating and analysing information and data with a view to the identification of emerging risks in the fields within its mission. An 'emerging risk' is understood to be a risk resulting from (a) a newly identified hazard to which significant exposure may occur or (b) an unexpected new or increased significant exposure or susceptibility to a known hazard.

Emerging chemical risks may arise from intentional or unintentional contamination of the food chain either by anthropogenic or "natural" chemicals. A systematic framework for the identification of emerging chemical risks in the food chain using data generated under the REACH regulation was published in 2014. The methodology proposed was further developed and tested on 100 substances registered under REACH (project report on REACH 1<sup>2</sup> & Oltmanns et al., 2018<sup>3</sup>). The tested screening procedure was then applied to the 15021 substances registered in REACH (project report on REACH 2<sup>4</sup> & Oltmanns et al., 2020<sup>5</sup>). Substances were assessed and scored for environmental release (tonnage and use information from REACH registration dossiers), biodegradation (predictions from BIOWIN models 3, 5 and 6 evaluated in a battery approach), bioaccumulation in food/feed (ACC-HUMAN steady modelling) and chronic human health hazards (classification according to the CLP Regulation for carcinogenicity, mutagenicity, reproductive toxicity and repeated dose toxicity as well as IARC classification for carcinogenicity). Prioritisation based on the scores assigned and additional data curation steps identified 212 substances that were considered "potential emerging risks" in the food chain.

A follow-up project has been proposed and agreed by the EFSA Scientific Committee at its meeting in June 2019 to analyse food samples for occurrence of substances in the priority list.

The technical offers submitted should follow the terms and definitions that are used in the International Standard ISO/IEC 17025 "General requirements for the competence of testing and calibration laboratories"<sup>6</sup>.

This call is based on EFSA's 2020-2022 draft Work Programme for grants and operational procurements as presented in Annex IX of the Programming Document 2020 – 2022, available on the EFSA's website<sup>7</sup>.

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<sup>2</sup> <https://www.efsa.europa.eu/en/supporting/pub/en-1050>

<sup>3</sup> J. Oltmanns, O. Licht, A. Bitsch, M.-L. Bohlen, S. E. Escher, V. Silano, M. MacLeod, R. Serafimova, G. E. N. Kass, C. Merten. 2018. Development of a novel scoring system for identifying emerging chemical risks in the food chain.. Environmental Science, Processes & Impacts. DOI: 10.1039/c7em00564d

<sup>4</sup> <https://www.efsa.europa.eu/en/supporting/pub/en-1597>

<sup>5</sup> J. Oltmanns, O. Licht, M.-L. Bohlen, M. Schwarz, S. E. Escher, V. Silano, M. MacLeod, H. P. J. M. Noteborn, G. E. N. Kass, C. Merten 2020. Potential emerging chemical risks in the food chain associated with substances registered under REACH. Environmental Science, Processes & Impacts. Environ. Sci.: 22, 105 DOI: DOI: 10.1039/c9em00369j

<sup>6</sup> <https://www.iso.org/obp/ui/#iso:std:iso-iec:17025:ed-3:v1:en>

<sup>7</sup> [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/amp2022.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/amp2022.pdf)



## 1.2 OBJECTIVES

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 this tender specification.

The **overall objective** of the contract will be to analyse food and feed for the presence of chemicals that are potential emerging risks using the 212 substances identified in previous work as a suspect list and using non-target analysis, and for a subset of identified substances to quantify levels and assess risks.

### **Specific objectives:**

The objectives of the contract resulting from the present procurement procedure will be as follows:

**Objective 1:** To apply a screening approach to 212 chemicals currently registered under the REACH legislation that were assigned high priority as potential unrecognised contaminants in the European food chain by Oltmanns et al. 2020 and in the EFSA external scientific report of 2019 as mentioned in the Background section. (set 1)

**Objective 2:** To concurrently apply non-target screening for halogenated organic chemicals which may have been introduced unintentionally through industrial and/or anthropogenic sources and have not been recognised as contaminants in the food chain before. (set 2)

It should be noted that objective 1 has higher importance than objective 2, although the offer must cover both.

