

TENDER SPECIFICATIONS

Reference: OC/EFSA/SCER/2018/02

Subject: Environmental Risk Assessment (ERA) of the application of nanoscience and nanotechnology in the food and feed chain

Procurement procedure: Open call

Project/Process code: SCER-03

Budget Line: 3210

Tender specifications purpose:

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

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

Additional guidance:

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

Submitting your tender on time:

Follow carefully the guidance in annex 2 "e-Submission quick reference guide for economic operators".

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

Please note that offers sent via e-mail will be rejected.

Provide EFSA with feedback:

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

INDICATIVE PROCEDURE TIMETABLE

Milestone	Date ¹	Comments
Launch date	29/06/2018	Date of publication being sent to OJ
Deadline for sending a request for clarification to EFSA	20/09/2018 at 14:30 (CET) six working days before the deadline for submission of offers	Attention: <i>Requests for clarification may only be submitted through the eTendering website as described in the Invitation Letter.</i>
"Receipt Time Limit" - Closing date and time for offers reception	28/09/2018 at 14:30 (CET)²	See details in the Invitation letter. Please also refer to part 3 of the tender specifications "How to submit your offer – e-Submission application guide" and the e-Submission quick reference guide for economic operators, link provided in annex 2.
Opening session	01/10/2018	10:30hr, EFSA premises, Parma
Notification of the evaluation results	November 2018	Estimated. <i>Attention: outcome of the present procurement procedure will be communicated to all tenderers to the e-mail address indicated in their offer. Accordingly, the tenderers who have submitted offers under the present call are strongly invited to check regularly the inbox in question.</i>
Contract signature	November 2018	Estimated

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

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

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

1.1 BACKGROUND

The Scientific Committee develops harmonised risk assessment methodologies on scientific matters of a horizontal nature in the fields within EFSA's remit where EU-wide approaches are not already defined. Under the mandate EFSA-Q-2016-00281³ it has developed recently Guidance on risk assessment of the application of nanoscience and nanotechnologies in the food and feed chain: Part 1, human and animal health (To be published in July). This document comprises essential starting information for this contract. For example, it has developed guidance for detailed physico-chemical characterisation as expected in EFSA dossiers, and highlights specific considerations when performing in vivo and in vitro studies with nanomaterial.

The main purpose of this call is to obtain a preparatory report to support a second part of the same mandate, namely EFSA is to produce a "Guidance on risk assessment of the application of nanoscience and nanotechnologies in the food and feed chain: Part 2, environment". The preparatory work provided by the successful tenderer resulting from this call will be evaluated and will serve as an information source for the mandate of EFSA.

This activity of the Scientific Committee is linked the EFSA's strategy 2020⁴, particularly to the objective to Prepare for future risk assessment challenges.

The present Call is based on EFSA's 2018 Work Programme for grants and operational procurements as presented in Annex IX of the EFSA Programming Document 2018 – 2020, available on the EFSA's website⁵.

1.2 OBJECTIVE

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

EFSA needs to produce a guidance document for the environmental risk assessment of nanomaterials within its remit. With this contract, EFSA seeks to start **collecting all relevant information and literature** in a preparatory **report**. Here below, the scope of the report is clarified.

Regulated Products in the remit of EFSA that undergo an environmental risk assessment and that may include nanomaterials are feed additives and plant protection products. These are reasonably foreseen to comprise nanomaterials (Peters et al., 2014)⁶ in new applications.

³ <http://registerofquestions.efsa.europa.eu/roqFrontend/wicket/page?0-1.ILinkListener-contentPane-listContainer-pageable-23-questionNumberLnk>

⁴ https://www.efsa.europa.eu/sites/default/files/corporate_publications/files/strategy2020.pdf

⁵ <http://www.efsa.europa.eu/en/corporate/pub/amp1820>

Nanomaterial: The report should cover the full scope of types of material as described in the recently published guidance for the risk assessment of human and animal health aspects (publication foreseen early July). This scope is considered scientifically complete. It includes small particles that retain characteristics of the nanoscale. Therefore, it is broader than the legally defined (engineered) nanomaterials in the Novel Food legislation⁷, the FIC Regulation⁸ and the as Recommended EC Definition (2011⁹), under review.

