

TENDER SPECIFICATIONS

Reference: OC/EFSA/PRAS/2014/01

Subject: Systematic literature review on Parkinson's disease and Childhood Leukaemia and mode of actions for pesticides

Procurement procedure: Open call

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.

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 repro.grants.and.procurements@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.

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

1.1 INDICATIVE PROCEDURE TIMETABLE

Milestone	Date ¹	Comments
Launch date	12/09/2014	Date of publication being sent to OJ
Deadline for sending a request for clarification to EFSA	22/10/2014	
Deadline for submission of offers	29/10/2014	See details in the Invitation letter ² .
Opening session	07/11/2014	14:30hr, EFSA premises, Parma
Notification of the evaluation results	DECEMBER 2014	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	DECEMBER 2014	Estimated

1.2 BACKGROUND

In 2013 EFSA published an external scientific report 'Literature review on epidemiological studies linking exposure to pesticides and health effects' carried out by the University of Ioannina Medical School in Greece (Ntanzi et al. 2013, <http://www.efsa.europa.eu/en/efsajournal/doc/497e.pdf>) covering scientific articles published between 2006 and 2012. A statistical significant association was observed through fixed and random effect meta-analyses between pesticide exposure and a number of health outcomes, in particular Parkinson's disease and childhood leukaemia.

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

² If you decide to submit an offer, in addition to following the instructions for offer submission set out in the invitation letter, please send a **separate email** to repro,grants.and.procurements@EFSA.europa.eu indicating that you have submitted an offer. Do not attach the offer to this separate email. The purpose of this **separate e-mail** is to ensure that we are aware an offer has been submitted.

Hence, EFSA is currently investigating the potential role of plant protection products (herein referred to pesticides) as risk factors involved in the pathogenesis of Parkinson's disease and childhood leukaemia.

1.3 OBJECTIVES AND TASKS

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.

The overall objective of the contract is to perform a systematic review (SR) to collect relevant publications from 1st January 1990 to the date at which the contract starts related to the mechanisms involved in the pathogenesis of Parkinson's disease and childhood leukaemia. This information will provide the basis for defining and mapping the causal linkages between a molecular initiating event and a final adverse effect at the biological level for both of these diseases. These systematic reviews should be conducted following the Guidance of EFSA adopted in 2010³.

In addition, a systematic review covering all the scientific articles published up to the date at which the contract starts should be carried out to identify the key steps in the pathogenesis of Parkinson's' disease and childhood leukaemia that might involve chemical agents (including pesticides).

The results from these systematic literature reviews will provide a framework for mapping the mode (and/or) mechanism of action behind Parkinson's' disease and childhood leukaemia and for understanding the possible involvement of chemical agents (including pesticides).

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

Task 1:

To perform a systematic literature review on the modes and mechanisms (i.e. at molecular, biochemical, organelles, cellular, tissue/organ level) involved in the pathogenesis of Parkinson's disease.

Task 2:

To identify the key steps in the pathogenesis of Parkinson's' disease that might involve chemical agents (including pesticides).

Task 3:

To perform a systematic literature review on the modes and mechanisms (i.e. at molecular, biochemical, organelles, cellular, tissue/organ level) involved in the pathogenesis of childhood leukaemia.

Task 4:

To identify the key steps in the pathogenesis of childhood leukaemia that might involve chemical agents (including pesticides).

Task 5:

To provide: **a)** a database of the publications retrieved (preferably in EndNote format) collecting the retrieved articles and an analysis of whether they meet the quality/relevance criteria;

b) a final report which will include extensively the (systematic) reviews carried out and a summary of the key events involved in the pathogenesis of both Parkinson's disease and childhood leukaemia by

³ Application of systematic review methodology to food and feed safety assessments to support decision making. EFSA Journal 2010; 8(6):1637[90 pp.]. doi:10.2903/j.efsa.2010.1637. Available online: <http://www.efsa.europa.eu/en/efsajournal/doc/1637.pdf>

using the adverse outcome pathway (AOP) approach as a prototype and including the identified chemical agents (including pesticides) having a potential role in the key events involved in the pathogenesis of these two diseases.