**Objective 3:** To fully quantify the occurrence of a limited number of chemicals in food and feed (set 3, where set 3 is a subset of sets 1 & 2).

**Objective 4:** To evaluate in more detail, in consultation with EFSA, the significance of the occurrence levels of analysed chemicals in set 3 to characterise their risks.

## 1.3 TASKS, DELIVERABLES, TIMELINE AND PAYMENTS

No.	Tasks & deliverables	Can be subcontracted? <sup>8</sup>	Deadline
1	<p><b>Task:</b> Prepare an inception report summarizing the discussion from the kick-off meeting and presenting the work plan in agreement with EFSA of the entire project duration.</p> <p><b>Deliverable:</b> Inception report<sup>9</sup> describing the workplan of the project.</p>	Yes	1 month from kick-off meeting

<sup>8</sup> 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.

<sup>9</sup> All reports shall be drafted according to the EFSA template on EFSA external scientific report.



2	<p><b>Task:</b> Selection of chemicals to be screened in food/feed for:</p> <ul style="list-style-type: none"> <li>• Suspect screening (set 1): 212 priority chemicals currently registered under the REACH legislation as described by Oltmanns et al. 2020</li> <li>• Non target screening (set 2): the contractor should propose a strategy for screening for the presence of halogenated organic substances in food and feed; the following substances should <u>not</u> be included in set 2: <ul style="list-style-type: none"> <li>○ substances which are physiologically present (i.e. endogenous compounds) in food/feed ;</li> <li>○ substances already risk assessed by EFSA and/or the Joint FAO/WHO Expert Committees (JECFA, JMPR) ;</li> </ul> </li> <li>• Prepare Interim Report 1 describing the above tasks and plans for the next steps.</li> </ul> <p><b>Deliverable:</b> Interim Report 1 describing execution of task 2 and 3.</p>	Yes	3 months from kick-off meeting
3	<p><b>Task:</b> Propose preparatory steps to be undertaken prior to the start of the actual screening:</p> <ul style="list-style-type: none"> <li>• For each (or group of) substance(s) in set 1: <ul style="list-style-type: none"> <li>○ To propose a strategy (scope, representativity, sampling strategy, number of samples, data processing) justifying the selection of target food and feed matrices from different locations to be screened for the presence of these substance(s); unprocessed/raw samples (e.g. primary agricultural products such as meat, fish and milk); to be cross checked with Oltmanns et al. 2020 where bioaccumulation was predicted for several food matrices;</li> <li>○ To define analytical chemical methodology to be applied for sample preparation, instrumental analysis, identification &amp; quantification of analytes, treatment of left-censored data, quality assurance and data processing for the suspect</li> </ul> </li> </ul>	Yes	3 months from kick-off meeting



	<p>screening of set 1 substances in the selected food and feed matrices ;</p> <ul style="list-style-type: none"> <li>○ To define a quality assurance strategy that will demonstrate sufficient sensitivity and selectivity for each screening methodology ;</li> </ul> <ul style="list-style-type: none"> <li>• For set 2: <ul style="list-style-type: none"> <li>○ The same food and feed matrices used for set 1 can be used for the non-target screening for the presence of emerging chemical substances defined as set 2;</li> <li>○ To define analytical chemical methodology to be applied for sample preparation, instrumental analysis, identification &amp; quantification of analytes, treatment of left-censored data, quality assurance and data processing ;</li> <li>○ To define a quality assurance strategy that will demonstrate sufficient sensitivity and selectivity for each screening methodology ;</li> <li>○ To propose a strategy for specifying reliability of structural assignments of identified substances as proposed by Schymanski et al.2014 ;</li> </ul> </li> <li>• Examples of instrumental analysis may include e.g. high-resolution LC-MS, LC-MS/MS, GC-MS, GC-MS/MS, TOF, Orbitrap); and for data processing e.g. using MS libraries and statistical approaches, such as metabolomics, principal component analysis for positive identification of the set 2 substances in the food and feed matrices.</li> <li>• The proposed strategies will need to be agreed with EFSA.</li> <li>• Prepare an interim report 1 describing above tasks and plan for the next steps.</li> </ul> <p><b>Deliverable:</b> Interim report 1 describing execution of task 2 and 3 and plan for the next steps.</p>		
4	<p><b>Task:</b> Carrying out suspect screening of set 1 to qualitatively establish the set 1 substances</p>	Yes	1 year from kick-off meeting