Environmental risk assessment (ERA): EFSA has a wide range of existing ERA guidance documents for conventional materials, per sector and also per organisms group (see <http://www.efsa.europa.eu/sites/default/files/applications/apdeskhow.pdf>). The report should describe the particularities of the nano-aspects. Prior work in this area can be found under REACH (<https://echa.europa.eu/-/reach-guidance-for-nanomaterials-published>) and at OECD level. The report has to be in line with international developments and demonstrate synergies/compatibilities with existing EFSA ERA guidance documents and approaches for conventional materials.

Specific objectives:

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

Objective 1: scoping exercise (deliverable 1)

1. Identify and describe in a report the areas in EFSA's remit that require ERA guidance for nanomaterials
2. Organise a survey with the Member States to understand whether they have any guidance/procedures in place to carry out ERA for nanomaterials, and whether they have received dossiers for substances in nanofomto be assessed for their possible impact on the environment. The contacts for such survey can be obtained through the EFSA Nano Network¹⁰ and the MS focal points¹¹.
3. Describe in the report the existing information under other EU legislation (e.g. the hazard information under the REACH registration) that may be relevant to environmental risk assessment of nanomaterials used in the food feed chain such as plant protection product, active substances, co-formulant, feed additive.

⁶ [Peters R, Brandhoff P, Weigel S, Marvin H, Bouwmeester H, Aschberger K, Rauscher H, Amenta M, Moniz FB, Gottardo and Mech A, 2014. Inventory of nanotechnology applications in the agricultural, feed and food sector. EFSA supporting publication 2014:11\(7\):EN-621, 125 pp. doi:10.2903/sp.efsa.2014.EN-621](#)

⁷ Regulation (EU) No 2015/2283 of the European Parliament and of the Council of 25 November 2015 on novel foods, amending Regulation (EU) No 1169/2011 of the European Parliament and of the Council and repealing Regulation (EC) No 258/97 of the European Parliament and of the Council and Commission Regulation (EC) No 1852/2001. OJ L 327, 11.12.2015, p. 1–22. See <http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32015R2283&from=EN>

⁸ Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers, amending Regulations (EC) No 1924/2006 and (EC) No 1925/2006 of the European Parliament and of the Council, and repealing Commission Directive 87/250/EEC, Council Directive 90/496/EEC, Commission Directive 1999/10/EC, Directive 2000/13/EC of the European Parliament and of the Council, Commission Directives 2002/67/EC and 2008/5/EC and Commission Regulation (EC) No 608/2004 OJ L 304, 22.11.2011, p. 18–63

⁹ Commission Recommendation 2011/696/EU of 18 October 2011 on the definition of nanomaterial. OJ L 275, 20.10.2011, p. 38–40, under revision.

¹⁰ <https://efsa.onlinelibrary.wiley.com/doi/10.2903/sp.efsa.2018.EN-1393>

¹¹ <https://www.efsa.europa.eu/en/people/fpmembers>

Objective 2: Collect in the report under deliverable 2, relevant existing ERA guidances applicable to nanomaterial from OECD, ECHA, other jurisdictions (e.g. Australia, Canada, USA), from relevant EU projects (e.g. NANOFATE¹², ENNSATOX¹³), and published literature suitable for regulatory science (e.g. Kah et al. 2018)¹⁴.

Objective 3: Provide in the report, by making use of already existing document where possible (e.g. EFSA / ECHA / and other EC guidances), the answers to the following **core task**:

- (1) to check and report if the existing guidances (e.g. EFSA guidances) and guidelines (e.g. OECD/EU guidance for testing/characterising substance/product properties and estimating levels and patterns or exposure in the agriculture environment)) are still applicable and sufficient. The questions to be addressed include for instance:
 - a. are all the relevant applications that might lead to nanomaterial emissions (from the food and feed chain) in the environment covered?
 - b. are the currently tested endpoints for ERA adequate for nanomaterial?
 - c. are the tested routes of exposure adequate to cover nanomaterial?
 - d. are current methods/models to measure/estimate environmental levels applicable to nanomaterials?
- (2) To identify and report additional nano-specific considerations of ERA of nanomaterial, including aspect for effect assessment and aspects for exposure/fate assessment. Meaning, that if the answers to the questions under point (1) are negative, the report has to describe any nano-specific approaches and any new element(s) that could be considered for environmental risk assessment of nanomaterials. As an example, the aim will be to describe the nano-specific approaches that could be considered for physicochemical characterisation of nanomaterials in different environmental media, or for hazard characterisation, factors affecting fate and behaviour, exposure patterns of nano-formulations within effect levels for test systems and any corresponding needs for adaptation duration effect testing. The report may further provide advice and rationales on practical aspects of nanomaterial characterisation, testing and risk assessment.

