# TENDER SPECIFICATIONS

**Reference:** OC/EFSA/PRAS/2017/01
**Subject:** Implementation and interpretation of *in-vitro* testing battery for the assessment of developmental neurotoxicity.
**Procurement procedure:** Open call
**Project/Process code:** PRAS-06
**Budget Line:** 3210

**Tender specifications purpose**:

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

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

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

**Submitting your tender on time:**
Follow carefully the guidance in annex 2 "e-Submission 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 | 24/07/2017 | |
| Deadline for sending a request for clarification to EFSA | 12/10/2017 | ***Attention:*** *Requests for clarification may only be submitted through the eTendering website as described in the Invitation Letter.* |
| "Receipt Time Limit" - Closing date and time for offers reception | **20/10/2017 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 | 23/10/2017 | 14:30hr, EFSA premises, Parma |
| Notification of the evaluation results | November 2017 | Estimated. *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.* |
| Contract signature | Estimate December 2017 | 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

Hazards associated with developmental neurotoxicity (DNT) are of interest for the risk assessment of chemical substances. They are however of particular interest for the regulatory risk assessment of pesticides and DNT studies, when triggered by specific conditions, are part of the data requirement according to Regulation No 1107/2009 and as indicated in Regulation 283/2013 setting out data requirements for active substances.

At present, there is no a priori requirement for pesticides or other chemicals to be tested for DNT effects prior to registration, but testing can be triggered based on observed neurotoxic effects in repeat-dose testing, a known neurotoxic mode of action, or a structure-activity alert, in Europe for pesticides, biocides and chemicals, and in USA for pesticides.

To date, DNT studies have been conducted on only 35 of the 485 pesticide active substances currently approved in EU. Although the majority of risk assessments can be considered protective for positive in vivo DNT effects, animal DNT testing is not sufficient, and an adequate in vitro testing battery is needed as a first step. More chemicals need to be tested for DNT effects and that for this purpose alternative high throughput/medium throughput assays should be developed to generate relevant and reliable data that can be used in regulatory decision making (EFSA 2013 neonicotinoid opinion, Bal-Price et al 2015, SOT/FDA colloquium 2016, Fritsche et al 2017).

A recent OECD/EFSA workshop on the use of non-animal test methods for regulatory purposes in the area of developmental neurotoxicity (DNT) proposed to develop a standardized in vitro testing battery that could be used to generate data on the effects of chemicals on the developing nervous system (Fritsche et al 2017). One of the many reasons is that available single in vitro test systems cannot fully mimic the immense complexity of human brain development, maturation and senescence. It was recognized that there is an urgent need for a testing strategy that supports regulatory decisions with two specific aims in mind. The first would be to use existing alternative test methods to help with the prioritization of chemicals for future testing, the second aim would be to generate data that help to guide risk management decisions. The workshop concluded that the task now is to establish performance standards and testing strategy guidance for an in vitro DNT testing battery (Fritsche et al 2017). The following points where considered of relevance for EFSA:

1) *The proposed draft in vitro testing battery to be used for the following regulatory purposes:*
   - *immediately, for screening of chemicals and prioritization,*
   - *followed by further harmonization in an international acceptance process through OECD, with an acknowledgement that improvements will continue to be made as science advances and regulatory acceptance increases and that changes in regulation i.e. data requirement, are needed.*

2) *An agreement was achieved on the need for a draft framework for regulatory use of DNT data through an integrated approach to testing and assessment (IATA). The framework should be driven by problem formulation as defined by decision-making needs. It should make efficient use of resources. As the potential impact*

*of the regulatory decision increases, data needs and resources use will increase to reduce the scientific uncertainty in estimates of risk and impact.*

The pesticide Unit submitted in 2016 a Standard Project Submission Form (SPSF) at the OECD for the preparation of guidance on the application and interpretation of *in-vitro* developmental toxicity assays and definition of a tiered approach to testing and assessment, led by EFSA, Danish EPA and US. The proposal was endorsed by OECD in April 2017.

The Pesticides Unit already awarded a contract for the preparation of a literature review on *in vitro* and alternative DNT testing methods. The report was published in the EFSA Journal on April 2015 and is considered as valid background documentation for the initiation of this activity. Additional documentation that should serve as a scientific background is the report prepared as a supportive documentation for the OECD/EFSA workshop 2016 (Fritsche et al. 2016).

The present Call is based on the Final work programme for grants and operational procurements 2017 as presented in Annex IX of the EFSA Programming Document 2017 – 2019, available on the EFSA's website[3].

