



**EUROPEAN COMMISSION**  
DIRECTORATE-GENERAL  
ENVIRONMENT  
**Directorate B – Circular Economy & Green Growth**  
**ENV.B.2 – Sustainable Chemicals**

## **CALL FOR TENDERS**

**ENV.B.2/ETU/2018/0009**

Study on

**Development of a study protocol for regulatory testing to identify  
endocrine disrupting substances in biotic systems**

## **TENDER SPECIFICATIONS**

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# **1. INFORMATION ON TENDERING**

## **Participation**

Participation in this procurement procedure is open on equal terms to all natural and legal persons coming within the scope of the Treaties, as well as to international organisations.

It is also open to all natural and legal persons established in a third country which has a special agreement with the Union in the field of public procurement on the conditions laid down in that agreement. Where the plurilateral Agreement on Government Procurement<sup>1</sup> concluded within the World Trade Organisation applies, the participation to this procedure is also open to all natural and legal persons established in the countries that have ratified this Agreement, on the conditions it lays down.

For British candidates or tenderers:

Please be aware that after the UK's withdrawal from the EU, the rules of access to EU procurement procedures of economic operators established in third countries will apply to candidates or tenderers from the UK depending on the outcome of the negotiations. In case such access is not provided by legal provisions in force candidates or tenderers from the UK could be rejected from the procurement procedure.

## **Contractual conditions**

The tenderer should bear in mind the provisions of the draft contract which specifies the rights and obligations of the contractor, particularly those on payments, performance of the contract, confidentiality, and checks and audits.

## **Compliance with applicable law**

The tender must comply with applicable environmental, social and labour law obligations established by Union law, national legislation, collective agreements or the international environmental, social and labour conventions listed in Annex X to Directive 2014/24/EU<sup>2</sup>.

## **Joint tenders**

A joint tender is a situation where a tender is submitted by a group of economic operators (natural or legal persons). Joint tenders may include subcontractors in addition to the members of the group.

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<sup>1</sup> See [http://www.wto.org/english/tratop\\_e/gproc\\_e/gp\\_gpa\\_e.htm](http://www.wto.org/english/tratop_e/gproc_e/gp_gpa_e.htm)

<sup>2</sup> Directive 2014/24/EU of the European Parliament and of the Council of 26 February 2014 on public procurement and repealing Directive 2004/18/EC (OJ L 94, 28.3.2014, p. 65).

In case of joint tender, all members of the group assume joint and several liability towards the Contracting Authority for the performance of the contract as a whole, i.e. both financial and operational liability. Nevertheless, tenderers must designate one of the economic operators as a single point of contact (the leader) for the Contracting Authority for administrative and financial aspects as well as operational management of the contract.

After the award, the Contracting Authority will sign the contract either with all members of the group, or with the leader on behalf of all members of the group, authorised by the other members via powers of attorney.

### **Subcontracting**

Subcontracting is permitted but the contractor will retain full liability towards the Contracting Authority for performance of the contract as a whole.

Tenderers are required to identify all subcontractors and provide an indication of the proportion of subcontracting. See Annex 2, questionnaire for joint bids and subcontracting.

During contract performance, the change of any subcontractor identified in the tender or additional subcontracting will be subject to prior written approval of the Contracting Authority.

### **Structure and content of the tender**

The tenders must be presented as follows:

Part A: Identification of the tenderer (see section 1.7)

Part B: Non-exclusion (see section 2.2)

Part C: Selection (see section 2.3)

Part D: Technical offer (see section 3)

Part E: Financial offer (see section 2.6)

Tenders shall be submitted in one original and two copies of the original as well as one copy on a USB key which must be identical to the original including annexes.

### **Identification of the tenderer**

The tender must include a cover letter signed by an authorised representative presenting the name of the tenderer (including all entities in case of joint tender) and identified subcontractors if applicable, and the name of the single contact point (leader) in relation to this procedure. Coherence must be ensured between the information in the cover letter and in Annex 1.