	<p>occurring in the food chain,</p> <ul style="list-style-type: none"> <li>• Collection of representative samples of food and feed (the same samples for set 1 and set 2)</li> <li>• Prepare extracts from collected representative food and feed samples and perform analysis for suspect screening of the presence of set 1 substances (see also previous task No.3-set 1).</li> <li>• Prepare interim reports on the materials and methods applied, and on the results of the screening survey with a full account of analytical performance of the screening methodology applied.</li> </ul> <p><b>Deliverables:</b></p> <ul style="list-style-type: none"> <li>• Interim report 2 after 6 months from kick-off meeting describing progress on tasks 4,5 &amp; 6 and plan for the next steps.</li> <li>• Interim report 3 after 9 months from kick-off meeting describing progress on tasks 4,5 &amp; 6 and plan for the next steps.</li> <li>• Interim report 4 after 12 months from kick-off meeting describing execution of task 4,5 &amp; 6 and plan for the next steps.</li> <li>• Database with results on set 1. Data need to be submitted in SSD2 (Standard Sample Description version 2) format.</li> </ul> <p>The link is as follows:  <a href="https://www.efsa.europa.eu/en/consultations/call/call-continuous-collection-chemical-contaminants-occurrence-data">https://www.efsa.europa.eu/en/consultations/call/call-continuous-collection-chemical-contaminants-occurrence-data</a></p>		
5	<p><b>Task:</b> Carrying out non target screening to identify qualitatively chemicals in set 2 according to protocol agreed under task 3.</p> <ul style="list-style-type: none"> <li>• Prepare extracts from collected representative food and feed samples and perform non-target screening to identify chemicals in-set 2.</li> <li>• Provide an analysis of likely sources of the identified emerging substances</li> <li>• Prepare interim reports on the materials and methods applied, and on the results of the screening survey with a full account of analytical performance of the screening methodology applied.</li> </ul> <p><b>Deliverables:</b></p> <ul style="list-style-type: none"> <li>• Interim report 2 after 6 months from</li> </ul>	Yes	1 year from kick-off meeting



	<p>kick-off meeting describing progress on tasks 4 &amp; 5 and plan for the next steps.</p> <ul style="list-style-type: none"> <li>• Interim report 3 after 9 months from kick-off meeting describing progress on tasks 4 &amp; 5 and plan for the next steps.</li> <li>• Interim report 4 after 12 months from kick-off meeting describing execution of task 4,5 &amp; 6 and plan for the next steps.</li> <li>• Database with results on set 2. Data need to be submitted in SSD2 (Standard Sample Description version 2) format. The link is as follows: <a href="https://www.efsa.europa.eu/en/consultations/call/call-continuous-collection-chemical-contaminants-occurrence-data">https://www.efsa.europa.eu/en/consultations/call/call-continuous-collection-chemical-contaminants-occurrence-data</a></li> </ul>		
6	<p><b>Task:</b> Propose a strategy on how to choose a limited number of substances for the next phase for full quantification (set 3).</p> <ul style="list-style-type: none"> <li>• Min 10 and max 20 substances <ul style="list-style-type: none"> <li>○ Propose a strategy to determine accuracy and precision of the quantifications (eg, using isotopically labelled standards and/or spike/recovery experiments ;</li> <li>○ Different scenarios can be proposed. A cost estimate per substance or substance group or per scenario should be given ;</li> <li>○ The composition of set 3 needs to be agreed with EFSA first; substances already risk assessed by EFSA and JECFA should not be included in set 3 unless there is evidence on a new source of exposure ;</li> </ul> </li> <li>• Develop a strategy what can be done with the remaining substances identified but not chosen for full quantification.</li> </ul> <p><b>Deliverables:</b></p> <ul style="list-style-type: none"> <li>• Interim report 4 after 12 months from kick-off meeting describing execution of task 4,5 &amp; 6 and plan for the next steps.</li> <li>• Draft scientific publication for a peer reviewed journal on project results of first phase of project;</li> </ul>	Yes	1 year from kick-off meeting
7	<p><b>Task:</b> Propose a strategy for the next steps after task 8 in support of evaluating the significance level of occurrence in set 3.</p> <ul style="list-style-type: none"> <li>• Exposure assessment: additional</li> </ul>	Yes	2 years from kick-off meeting