**References**


Bal-Price A, Crofton KM, Leist M, Allen S, Arand M, Buetler T, Delrue N, FitzGerald RE, Hartung T, Heinonen T, Hogberg H, Bennekou SH, Lichtensteiger W, Oggier D, Paparella M, Axelstad M, Piersma A, Rached E, Schilter B, Schmuck G, Stoppini L, Tongiorgi E, Tiramani M, Monnet-Tschudi F, Wilks MF, Ylikomi T, Fritsche E. (2015) International STakeholder NETwork (ISTNET): creating a developmental neurotoxicity (DNT) testing road map for regulatory purposes. Arch Toxicol. , 89(2):269-87.

EFSA Scientific Opinion on the developmental neurotoxicity potential of acetamiprid and imidacloprid1 EFSA Panel on Plant Protection Products and their Residues (PPR)2, 3 European Food Safety Authority (EFSA), Parma, Italy, EFSA Journal 2013;11(12):3471 http://www.efsa.europa.eu/sites/default/files/scientific_output/files/main_documents/3471.pdf

Fritsche E, Crofton KM, Hernandez AF, Hougaard Bennekou S, Leist M, Bal-Price A, Reaves E, Wilks MF, Terron A, Solecki R, Gourmelon A.
OECD/EFSA workshop on developmental neurotoxicity (DNT): The use of non-animal test methods for regulatory purposes.
ALTEX. 2017;34(2):311-315. doi: 10.14573/altex.1701171. PubMed ID: 28407175

Fritsche E, Henrik Alm, Jenny Baumann, Lieve Geerts, Helen Håkansson ,Stefan Masjosthusmann, Hilda Witters. (2015) Literature review on in vitro and alternative Developmental Neurotoxicity (DNT) testing methods
http://onlinelibrary.wiley.com/doi/10.2903/sp.efsa.2015.EN-778/abstract

Fritsche E., 2016 OECD-EFSA DNT Workshop-small.pptx
https://www.efsa.europa.eu/sites/default/files/12.FRITSCHE.pdf

OECD/EFSA Workshop on Developmental Neurotoxicity (DNT): the use of non-animal test methods for regulatory purposes
http://www.efsa.europa.eu/en/search/site/dnt%2520fritsche?keys=dnt%20fritsche


[3] http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/amp1719.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 these tender specifications.

EFSA is launching this procurement procedure in order to provide an adequate scientific background and facilitate the preparation of this guidance. The overall goal of this procurement is to accelerate the development and use of in vitro test methods, conducted in a human relevant cell system, capable of cost and time efficient testing of chemicals for the potential to disrupt the development of the nervous system i.e. prediction of neurodevelopment hazards to human health. This work shall be conducted in two Phases. The first Phase will focus on the development of the test systems, generation of data using relevant chemicals for validation purposes, and the design and employment of data analysis tools. The second Phase will include: the development of data interpretation and use guidance, descriptions of possible application domains, and case studies of data use in an IATA context.

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

- Phase 1: **Development of the test system**
    1. **Define an in-vitro testing battery covering key developmental processes specific for normal brain development and maturation i.e. neural stem cells commitment and differentiation, neuronal and glial proliferation, migration differentiation into various neuronal and glial subtypes, synaptogenesis, pruning, myelination, networking and terminal functional neuronal and glial maturation. The in vitro neuronal models derived from human induced pluripotent stem cells (hiPSC) should be considered as a preferred option for developmental neurotoxicity test system.**
    2. For the testing battery, provide recommendations for orthogonal assays, the ones relevant for the improvement of the overall predictive accuracy.
    3. Identify gaps in the testing battery; those are important for regulatory application. This should include both gaps in biological (e.g., pathways, processes, lack of metabolic capacity) and chemical space (e.g., inability to test volatile chemicals).
    4. **Development of a road map for the 'fit for purpose' validation of the individual tests and the whole battery. This shall require an outline that differentiates the feasibility and differences between such a validation and a traditional ECVAM validation.**
    5. **Development and testing of a chemical library for challenging this battery leading to scientific validation of the individual tests, as well as entire battery. This list should include assay specific controls, and positive and negative chemicals relative to in vivo nervous system development. This list should be large enough to allow a computational comparison of assays that provides estimates of balanced accuracy of individual assay as well as batteries of assays.**

- Phase 2 **Reporting phase**
    1. Definition of the biological/toxicological application domain of the individual tests and the whole testing battery.

2. **Draft guidance for the conduction of in vitro DNT testing using the battery and interpretation of the battery test results.**
3. Development of case studies for use of data resulting from the test battery with the IATA framework. The case studies should be applicable to regulatory decisions that require different degrees of decision uncertainty (e.g., inclusion of mechanistic understandings derived from the test battery in support of pesticide regulations; use of data on previously untested chemicals in a weight of evidence approach to chemical prioritization).