In a first step A (deliverable 3), the tenderer should provide a **Table of content + summary contents for the report**. The structure of the Table of content with the "core task" will be well organised (in line with the current ERA practices for conventional materials). As an example, the structure may be built up according to:

- 1.application of the nanomaterial (nanopesticides or Feed additive)
- 2.effect on the non-target organisms (on aquatic organisms, on soil organisms, on birds and mammals, on bees)
- 3.effect and/or exposure assessment

Upon approval of the Table of content and the summary contents, **in step B** the **full report** will be developed (deliverables 4, 5 and 6) that describes in detail the nano-specific aspects identified in addition to the current ERA practices in each of the relevant sectors.

¹² <http://www.nanofate.eu/>

¹³ https://cordis.europa.eu/result/rcn/54945_en.html

¹⁴ [Kah M, Kookana R S, Gogos A, Buchelli T D, 2018. A critical evaluation of nanopesticides and nanofertilizers against their conventional analogues. Nature Nanotechnology, 2018, Vol.418. doi: 10.1038/s41565-018-0131-1](https://doi.org/10.1038/s41565-018-0131-1)

1.3 TASKS, DELIVERABLES, TIMELINE AND PAYMENTS

No	Tasks	Can be subcontracted? ¹⁵	Deadline for finalisation
1	Related to objective 1: scoping document	Yes	3 months after the entry into force of the contract
2	Related to objective 2: Collect relevant existing ERA guidances and literature applicable to nanomaterial	Yes	4 months after the entry into force of the contract
3	Related to objective 3A: Table of content + summary contents of the report	Yes	5 months after the entry into force of the contract
4	Related to objective 3B: Final report including all the tasks requested in all objectives	No	18 months after the entry into force of the contract
No	Meetings		Deadline for finalisation
1	Kick off meeting (physical meeting in Parma - one day) During this meeting, in addition to project operational implementation it can be considered as an opportunity to discuss administrative and financial matters related to contract implementation, as well as the work and meeting planning.		Within 1 month after the entry into force of the contract
2	Monthly project review meetings via teleconference This meeting has to be prepared one week in advance with making accessible the latest version of the document to EFSA, with a clear agenda and afterwards being followed up with a list of agreements and tasks, kept as a log.		Each months after the entry into force of the contract
3	Mid-term meeting (physical meeting in Parma - one day), to review the outcome of objective 3A (deliverable 3).		5,5 months after the entry into force of the contract
4	Mid-term meeting (physical meeting in Parma - one day), To review the draft outcome of objective 3B (deliverable 4)		12,5 months after the entry into force of the contract
5	Final meeting (physical meeting in Parma - one day), to review the final outcome of objective 3B		18 months after the entry into force of the contract
No	Deliverables		Deadline for submission to EFSA
1	<u>Interim Report 1</u> on objective 1 in Word format		3 months after the entry into force of the contract
2	<u>Interim Report 2</u> on objective 2 in Word format, accompanied by a folder with the full text of publicly available and relevant documents/literature in electronic format (e.g. pdf)		4 months after the entry into force of the contract
3	<u>Interim Report 3</u> on objective 3A in Word format		5 months after the entry into force of the contract
4	<u>Draft final report</u> including all objectives 1 to 3B in Word format, accompanied by 1. the folder with the full text of publicly available and relevant documents/literature in electronic format		12 months after the entry into force of the contract

¹⁵ If a subcontractor provides the whole or a very large part of the financial capacity OR executes the whole or a very large part of the tasks, EFSA may demand that that the subcontractor signs the contract.