	<p>evidence from scientific literature will be provided by EFSA.</p> <ul style="list-style-type: none"> <li>• Hazard characterisation: additional evidence from scientific literature will be provided by EFSA.</li> <li>• Risk assessment</li> <li>• Prepare interim reports on the materials and methods applied, and on the results of the full quantification with a full account of analytical performance of the screening methodology applied</li> </ul> <p>The proposed strategy needs to be agreed by EFSA first.</p> <p><b>Deliverables:</b></p> <ul style="list-style-type: none"> <li>• Interim report 5 after 15 months from kick-off meeting describing progress on tasks 7 &amp; 8 and plan for the next steps.</li> <li>• Interim report 6 after 18 months from kick-off meeting describing progress on tasks 7 &amp; 8 and plan for the next steps.</li> <li>• Interim report 7 after 21 months from kick-off meeting describing progress on task 7 &amp; 8 and plan for the next steps.</li> <li>• Interim report 8 after 24 months from kick-off meeting describing progress on task 7 &amp; 8 and plan for the next steps.</li> </ul>		
8	<p><b>Task:</b> Full quantification of min 10 and max 20 substances (set 3 =subset of 1 and subset 2):</p> <ul style="list-style-type: none"> <li>• To cover different types of food samples: different samples from plant and animal origin must be included (among these covering aquatic and terrestrial organisms).</li> <li>• Carrying out an in-depth investigation performed for at least 2 and preferably 3 or more countries.</li> <li>• The contractor should propose an approach to be applied for analysis: use of high resolution LC-MS, LC-MS/MS, GC-MS and/or GC-MS/MS, Orbitrap or similar should be mandatory, Information on detection capability (sensitivity), resolution power, targeted recoveries, approach for quantification, treatment of left-censored data, quality assurance measures, successful participation in proficiency test of similar compounds (if available)</li> <li>• Full reporting of accuracy and precision of measured concentrations for each of the</li> </ul>	Yes	2.5 years from kick-off meeting



	<p>substances.</p> <p><b>Deliverables:</b></p> <ul style="list-style-type: none"> <li>• Interim report 5 after 15 months from kick-off meeting describing progress on tasks 7 &amp; 8 and plan for the next steps.</li> <li>• Interim report 6 after 18 months from kick-off meeting describing progress on tasks 7 &amp; 8 and plan for the next steps.</li> <li>• Interim report 7 after 21 months from kick-off meeting describing progress on task 7 &amp; 8 and plan for the next steps.</li> <li>• Interim report 8 after 24 months from kick-off meeting describing progress on task 7 &amp; 8 and plan for the next steps.</li> <li>• Interim report 9 after 27 months from kick-off meeting describing progress on task 7 &amp; 8 and plan for the next steps.</li> <li>• Interim report 10 after 30 months from kick-off meeting describing execution &amp; finalisation of task 7 &amp; 8 and plan for the next steps.</li> <li>• Database with results on set 3. Data need to be submitted in SSD2 (Standard Sample Description version 2) format. The link is as follows: <a href="https://www.efsa.europa.eu/en/consultations/call/call-continuous-collection-chemical-contaminants-occurrence-data">https://www.efsa.europa.eu/en/consultations/call/call-continuous-collection-chemical-contaminants-occurrence-data</a></li> </ul>		
9	<p><b>Task:</b> Full characterisation of the emerging risks by linking the results obtained under task 8 to toxicological profiles of the substances with the aim of identification of emerging risks.</p> <p><b>Deliverables:</b></p> <ul style="list-style-type: none"> <li>• Interim report 11 after 33 months from kick-off meeting describing progress of task 9.</li> <li>• Final report according to EFSA template on EFSA external scientific report describing execution and results of all tasks and providing recommendations on follow up work.</li> <li>• Draft scientific publication for a peer reviewed journal on project results of</li> </ul>	Yes	3 years from kick-off meeting