### 1.3 TASKS, DELIVERABLES, TIMELINE AND PAYMENTS

| No | Tasks | Can be subcontracted? [4] | Deadline for finalisation |
|---|---|---|---|
| 1 | Provide a detailed project outline indicating the strategy that the contractor is intended to apply in order to successfully achieve phase 1 objectives 1 to 5 | No | To be prepared for presentation at the kick-off meeting. |
| 2 | Provide an interim draft report covering phase 1, objectives 1 to 4. The interim draft report should clearly indicate a proposal for the testing strategy and method validation including relevance of the test systems, detailed testing protocols, number and identification of chemicals that will be tested (specific controls and positive and negative chemicals relative to in vivo nervous system development). | No | 2 months after the kick-off meeting |
| 3 | Execution of the experimental work (phase 1, objective 5) | Yes | 13 months after the kick-off meeting |
| 4 | Detailed collection of the results of testing of the chemical library including a quantitative evaluation. The result should be presented as an appendix of the interim draft report and the format should allow for a computational comparison of the assays. | Yes | 14 months after the kick-off meeting |
| 5 | Interim draft report for phase 2, objectives 1 to 3 | No | 16 months after the kick-off meeting |
| 6 | Final report | No | 18 months after the kick off meeting |
| **No** | **Meetings** | | **Deadline for finalisation** |
| 1 | Kick off meeting (physical meeting in Parma - one day - to be attended as a minimum by the project manager of the contractor's team).<br>During this meeting, in addition to operational implementation of the project, it can be considered | | Maximum 1 month after the entry into force of the contract |

[4] 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.

| | | |
|---|---|---|
| | as an opportunity to discuss administrative and financial matters related to contract implementation. | |
| 2 | Project review meetings via teleconference (as a minimum by the project manager and at least one member of each institution if the contractor is a consortium). | One per month for the duration of the experimental work |
| 3 | 1 final meeting physical meeting in Parma - one day - (as a minimum attended by the project manager and at least one member of each institution if the contractor is a consortium) in order to discuss the interim draft report 3 for phase 2. | 17 months from kick off meeting |
| **No** | **Deliverables** | **Deadline for submission to EFSA** |
| 1 | Detailed project outline (task 1) | 1 months after the entry into force of the contract and in time for the kick-off meeting. |
| 2 | Interim draft report 1 covering tasks 1 and 2 | 2 months from the kick-off meeting |
| 3 | Interim draft report 2 including tabulation of the results from the experimental work executed under tasks 3 and 4. | 15 months from kick off meeting |
| 4 | Interim draft report 3 including activities under task 5 | 16 months from kick off meeting |
| 5 | Final report | 18 months from kick off meeting |
| **No** | **Payments** | **Linked to approval by EFSA of deliverable No** |
| 1 | Interim payment of 30% | 1 & 2 |
| 2 | Payment of the balance of 100% - 30% of the interim payment | 5 |

The working language for the contract implementation: execution of tasks, meetings and all deliverables shall be English. Further, any written deliverables must be of the highest standard of English which must not require further proof-reading or editing.

### 1.4 INFORMATION ON THE CONTRACT

**Type of contract:** direct contract

**Nature of expense:** services

**Duration of tasks in direct contracts:** 18 months from the kick off meeting.

**Budget information:** The maximum budget EFSA has available is 400,000 €. 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 10% of the original direct contract duration of 18 months.

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

## PART 2 EVALUATION - HOW WILL YOUR OFFER BE ASSESSED?

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

### 2.1 OPENING OF OFFERS

The main aim of the public opening session is to check whether the offer received was dispatched within the closing date for tender receipt[5] 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: Exclusion criteria (Declaration on Honour on exclusion criteria); Selection criteria (Declaration on Honour on selection criteria), including economic & financial capacity.

### 2.3 GROUNDS FOR EXCLUSION

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

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

Tenderers must not be in one of the exclusion situations listed in the **EFSA Guidance for tenderers** available at EFSA website.

**Evidence requested in the offer:**

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

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

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

## 2.4 SELECTION CRITERIA

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

**A) ECONOMIC AND FINANCIAL CAPACITY:**

The tenderer must have the following economic and financial capacity to perform the contract, in particular the tenderer must have generated an overall annual turnover of at least 400,000 € in each of the last 3 closed financial years (2016, 2015 and 2014).