1.4 DELIVERABLES, TIMELINE AND PAYMENTS

No	Deliverables and meetings	Deadline for finalisation
M1	Kick off meeting (teleconference) to discuss the objectives and the tasks to be carried out for the assignment	1 week after the entry into force of the contract
D1	Provide a project outline containing the search strategy (e.g. key words, search strings, databases to be used, inclusion and exclusion criteria and methodological quality assessment criteria) to be used to perform the systematic literature review on mechanisms involved in the pathogenesis of Parkinson's disease and childhood leukaemia in relation to exposure to chemical agents (including pesticides)	3 weeks after the entry into force of the contract
M2	Tele/web conference with EFSA to discuss and agree on the project outline	1 month after the entry into force of the contract
D2	Provide an interim report 1 containing the draft results obtained under Task 1	3 months after the entry into force of the contract
M3	Tele/web conference with EFSA to discuss and agree the interim report 1	3.5 months after the entry into force of the contract
D3	Provide an interim report 2 containing the draft results obtained under Task 2	6 months after the entry into force of the contract
M4	Tele/web conference with EFSA to discuss and agree the interim report 2	6.5 months after the entry into force of the contract
D4	Provide an interim report 3 containing the draft results obtained under Task 3	8 months after the entry into force of the contract
M5	Tele/web conference with EFSA to discuss and agree the interim report 3	8.5 months after the entry into force of the contract
D5	Provide an interim report 4 containing the draft results obtained under Task 4	10 months after the entry into force of the contract
M6	Tele/web conference with EFSA to discuss and agree the interim report 4	10.5 months after the entry into force of the contract
D6	Summarise the data in a draft final report containing all results and evaluations obtained from Tasks 1 to 5	11 months after the entry into force of the contract
M7	One day physical meeting in Parma to discuss the draft final report	11.5 months after the entry into force of the contract
D7	Provide the final report summarising all results	12 months after the entry into force of the contract

No	Payment/s	Linked to approval by EFSA of deliverable No
1	Interim payment of 40 %	D1, D2, D3
2	Balance payment of 60%	D4, D5, D6, D7

The working language for the contract implementation: execution of tasks, meetings and deliverables shall be English. The deliverables shall be delivered to EFSA in excel (preferably EndNote database) and word format (final report) using the template of EFSA.

1.5 INFORMATION ON THE CONTRACT

Type of contract: direct contract

Nature of expense: services

Duration of tasks in direct contracts: 12 months after the entry into force of the contract

Budget information: The maximum budget EFSA has available is 200,000 €. Any offer exceeding this maximum will not be retained for contract award.

1.6 OWNERSHIP AND INTELLECTUAL PROPERTY RIGHTS

SPECIFIC INFORMATION ON INTELLECTUAL PROPERTY RIGHTS:

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

The draft contract attached in **Annex 6** 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.

1.7 ADDITIONAL INFORMATION

By virtue of article 134(1f) and article 134(3) of the Rules of Application of the Financial Regulation, EFSA reserves the option to launch further negotiated procedure, with the contractor chosen as a result of the present call for tender, for new services consisting in the repetition of similar services during the three years following the signature of the original contract.

PART 2 EVALUATION - HOW WILL YOUR OFFER BE ASSESSED?

In case you decide to apply as a consortium or involve subcontractors in your offer, 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 set deadline for tender submission and using the prescribed double envelope system and if the confidentiality and integrity of offers was preserved.

2.2 GROUNDS FOR EXCLUSION

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.

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 available in **Annex 3a**. In case of a consortium submitting an offer, or in case of subcontracting, such declaration should be submitted for each consortium member and for each identified subcontractor.
- Tenderers should provide an Institutional declaration of interests, using the template in **Annex 3b**. In case of a consortium and/or in case of subcontracting, such declaration should be completed separately and submitted for each consortium member and for each identified subcontractor.

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.

2.3 SELECTION CRITERIA

A) ECONOMIC AND FINANCIAL CAPACITY:

The tenderer must have the following economic and financial capacity to perform the contract:

- The tenderer must be in a stable financial position;
- The tenderer must have generated an overall annual turnover of at least 400,000 € in each of the closed financial years (2013, 2012, 2011).