	second phase of project.		
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No.	Meetings	Deadline for finalisation
1	Kick-off meeting: physical meeting in Parma – one day <sup>10 11</sup> During this meeting, in addition to operational implementation the administrative and financial matters related to contract implementation will be discussed.	2 months after entry into force of contract
2	Interim meeting 1: half day <sup>12</sup> teleconference To discuss & review Interim Report 1	3 months from kick off meeting
3	Interim meeting 2: physical meeting in Parma – one day To discuss & review Interim Report 2	6 months from kick off meeting
4	Interim meeting 3: half day teleconference To discuss & review Interim Report 3	9 months from kick off meeting
5	Interim meeting 4: physical meeting at contractor’s venue – one day To discuss & review Interim Report 4, set 1 and set 2	12 months from kick off meeting
6	Interim meeting 5: half day teleconference To discuss & review Interim Report 5	15 months from kick off meeting
7	Interim meeting 6: physical meeting in Parma – one day To discuss & review Interim Report 6 & draft publication	18 months from kick off meeting
8	Interim meeting 7: half day teleconference To discuss & review Interim Report 7	21 months from kick off meeting
9	Interim meeting 8: physical meeting in Parma – one day To discuss & review Interim Report 8	24 months from kick off meeting
10	Interim meeting 9: half day teleconference To discuss & review Interim Report 9	27 months from kick off meeting
11	Interim meeting 10: physical meeting in Parma – one day To discuss & review Interim Report 10 & set 3	30 months from kick off meeting
12	Interim meeting 11: half day teleconference To discuss & review Interim Report 11	33 months from kick off meeting
13	Final meeting: physical meeting in Parma – one day To discuss & review final project report & draft publication	36 months from kick off meeting

No.	Summary of deliverables and timeline	Deadline for finalisation
1	Inception report on project workplan	1 month from kick- off meeting

<sup>10</sup> One day meeting = 8 hours

<sup>11</sup> In case of COVID 19 emergency measures some of the planned physical meetings may need to be held as virtual meetings.

<sup>12</sup> Half day meeting = 4 hours



2	Interim Report 1 covering tasks 2 & 3 & next steps	3 months from kick-off meeting
3	Interim Report 2 describing progress on tasks 4,5 & 6 & next steps	6 months from kick-off meeting
4	Interim Report 3 describing progress on tasks 4,5 & 6 & next steps	9 months from kick-off meeting
5	Interim Report 4 describing execution of tasks 4,5 & 6 & next steps	12 months from kick-off meeting
6	Database with results on set 1	12 months from kick-off meeting
7	Database with results on set 2	12 months from kick-off meeting
8	Interim Report 5 describing progress on tasks 7 & 8 & next steps	15 months from kick-off meeting
9	Interim Report 6 describing progress on tasks 7 & 8 & next steps	18 months from kick-off meeting
10	Draft scientific publication for a peer reviewed journal on project results of first phase of project	18 months from kick-off meeting
11	Interim Report 7 describing progress on tasks 7 & 8 & next steps	21 months from kick-off meeting
12	Interim Report 8 describing progress on tasks 7 & 8 & next steps	24 months from kick-off meeting
13	Interim Report 9 describing progress on tasks 7 & 8 & next steps	27 months from kick-off meeting
14	Interim Report 10 describing execution of tasks 7 & 8 & next steps	30 months from kick-off meeting
15	Database with results on set 3.	30 months from kick-off meeting
16	Interim Report 11 describing progress on tasks 9 & next steps	33 months from kick-off meeting
17	Final project report describing execution of task 9, entire project execution and related results.	36 months from kick-off meeting
18	Draft scientific publication for a peer reviewed journal on project results of second phase of project	36 months from kick-off meeting

No.	Payments	Linked to EFSA approval of deliverable No.
1	Interim payment 1 of 30 %	1 & 2 & 3 & 4 & 5 & 6 & 7
2	Interim payment 2 of 30 %	8 & 9 & 10 & 11 & 12
3	Payment of the balance of 100% - 60% of the interim payment	13 & 14 & 15 & 16 & 17 & 18

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.