In case of joint tender, the cover letter must be signed either by an authorised representative for each member, or by the leader authorised by the other members with powers of attorney. The signed powers of attorney must be included in the tender as well. Subcontractors that are identified in the tender must provide a letter of intent signed by an authorised representative stating their willingness to provide the service presented in the tender and in line with the present tender specifications.

The tenderer (and each member of the group in case of joint tender) must declare whether it is a Small or Medium Size Enterprise in accordance with [Commission Recommendation 2003/361/EC](#). This information is used for statistical purposes only.

All tenderers (including all members of the group in case of joint tender) must provide a signed Legal Entity Form with its supporting evidence. The form is available on: [http://ec.europa.eu/budget/contracts\\_grants/info\\_contracts/legal\\_entities/legal\\_entities\\_en.cfm](http://ec.europa.eu/budget/contracts_grants/info_contracts/legal_entities/legal_entities_en.cfm)

Tenderers that are already registered in the Contracting Authority's accounting system (i.e. they have already been direct contractors) must provide the form but are not obliged to provide the supporting evidence.

The tenderer (or the leader in case of joint tender) must provide a Financial Identification Form with its supporting documents. Only one form per tender should be submitted. No form is needed for subcontractors and other members of the group in case of joint tender. The form is available on: [http://ec.europa.eu/budget/contracts\\_grants/info\\_contracts/index\\_en.cfm](http://ec.europa.eu/budget/contracts_grants/info_contracts/index_en.cfm)

## **2. EVALUATION AND AWARD**

### **2.1. Evaluation steps**

The evaluation is based solely on the information provided in the submitted tender. It involves the following:

- Verification of non-exclusion of tenderers on the basis of the exclusion criteria
- Selection of tenderers on the basis of selection criteria
- Verification of compliance with the minimum requirements set out in these tender specifications
- Evaluation of tenders on the basis of the award criteria

The contracting authority may reject abnormally low tenders, in particular if it established that the tenderer or a subcontractor does not comply with applicable obligations in the fields of environmental, social and labour law.

The Contracting Authority will assess these criteria in no particular order. The successful tenderer must pass all criteria to be awarded the contract.

## **2.2. Verification of non-exclusion**

All tenderers must provide a declaration on honour (see Annex 5), signed and dated by an authorised representative, stating that they are not in one of the situations of exclusion listed in that declaration on honour.

In case of joint tender, each member of the group must provide a declaration on honour signed by an authorised representative.

In case of subcontracting, subcontractors whose capacity is necessary to fulfil the selection criteria must provide a declaration on honour signed by an authorised representative.

The Contracting Authority reserves the right to verify whether the successful tenderer is in one of the situations of exclusion by requiring, at any point during the procedure, the supporting documents listed in the declaration on honour.

In any event, the successful tenderer must provide the documents mentioned in the declaration on honour before signature of the contract and within a deadline given by the contracting authority. This requirement applies to each member of the group in case of joint tender and to subcontractors whose capacity is necessary to fulfil the selection criteria.

The obligation to submit supporting evidence does not apply to international organisations.

A tenderer (or a member of the group in case of joint tender, or a subcontractor) is not required to submit the documentary evidence if it has already been submitted for another procurement procedure and provided the documents were issued not more than one year before the date of their request by the contracting authority and are still valid at that date. In such cases, the tenderer must declare on its honour that the documentary evidence has already been provided in a previous procurement procedure, indicate the reference of the procedure and confirm that there has been no change in its situation.

A tenderer (or a member of the group in case of joint tender, or a subcontractor) is not required to submit a specific document if the contracting authority can access the document in question on a national database free of charge.

## **2.3. Selection criteria**

Tenderers must prove their legal, regulatory, economic, financial, technical and professional capacity to carry out the work subject to this call for tender.

The tenderer may rely on the capacities of other entities, regardless of the legal nature of the links which it has with them. It must in that case prove to the Contracting Authority that it will have at its disposal the resources necessary for performance of the contract, for example by producing an undertaking on the part of those entities to place those resources at its disposal.