	(e.g. pdf) and 2. the compiled list of bibliographic references/literature in EndNote database	
5	<u>Updated Draft final report</u> including all objectives 1 to 3B in Word format accompanied by 1. the updated folder with the full text of publicly available and relevant documents/literature in electronic format (e.g. pdf) and 2. the updated list of bibliographic references/literature in EndNote database	15 months after the entry into force of the contract
6	<u>Final report</u> including all the objectives 1 to 3B in Word format, accompanied by 1. the final folder with the full text of publicly available and relevant documents/literature in electronic format (e.g. pdf) and 2. the completed list of bibliographic references/literature in EndNote database	17.5 months after the entry into force of the contract
No	Payments	Linked to approval by EFSA of deliverable No
1	Interim payment 1 of 30 %	Linked to the approval of Deliverable 3
2	Payment of the balance of 100%- (30% of the interim payment)	Linked to the approval of Deliverable 6 (final report including all objectives)

The working language for the contract implementation: execution of tasks, meetings and deliverables shall be English. The deliverables shall be delivered to EFSA in electronic format on a common accessible drive.

1.4 INFORMATION ON THE CONTRACT

Type of contract: direct contract

Nature of expense: services

Duration of tasks in

direct contracts: 18 months after the entry into force of the contract

Budget information: The maximum budget EFSA has available is 200.000,00 €. Any offer exceeding this maximum will not be retained for contract award.

Possible increase to direct contract duration

EFSA reserves the option to extend the duration of the direct contract resulting from the present call for tender, for a period which does not go beyond 30% of the original direct contract duration of 18 months.

1.5 OWNERSHIP AND INTELLECTUAL PROPERTY RIGHTS AND USE OF RESULTS

SPECIFIC INFORMATION ON INTELLECTUAL PROPERTY RIGHTS:

As regards any product or delivery commissioned by EFSA and developed by the contractor in the context of the contract resulting from this call for tenders as well as source codes of IT applications and models 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 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 AND USE OF RESULTS

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

Use of results

EFSA is committed to the publication of contract deliverables in the Knowledge Junction in order to improve transparency, reproducibility and evidence reuse. The [Knowledge Junction](#)¹⁶ 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 with attribution to the contractor.

¹⁶ Learn more at <http://www.efsa.europa.eu/en/press/news/161114>

PART 2 EVALUATION - HOW WILL YOUR OFFER BE ASSESSED?

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

2.1 OPENING OF OFFERS

The main aim of the public opening session is to check whether the offer received was dispatched within the closing date for tender receipt¹⁷ 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 Declarations of Interest and Individual Declarations of Interest); Exclusion criteria (Declaration on Honour on exclusion criteria); Selection criteria (Declaration on Honour on selection criteria).

2.3 GROUNDS FOR EXCLUSION

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

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

In addition to the tenderers established in countries eligible in line with **General guidance on EFSA procurements** available at EFSA website, this call for tenders is open, without creating a precedent or obligation for the future, also to tenderers from the following countries: **Australia, United States of America and Canada.**

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

Evidence requested in the offer:

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

¹⁷ **Do not wait until the last day to upload your offer. Responsibility rests with you to ensure that your tender is fully, completely and correctly uploaded before the time limit for receipt. Failure to respect the time limit for receipt will result in the rejection of your offer for non-compliance with the deadline for tenders.**

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

2.4 SELECTION CRITERIA

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

A) ECONOMIC AND FINANCIAL CAPACITY:

The tenderer must have the following economic and financial capacity to perform the contract, in particular the tenderer must have generated an overall annual turnover of at least 150,000.00 € in each of the last 2 closed financial years (2017, and 2016).

Evidence requested in the offer:

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

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

B) TECHNICAL AND PROFESSIONAL CAPACITY:

The tenderer must have the technical and professional capacity to perform the contract in accordance with the specifications below. In accordance with article 148(6) RAP, if EFSA, based on the assessment of the 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.