#### 1.4 INFORMATION ON THE CONTRACT

<b><u>Nature of expense</u></b>	Services
<b><u>Type of contract</u></b>	Direct
<b><u>Place of performance</u></b>	Contractor's premises



### **Duration of tasks in direct contract**

36 months after entry into force of the contract.

### **Budget information**

The maximum budget EFSA has available is 400,000 €. Any offer exceeding this maximum will be excluded from further assessment during evaluation.

### **Important information for British tenderers:**

As a consequence of the UK withdrawal from the European Union on 31 January 2020 and entry into force the Withdrawal Agreement ratified by the UK and the European Union, the UK will have a special status with the European Union until the end of the Transition Period (31 December 2020). The Transition Period, based on the Withdrawal Agreement, may be extended once up to two years. A decision on any Transition Period extension shall be taken by the European Union and the UK before July 2020.

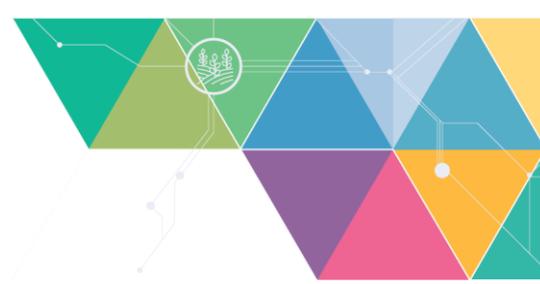
During the Transition Period, economic operators established in the UK may continue to bid for EFSA calls for tenders. For any contracts awarded to UK established economic operators prior to the end of the Transition Periods, these contracts should be implemented in accordance with their contractual terms until their end-date, including any modifications where necessary. For any procurement procedures ongoing (i.e. no contract signed yet) at the end of the Transition Period, economic operators established in the UK will no longer be entitled to participate and will be excluded from any ongoing procedure for which the contract has not yet been signed.

## **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 Junction](#)<sup>13</sup> 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.

<sup>13</sup> <http://www.efsa.europa.eu/en/press/news/190117> and <https://zenodo.org/communities/efsa-kj/?page=1&size=20>



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](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.

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

#### Confidentiality

EFSA will disregard general statements that the whole tender or substantial parts of it contain confidential information. Tenderers need to mark clearly the information they consider confidential and explain why it may not be disclosed. EFSA reserves the right to make its own assessment of the confidential nature of any information contained in the tender.



## **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 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); 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](#).

#### **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.



Further supporting evidence in support of this declaration may be requested from the successful tenderer prior to signature of the contract. 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

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**

The tenderer must have generated an overall annual turnover of at least 400,000 € in each of the last 2 closed financial years (2019 and 2018).

#### ***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.

EFSA will request proof of annual turnover from the successful tenderer prior to signature of the contract. 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.

### **B) Technical and professional capacity**

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

- a) extensive and demonstrable experience in trace organic chemical analysis and data evaluation, and chemical risk assessment.
- b) Ability to provide a team of experts compliant with these specific expertise requirements:
  - At least 1 expert in trace organic chemical analysis and data evaluation with at least 10 years of experience;
  - At least 1 expert in exposure assessment, in toxicology and risk assessment area with at least 10 years of experience;
  - The team of experts must have individually an excellent level of spoken and written standard UK English. For non-native speakers, this should be demonstrated by an Official certificate of English proving a C1 level OR at least 3 years of work in an English-speaking environment;



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

- c) A proven record showing high-level expertise in official food control or in chemical analysis of ultra-trace levels, such as of environmental contaminants or residues of pesticides, or veterinary drugs in food and feed.
- d) Participation in interlaboratory studies for e.g. environmental contaminants or residues of pesticides or veterinary drugs in food or feed by high-resolution LC-MS, LC-MS/MS, GC-MS or GC-MS/MS (TOF, Orbitrap or similar).
- e) Experience in exposure assessment and evaluating the impact of chemicals on human health.