### **2.3.1. Declaration and evidence**

The tenderers (and each member of the group in case of joint tender) and subcontractors whose capacity is necessary to fulfil the selection criteria must provide the declaration on

honour (see Annex 5), signed and dated by an authorised representative, stating that they fulfil the selection criteria applicable to them individually. In case of joint tender or subcontracting, the criteria applicable to the tenderer as a whole will be verified by combining the various declarations for a consolidated assessment.

This declaration is part of the declaration used for exclusion criteria (see section 2.2) so only one declaration covering both aspects should be provided by each concerned entity.

The Contracting Authority will evaluate selection criteria on the basis of the declaration on honour and evidence submitted for the legal and regulatory, financial and economic and technical and professional capacity of the tenderers.

A tenderer (or a member of the group in case of joint tender, or a subcontractor) is not required to submit the documentary evidence if it has already been submitted for another procurement procedure and provided the documents were issued not more than one year before the date of their request by the contracting authority and are still valid at that date. In such cases, the tenderer must declare on its honour that the documentary evidence has already been provided in a previous procurement procedure, indicate the reference of the procedure and confirm that there has been no change in its situation.

A tenderer (or a member of the group in case of joint tender, or a subcontractor) is not required to submit a specific document if the contracting authority can access the document in question on a national database free of charge.

### **2.3.2. Legal and regulatory capacity criteria and evidence**

Tenderers must prove that they are allowed to pursue the professional activity necessary to carry out the work subject to this call for tenders. The tenderer (including each member of the group in case of joint tender) must provide the following information in its tender if it has not been provided with the Legal Entity Form:

- For legal persons, a legible copy of the notice of appointment of the persons authorised to represent the tenderer in dealings with third parties and in legal proceedings, or a copy of the publication of such appointment if the legislation applicable to the legal person requires such publication. Any delegation of this authorisation to another representative not indicated in the official appointment must be evidenced.
- For natural persons, if required under applicable law, a proof of registration on a professional or trade register or any other official document showing the registration number.

### **2.3.3 Economic and financial capacity criteria and evidence**

The tenderer must have the necessary economic and financial capacity to perform this contract until its end. The tenderer must comply with the following selection criteria:

Annual turnover of the last two financial years above EUR 384.000 (three hundred and eighty-four thousand euros); this criterion applies to the tenderer as a whole, i.e. the combined capacity of all members of a group and identified subcontractors in case of a joint tender.



**In order to prove their capacity, the tenderer must submit with its tender the following evidence:**

- Copy of the profit and loss accounts for the last two years for which accounts have been closed from each concerned legal entity;
- Failing that, appropriate statements from banks;
- If applicable, evidence of professional risk indemnity insurance.

If, for some exceptional reason which the Contracting Authority considers justified, a tenderer is unable to provide one or other of the above documents, it may prove its economic and financial capacity by any other documents which the Contracting Authority considers appropriate. In any case, the Contracting Authority must at least be notified of the exceptional reason and its justification. The Commission reserves the right to request any other document enabling it to verify the tenderer's economic and financial capacity.

### **2.3.4 Technical and professional capacity criteria and evidence**

#### **Criteria and evidence relating to tenderers**

Tenderers (in case of a joint tender the combined capacity of all members of the group and identified subcontractors) must comply with the criteria listed below:

The project references indicated below consist of a list of relevant services provided (i.e. fully delivered) in the past *five* years, with the sums, dates and clients, public or private, accompanied by statements issued by the clients.

- **Criterion A1:** The tenderer must prove experience in the field of scientific aspects of endocrine disruptors, development of ecotoxicological testing methods, OECD process on the development of Test Guidelines for testing and assessment as well as in the collection and assessment of ecotoxicological data on chemicals and statistical analyses applied to test method development.

**Evidence A1:** The tenderer must provide references for at least 3 projects delivered in these fields in the last five years with a minimum value for each project of € 100 000.

- **Criterion A2:** The tenderer must prove capacity to work and draft reports in English.