Evidence requested in the offer:

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

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

**B) 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 **and should provide a team of experts who have demonstrable experience in** developmental neurotoxicity:

a) The tenderer must have extensive and demonstrable experience in the field of developmental neurotoxicity and must be able to provide a team of individuals compliant with the following expertise requirements:

- One **project manager** with at least 10 years' experience in the field of developmental neurotoxicity with demonstrable experience in the in-vitro systems for assessing developmental neurotoxicity. The project manager should provide evidence of having published at least 10 publications in international Journals and/or authorship of commissioned reports in the field of developmental neurotoxicity in the last 10 years;
- One **back-up project manager** with at least 3 years' experience in the field of developmental neurotoxicity with demonstrable experience in the in-vitro systems for assessing developmental neurotoxicity. The back-up project manager should provide evidence of having published at least 5 publications in international Journals and/or authorship of commissioned reports in the field of developmental neurotoxicity in the last 10 years;
- A **team of at least 2 other individuals**, each with at least 1 years' experience in the field of developmental neurotoxicity with

demonstrable experience in the in-vitro systems for assessing developmental neurotoxicity.

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

b) The tenderer must provide evidence of access to laboratory facilities which are able to conduct in vitro neurodevelopmental toxicity studies, including the capability and experience in using human inducible pluripotent stem cells (hiPSC). Evidence should be provided that the laboratory has conducted in vitro neurodevelopmental toxicity studies and ability to work with hiPSC for at least 5 years.

Specific Evidence requested for professional and technical capacity:

| | |
|---|---|
| For requirement a): | The detailed CV's of the individuals proposed as Project Manager, back-up Project Manager and other team members, 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.<br><br>For the Project Manager and back-up Project Manager, tenderers should provide a list of at least publications in international journals and/or authorship of commissioned reports in the field of developmental neurotoxicity. Half of the published literature should refer to original works following application of in-vitro neurodevelopmental systems. |
| For requirement b): | A Statement confirming that the tenderer will have access to laboratory facilities which are able to conduct in vitro neurodevelopmental toxicity studies, including the capability and experience in using human inducible pluripotent stem cells (hiPSC) and fully taking into account the minimum requirements detailed above. |

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**<br><br>To be completed by the tenderer or by the leading partner in case of a joint offer. |
| 2 | **Confirmatory statement of resources**<br><br>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). |
| 3 | **Allocation of tasks between the partners/subcontractors**<br><br>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. |

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/EU[6].

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 (80 points - minimum threshold 70%)**

[6] OJ L 94 of 28.03.2014, p. 65

Tenderers should provide a detailed description of how they intend to carry out the tasks described in these tender specifications. Points will be awarded for the following:

- Convincing justification of the choice of proposed methodology; advantages and disadvantages; **40 points**

- Logical and structured step by step explanation of methodology; **40 points**

**2. PROJECT ORGANISATION (20 points)**

- Clear and detailed information on distribution of the tasks among the project team; 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); **10 points**
- The internal team communication; 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**

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

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

Offers must score at least 70% for criterion number 1, and at least 70% of maximum possible total points against the quality award criteria overall.

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 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:

**TOTAL SCORE OF THE EVALUATED OFFER (C) =**

**30 * Cheapest price offer/price of tender X**

**+**

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

# PART 3 HOW TO SUBMIT YOUR OFFER – 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[7]. In case you don't have an EU Login, you can create an account at any moment. For more information see the EU login help. After logging in with your EU Login password, the e-Tendering will then display a button 'submit your tender' and you will be able to access the e-Submission.

**Information to be filled in**

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

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

[7] Previously called European Commission authentication system (ECAS)

- **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 available in the e-Submission help page, under the section "Quick Guide", where you will find:

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

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

**Documents to be signed and dated while creating your Tender**

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

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

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

**Re-submission or alternative tender**

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

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

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

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

**Withdrawal of tenders**

If after submitting a tender, you wish to completely withdraw your tender, you must formally notify that you wish to withdraw your submitted Tender(s).This notification must be signed by the same authorised legal representative(s) who previously signed the tender(s) in question. The notification must be sent to address indicated in the paragraph below (Contact), stating the reference to the call for tenders and the Tender ID(s) you wish to withdraw.

**Deadline for receipt of tenders**

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

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

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

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

For more information or technical support on e-Submission, please visit the e-Submission help site.

**CONTACT**

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

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

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

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

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

## ANNEX 1 - FINANCIAL OFFER TEMPLATE

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 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, 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.

| | |
|---|---|
| **ALL INCLUSIVE TOTAL PRICE**<br><br>**to be used for the evaluation and for the contract in the case of award.** | ..... € |

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**

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