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

- a) The **tenderer** must have extensive and demonstrable experience in the evaluation of substances in the food and feed chain, and in the provision of services described in the technical specifications,
- b) The tenderer must have the ability to provide a team of experts compliant with the following specific expertise requirements (one person can cover more than one profile requirement):
 - One overall working group coordinator to manage the project and to prepare the monthly progress meetings with EFSA and distribute/collect tasks.
 - Experts with 5 years' experience in environmental risk assessment of substances in general and plant protection products in particular (at least one expert for exposure and at

- least one expert for effect), and with specific expertise of working with nanomaterials.
 - At least one expert with 5 years' experience in environmental risk assessment of feed additives.
 - At least one expert in measuring and modelling predicted environmental concentration (PEC) of substances; preferably nanomaterials.
 - At least one overall regulatory scientist/risk assessor to ensure high relevance and compatibility of the outputs with EFSA procedures and regulatory risk assessments: quality, completeness, thoroughness, clarity.
 - At least one overall regulatory scientist/risk assessor with in depth knowledge of ongoing international guidance developments, in particular at ECHA and OECD level, to ensure high relevance and compatibility of the outputs.
- c) The team of experts must have an excellent level of spoken and written standard UK English at individual and overall levels. For non-native speakers, this should be demonstrated by an Official certificate of English proving a C1 level OR a proof for at least 3 year working in an English-speaking environment.

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

- d) The tenderer must have wide access to the literature search databases for the contract execution.
- e) The tenderer must have access to environmental modelling tools/systems.
- f) The tenderer must have an architecture for digital cooperation, in particular:
- g) Video/tele-meeting facilities for the monthly progress meetings, and
- h) Common document management system for access to the latest version and relevant publications. Preferably, the tenderer should work with office 365 for simultaneous progress on one unique version of the document.

Specific Evidence requested for professional and technical capacity: both have to be proven by descriptions of each requirement.

For requirement a):	A list of major relevant project(s) and publication(s) related to the subject of this assignment carried out in the course of the past years.
For requirements b and c):	Detailed CVs of all team members proposed for the assignment, taking into account the minimum expertise requirements detailed above; EFSA strongly recommends submitting the CVs in the EU CV format which can be accessed here .
For requirements d) and e)	A Statement confirming that the tenderer will have access to the Databases and tools for the contract execution.
For requirement f) g) and h):	A Statement confirming that the tenderer will have access to the required technical equipment for contract execution.
	Institutional declaration of interests available in Annex 7 <i>In case of a group of economic operators and/or in case of subcontracting, such declaration should be completed separately and submitted for each partner and for each identified subcontractor.</i>
	Individual declarations of interests available in Annex 8

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

GENERIC EVIDENCE COMMON FOR ALL SELECTION CRITERIA:

1	Declaration on Honour on selection criteria available in Annex 5 <i>To be completed by the tenderer or by the leading partner in case of a joint offer.</i>
2	Confirmatory statement of resources <i>In case of a joint offer from a group of economic operators and/or in case of subcontracting, the tenderer must provide a statement confirming that they will have at their disposal the resources necessary for performance of the contract by producing a commitment on the part of those entities (i.e. each partner in a joint offer and/or each subcontractor).</i>
3	Allocation of tasks between the partners/subcontractors <i>In case of a joint offer from a group of economic operators or in case of subcontracting, the tenderer should provide a statement clearly defining the allocation of tasks between the entities.</i>

Please note that you do not have to submit any of the above-mentioned evidence if already submitted to EFSA in response to any previous EFSA call, provided the evidence

is exactly the same as requested in these tender specifications. If you avail yourself of this possibility, you have to specify the reference of the EFSA call for tenders under which you have already submitted the evidence to EFSA.

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

2.5 COMPLIANCE WITH TENDER SPECIFICATION AND MINIMUM REQUIREMENTS

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

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

- do not comply with minimum requirements laid down in the tender specifications (non-compliance);
- propose a solution different from the one that is imposed;
- propose a price above the fixed maximum set in the specifications;
- are submitted as variants, when the specifications do not authorise them;
- do not comply with applicable obligations under environmental, social and labour law established by Union law, national law and collective agreements or by the international environmental, social and labour law provisions listed in Annex X to Directive 2014/24/EU¹⁸.