**Evidence A2:** The tenderer must provide one document of at least 10 pages (report, study, etc.) in this language that it has drafted and published or delivered to a client in the last five years. The verification will be carried out on 5 pages of the document.

**In order to prove their capacity, the tenderer must submit with its tender the evidence listed above.**

#### **a. Criteria and evidence relating to the team delivering the service:**

The team delivering the service should include, as a minimum, the following profiles:

**Criterion B1 - Project Manager:** At least 4 years' experience in project management, including overseeing project delivery, quality control of delivered service, client orientation and conflict resolution experience in projects with minimum value of € 100 000, with experience in management of teams of at least 5 people.

**Evidence B1:** CV

#### **Criterion B2 – Project team expertise**

- **Expertise in scientific aspects of endocrine disruptors:** Relevant higher education degree and at least 5 years' experience in the field of endocrine disruptors.

- **Expertise in ecotoxicology and risk assessment of chemicals:** Relevant higher education degree and 5 years' professional experience in the field of regulatory hazard assessment of chemicals for the environment in the context of the EU legislation on chemicals (e.g. REACH, Biocides, Plant Protection Products).

- **Expertise in development of test methods and in statistics:** Relevant higher education and at least 3 years' experience in the field of development of test methods and in statistics.

**Evidence B2 :** CVs and indication of the intended function in the delivery of the service

**Criterion B3 - Language quality check:** At least 50% members of the team should have at least C1 level in the Common European Framework for Reference for Languages<sup>3</sup> in English.

**Evidence B3:** A language certificate or past relevant experience.

**In order to prove their capacity, the tenderer must submit with its tender the evidence listed above.**

#### **2.4. Compliance with the minimum requirements**

The technical offer must cover all aspects and tasks required in the technical specifications and provide all the information needed to apply the award criteria. Offers deviating from the requirements or not covering all requirements may be rejected on the basis of non-compliance with the tender specifications and will not be evaluated.

#### **2.5. Award criteria**

The contract will be awarded to the most economically advantageous tender, according to the 'best price-quality ratio' award method. The quality of the tender will be evaluated based on the following criteria. The maximum total quality score is 100 points.

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<sup>3</sup> See [http://www.coe.int/t/dg4/linguistic/Cadre1\\_en.asp](http://www.coe.int/t/dg4/linguistic/Cadre1_en.asp)

A maximum of 50 points will be attributed to criterion 1, a maximum of 35 points will be attributed to criterion 2, and a maximum of 15 points will be attributed to criterion 3. In addition a minimum threshold will be set up under this system of points:

- Technical sufficiency levels: Selected companies will have to score a minimum of 25, 18 and 8 points under criteria 1, 2 and 3 respectively, with a minimum total of 65 points.

Assessment of the tenders will focus on the quality of the proposed services therefore tenderers should elaborate on all points addressed by these specifications in order to score as many points as possible. The mere repetition of mandatory requirements set out in these specifications, without going into details or without giving any added value, will only result in a very low score. In addition, if certain essential points of these specifications are not expressly covered by the tender, the Commission may decide to give a zero mark for the relevant qualitative award criteria.

### **1 Quality of the proposed methodology (50 points – minimum threshold 25)**

This criterion assesses the suitability and strength of the proposal as measured against the requirements of the tasks in terms of the technical content, completeness, originality of ideas (*where appropriate*) and proposed effort. Furthermore, the degree to which the methodology shows the capacity to resolve the questions underlying in the tender in a realistic and well-structured way, as well as demonstrate that the methods proposed are suited to the needs set out by the Commission in the Technical Specifications (see part 3) will be assessed under this criterion.

### **2 Organisation of the work and allocation of resources (35 points – minimum threshold 18)**

This criterion will assess how the roles and responsibilities of the proposed team and of the economic operators (in case of joint tenders, including subcontractors if applicable) are distributed for each task. It also assesses the global allocation of time and resources to the project and to each task or deliverable, and whether this allocation is adequate for the work. The tender should provide details on the allocation of time and resources and the rationale behind the choice of this allocation. Details should be provided as part of the technical offer and not simply as part of the financial offer.