***Evidence requested in the offer:***

□ Requirement a): At least three projects or scientific publications related to requirements a, carried out in the course of the past 5 years;

□ Requirement b): Detailed CVs of the Project team members proposed for the assignment. EFSA strongly recommends submitting the CVs in the EU CV format which can be accessed [here](#); For the English language requirement, provision of the language certification or details in the CV of having worked in an English speaking environment for at least three years;

□ Requirement c): At least 5 publications or reports related to requirement c, carried out in the course of the past 10 years;

□ Requirement d): At least one inter-laboratory study on methods of analysis in the fields mentioned under requirement d, carried out in the course of the past 10 years;

Requirement e): At least 5 publications or reports related to requirement e, carried out in the course of the past 10 years;

□ **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 in the offer:***

The tenderer proposed for contract award will be requested, prior to and as a condition of contract signature, 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/EU<sup>14</sup> and compliance with data protection obligations resulting from Regulation (EU) 2016/679 and Regulation (EU) 2018/1725<sup>15</sup>.

<sup>14</sup> OJ L 94 of 28.03.2014, p. 65

<sup>15</sup> 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>



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

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

### **A) QUALITY AWARD CRITERIA**

#### **1. METHODOLOGY PROPOSED FOR IMPLEMENTATION (70 points – minimum threshold 60% i.e. 42/70 to pass minimum quality threshold for this criteria)**

- Convincing justification of the choice of proposed methodology; advantages and disadvantages for objective 1; structured step by step explanation of methodology to address objective 1; **25 points**
- Convincing justification of the choice of proposed methodology; advantages and disadvantages for objective 2; structured step by step explanation of methodology to address objective 2; **15 points**
- Convincing justification of the choice of proposed methodology; advantages and disadvantages for objective 3; structured step by step explanation of methodology to address objective 3; **15 points**
- Convincing justification of the choice of proposed methodology; advantages and disadvantages for objective 4; structured step by step explanation of methodology to address objective 4; **15 points**

#### **2. PROJECT ORGANISATION & MEASURES TO GUARANTEE QUALITY OF DELIVERABLES (30 points)**

- Clear and detailed information on distribution of the tasks among the project team; clarity on who does what, when and why. In case of joint offer & subcontractors, justify why the partner/subcontractor is proposed to do the particular task/work-package); **10 points**
- The internal team communication; and in case of joint offers & subcontractors also the communication between joint offers partners and subcontractors; **5 points**
- The communication with EFSA (who, how, when); **5 points**
- Role of team leader / leading partner in quality assurance; **5 points**
- Special additional measures for quality assurance proposed for this particular project; **5 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 60% for award criteria (i.e. a minimum of 42 points out of the 70 points available) and overall score at least 70% of maximum possible total points against the quality award criteria.

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

### **B) PRICE AWARD CRITERION**

Tenders which passed the quality thresholds 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**

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:

$$\begin{aligned} \text{TOTAL SCORE OF THE EVALUATED OFFER (C) =} \\ & 30 * \text{Cheapest price offer/price of tender X} \\ & + \\ & 70 * \text{Total quality score (out of 100) for all quality award criteria of tender} \\ & \quad \text{X/100} \end{aligned}$$



## **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. A tender received after the deadline indicated in the procurement documents will be rejected.**

### **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](#)<sup>16</sup>. 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:

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<sup>16</sup> 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.
- **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 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](mailto: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.

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](mailto:EFSAProcurement@efsa.europa.eu).
- Notifications for re-submission or withdrawal of tenders must be sent to: [EFSAProcurement@efsa.europa.eu](mailto: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**

Tenderers are requested to use this template for preparing 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 400,000 €. 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, travel, 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.
- 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;"><b>ALL INCLUSIVE TOTAL PRICE</b></p> <p style="text-align: center;"><b>to be used for the evaluation and for contract implementation in the case of award.</b></p>	<p style="text-align: right;">..... €</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.