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

2.6 AWARD CRITERIA

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

A) QUALITY AWARD CRITERIA

1. METHODOLOGY PROPOSED FOR IMPLEMENTATION (50 points - minimum threshold 50%)

- Convincing justification of the choice of proposed methodology; advantages and disadvantages; **30 points**
- Logical and structured step by step explanation of methodology; **20 points**

2. PROJECT ORGANISATION (30 points – minimum threshold 50%)

- Clear and detailed information on distribution of the tasks among the project team (who does what, when and why); and in case of joint offer & subcontractors, clarity on who does what, when and why (justify why the partner/subcontractor is proposed to do the particular task/work-package); **15 points**
- Clarity of organization of project into work packages, if suitable or requested in tender specifications **15 points**

3. MEASURES TO GUARANTEE QUALITY OF DELIVERABLES AND TO MEET DEADLINES (20 points - minimum threshold 50%)

¹⁸ OJ L 94 of 28.03.2014, p. 65

This is to assess the quality assurance mechanisms put in place to guarantee the high quality of deliverables and how the contractor will ensure to meet the agreed deadlines for deliverables:

- Role of working group coordinator / leading partner in quality assurance and any other proposed special measures for quality assurance for this particular project; **10 points**
- Measures to ensure availability of proposed team members and mitigation strategies to cover absences; **5 points**
- Measures proposed to ensure the meeting of the deadlines; **5 points**

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

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

Offers must score at least 50% for each criterion, and 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 the subsequent stages of the evaluation process.

B) PRICE AWARD CRITERION:

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

- 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:

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

<p>TOTAL SCORE OF THE EVALUATED OFFER (C) =</p> <p>30 * Cheapest price offer/price of tender X</p> <p>+</p> <p>70 * Total quality score (out of 100) for all quality award criteria of tender X/100</p>

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

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

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

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

How to Submit your Tender in e-Submission

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

In order to have access to e-Submission, you will need to "Subscribe to call for tenders" on TED e-Tendering first. To subscribe, you will need to login with your an [EU Login](#)¹⁹. In case you don't have an [EU Login](#), you can [create an account](#) at any moment. For more information see the [EU login help](#). After logging in with your EU Login password, the e-Tendering will then display a button 'submit your tender' and you will be able to access the e-Submission.

Information to be filled in

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

- **Signed declaration on Honour 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 in Annex 4.
- **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 in **Annex 5**.
- **Exclusion criteria.** If requested in the tender specifications, the tenderer and all members of a joint tender including subcontractors – if applicable – must provide the documentary evidence for exclusion criteria,

¹⁹ Previously called European Commission authentication system (ECAS)

- **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:

- **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.

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.
- Notifications for re-submission or withdrawal of tenders must be sent to: EFSAProcurement@efsa.europa.eu

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

- For technical support on e-Submission, please contact support as described in the help page:

https://webgate.ec.europa.eu/supplier_portal_toolbox/esubmissionFileProject/files/BT3/spotsHelpPage_en.html

ANNEX 1 - FINANCIAL OFFER TEMPLATE

FINANCIAL OFFER

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

- As referred to in part 1.4, the maximum budget EFSA has available for this assignment is **200.000,00 €**. Any offer exceeding this maximum will not be retained for contract award.
- Prices must be quoted in Euro using the conversion rates published in the C series of the Official Journal of the European Union on the day when the invitation to tender was issued. This information is also available on the website of the European Central Bank at the following URL: <http://www.ecb.int/stats/eurofxref/>.
- Pursuant to the provisions of Article 9 of the Italian Law n. 17 dated 10/01/2006 and under Article 151 of Council Directive 2006/112/EC, EFSA is exempt from all duties, taxes and other charges, including VAT. For this reason, all prices given in the financial breakdown should be free of VAT and other taxes or duties.
- The price offered below is understood to be all inclusive. For example any additional costs which can be incurred by the contractor in performing the contract, such as overheads, travelling and subsistence/accommodation expenses, etc. should also be factored in to the all-inclusive price. In addition, if the deliverables incorporate pre-existing rights, the tenderer should factor into their total price the cost of licensing those pre-existing rights to EFSA.

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

Date:

Name of person signing the financial offer:

His/her position in the company:

His/her signature:

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

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

ANNEX 3 - DRAFT CONTRACT

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

ANNEX 4 - DECLARATION ON HONOUR ON EXCLUSION CRITERIA

ANNEX 5 - DECLARATION ON HONOUR ON SELECTION CRITERIA

ANNEX 6 – ADMINISTRATIVE DATA FORM

ANNEX 7 – INSTITUTIONAL DECLARATION OF INTERESTS

ANNEX 8 – INDIVIDUAL DECLARATION OF INTERESTS

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