The financial stability of the tenderer will be assessed based on the indicators contained in the Annex 4 - Simplified financial statement. Tenderers, after they have completed the statement, can see each indicator's value as calculated by the embedded formula. The indicators used are those commonly used for the financial analysis of a company health. Please note that one negative indicator doesn't mean an automatic exclusion. It will be a consolidated risk analysis considering all ratios, in case of consortium/subcontracting even considering the capacities/financial stability of all consortium members/subcontractors. Only if 2 or more indicators at the same time present negative values (for example: significant losses, debt ratio > 80%, negative net working capital, EBITDA < 0, etc), or if the situation is worsening over the presented years, a further in-depth financial analysis will be carried out. However, even in this case the tenderer will be given the opportunity to provide further explanations about the worrying financial position and measures taken to revert the trends. Such clarification request is likely to be accompanied with the request to provide the most recent data available.

Evidence requested:

1. The tenderer, which according to the law of the country in which it is established is required to publish the balance sheet, shall complete and include in the offer a simplified financial statement, using the template in Annex 4 - Simplified financial statement, to be signed by the chief accounting officer of the organisation;
2. The tenderer, which according to the law of the country in which it is established is not required to publish the balance sheet, and which is not a physical person, shall provide the information on annual budget allocated to finance the operational activities;
3. The tenderer, which according to the law of the country in which it is established is not required to publish the balance sheet, and is a physical person, shall provide information on the gross yearly income.

Simplified financial statements are to be provided for all consortium partners and subcontractors proposed in the offer.

Please note that you do not have to submit the evidence requested on economic and financial capacity if already submitted to EFSA in response to any previous EFSA call, provided the evidence is exactly the same as requested in this 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.

B) TECHNICAL AND PROFESSIONAL CAPACITY:

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

- a) The tenderer must provide a multidisciplinary team of experts with a higher University degree (i.e. MSc or higher) in relevant scientific areas such as biology, toxicology or human medicine, having a minimum of three years of demonstrable experience in any of these fields.

- b) Each of the members of the team of experts must have a minimum of three years of proven experience after graduation in retrieving data from databases, drafting high quality scientific reports and/or scientific articles written in English
- c) The team of experts must have overall 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 a self-certification in the CV or at least 3 years work experience in an English-speaking environment.

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

- d) The tenderer must have access to the bibliographic databases PubMed and Web of Science
- e) The tenderer must have access to a reference manager software compatible with EndNote™

Evidence requested:

- For requirement a), 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 minimum technical requirement d) and e): A statement confirming that the tenderer will have access to the above mentioned databases and software for the contract execution.

The evidence requested must be included in the offer for consortium partners/subcontractors only if the capacity of those partners/subcontractors is necessary to satisfy those minimum capacity requirements.

COMMON FOR ALL SELECTION CRITERIA:

1. In the case of a consortium submitting an offer and/or an offer being submitted by an entity sub-contracting some tasks, the economic, financial, technical and professional capacity requirements are to be met on a consolidated level.
2. 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.

2.4 COMPLIANCE WITH TENDER SPECIFICATION

Please note your offer will inevitably be assessed for compliance with tender specifications before its assessment against the award criteria.

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

- do not comply with requirements laid down in the tender specifications (noncompliance);
- propose a solution different from the one that is imposed;
- propose a price above the fixed maximum set in the specifications or in the contract notice;
- are submitted as variants, when the contract notice or the specifications do not authorise them.

In all these cases, the ground 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.

2.5 AWARD CRITERIA

The offers compliant with the technical specifications, not falling in one of the grounds for exclusion and complying with the selection criteria 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)

This is to assess the degree to which the methodology proposed shows the capacity to resolve the questions underlying the tender in a realistic and well-structured way as well as to whether the methods proposed are in conformity with the needs of EFSA and the technical specifications:

- I. Logical and structured step by step explanation of methodology; **10 points**
- II. Search strategy proposed; **30 points**
- III. Proposed inclusion and exclusion criteria; **30 points**
- IV. Risks/issues associated with the proposed methodology which might appear in implementation of assignment and the proposed ways to overcome those risks/issues; **10 points**

2. PROJECT MANAGEMENT: (20 points)

- I. A detailed and clear description of the individual responsibilities of the team members, including the identification of the project leader of the team; **5 points**
- II. Measures to put in place to meet deadlines and other measures (e.g. back-up plans) to ensure that the agreed deadlines are met; **5 points**
- III. Proposed measure for checking the quality of the work; **5 points**
- IV. Internal communication between members of the team and external communication with EFSA; **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 of maximum possible total points against the quality award criteria.

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

B) PRICE AWARD CRITERION:

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

- I. the financial 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 VALUE FOR MONEY OFFER:

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 best value for money offer based on the formula:

TOTAL SCORE OF THE EVALUATED OFFER (C) = ITS QUALITY SCORE (A) / ITS PRICE (B)

PART 3 CONTENT OF THE OFFER - WHAT SHOULD YOUR OFFER CONSIST OF?

Annex 1 - OFFER COMPLETENESS CHECKLIST

- The below checklist is designed to help the tenderers to ensure that all requested documentation is provided to EFSA.
- The offer must be submitted in line with double envelope system described in the Invitation letter.
- This checklist should be signed and included in the offer.
- Please tick ✓ in the boxes provided if the document is attached to the offer.

The offer must contain one original unbound signed paper version and one electronic version (on CD Rom or USB key, in PDF format) of all the following documents:

<input type="checkbox"/>	TECHNICAL OFFER containing: <ul style="list-style-type: none"> ➢ the details of methodology proposed for implementation which the tenderer intends to apply to meet the objective/s taking into account all aspects described in the technical specification, covering all requirements detailed in award criteria 1; this information will be used for award criteria 1 ➢ description of the project management for the implementation of the project, covering all requirements detailed in award criteria 2; this information will be used for award criteria 2; <p><i>If your offer envisages a consortium and/or subcontracting you must provide a clear explanation about the reasons for this decision and the division of tasks.</i></p>
<input type="checkbox"/>	FINANCIAL OFFER using the standard form provided in Annex 2 of these tender specifications.
<input type="checkbox"/>	If applicable, a Statement on IPR aspects , such as list of pre-existing rights, see part 1.6 of the tender specifications must be provided
<input type="checkbox"/>	In case of consortium and/or subcontracting: provide a short document indicating the name of each consortium member and/or subcontractor, indicating who is consortium leader, consortium partner and who is subcontractor.
<input type="checkbox"/>	In case of subcontracting: please indicate here the %..... proportion of subcontracting
<input type="checkbox"/>	The exclusion criteria related evidence requested in part 2.2 of the tender specifications
<input type="checkbox"/>	The economic, financial, technical and professional capacity evidence requested in part 2.3 of the tender specifications
<input type="checkbox"/>	The administrative data using the 3 forms provided in Annex 5 of the tender specifications.
<input type="checkbox"/>	This checklist signed and dated.

It is important to ensure that:

- The offer is formulated in one of the official languages of the EU (with a preference for the use of English, French or Italian).
- Both the technical and financial offers are signed by the tenderer or his duly authorised agent.
- The offer is perfectly legible in order to rule out any ambiguity.

Name:

Signature:

Date:

Annex 2 - 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 1.5, the maximum budget EFSA has available for this assignment is **200,000 €**. 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, cost incurred for allowing full access for EFSA to scientific publications referred to in the final delivery prepared under the contract, etc; should also be factored in to the all inclusive price.

<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>(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>	<div style="border: 1px solid black; height: 30px; background-color: yellow; position: relative;"> € </div>
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Tenderer name:

Date:

Name of person signing the financial offer:

His/her position in the company :

His/her signature:

Annex 3a - DECLARATION ON HONOUR

[download here](#)

ANNEX 3b - INSTITUTIONAL DoI

Applicable only to science calls, all of them

[download here](#)

Annex 4 - SIMPLIFIED FINANCIAL STATEMENT

[download here](#)

Annex 5 - ADMINISTRATIVE DATA

[download here](#)

Annex 6 - 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.