### **3 Quality control measures (15 points – minimum threshold 8)**

This criterion will assess the quality control system applied to the service foreseen in these tender specifications concerning the quality of the deliverables, the language quality check, and continuity of the service in case of absence of a member of the team. The quality control system should be detailed in the tender and specific to the tasks at hand; a generic quality control system will result in a low score.

#### **2.5.1 Ranking and Award**

Having examined the tenders from a technical point of view, the evaluation committee will proceed considering which is the economically most advantageous offer taking into account **only those tenders that have obtained at least 65 out of the 100 points that are available**

**for the technical quality of the bid.** The evaluation committee will then proceed with the financial comparison of the tenders retained for further consideration according to the ranking procedure below.

The bid offering the best value for money will be chosen, provided that the minimum number of points cited above is achieved. The ranking of the tenders will be calculated as follows:

- All bids that do not reach the stated technical sufficiency levels for each individual award criteria will not be considered for contract award.
- All bids that have passed the individual levels and score 65 or higher are deemed to be technically sufficient. Then the price is divided by the total number of points awarded to obtain the price-quality ratio. The award of the contract will be made in accordance with the lowest ratio.

The Commission reserves the right not to select any tender if the amounts tendered exceed the budget envisaged for this project.

## **2.6.Financial offer**

The maximum budget allocated to this contract is fixed at € 400 000 (Four hundred thousand Euros) excluding VAT (including fees, travel and all other costs. **Travel and subsistence expenses should be part of the lump sum and will not be refunded separately**). Any offers received that do not respect this maximum budget will be automatically excluded from the evaluation procedure. For guidance purposes see Annex 3.

The price for the tender must be quoted in euro. Tenderers from countries outside the euro zone have to quote their prices in euro. The price quoted may not be revised in line with exchange rate movements. It is for the tenderer to assume the risks or the benefits deriving from any variation.

Prices must be quoted free of all duties, taxes and other charges, including VAT, as the European Union is exempt from such charges under Articles 3 and 4 of the Protocol on the privileges and immunities of the European Union. The amount of VAT may be shown separately.

## **3. TECHNICAL SPECIFICATIONS**

### **Background**

The presence of certain toxicants/chemicals can perturb the endocrine system and induce a variety of responses, some of which can cause severe adverse effects in humans and wildlife. In order to protect human health and the environment, it is therefore important to identify those substances that can cause adverse effects *via* disruption of the endocrine system.

Availability of test methods is an important factor in our ability to identify the substances that cause adverse effects *via* disruption of the endocrine system and in ensuring a high level of protection of human health and the environment. To ensure that test methods (TMs) are internationally and mutually accepted a test guideline development programme (TGP) has

been established under the auspices of the OECD. EU legislation regulating chemical substances often includes testing of the substances according to the EU Test Methods Regulation (TMR)<sup>4</sup>, which predominantly contains test guidelines (TGs) developed under the OECD. Therefore, the OECD TGP is of utmost importance for the EU regulatory processes on chemical substances. The OECD's Endocrine Disrupter Testing and Assessment Advisory Group (EDTA AG) coordinates development of testing and assessment approaches for endocrine disruptors (EDs).

Despite the progress achieved on the development and validation of TGs for evaluation of EDs and associated guidance documents under the OECD auspices over the last 20 years (see Annex 1), there are still some gaps and weaknesses in the current test methods for evaluation of EDs<sup>5678</sup>. These gaps present a serious issue which needs to be adequately addressed. The European Commission Services commissioned a study<sup>9</sup> and organised an expert workshop in Brussels on 30 May - 1 June 2017 with the objectives of:

- Identifying gaps in test methods;
- Identifying ways to address those gaps; and
- Prioritising further development and validation of TMs and testing approaches in this area.

The study and the workshop followed an earlier JRC expert survey on identification of gaps in available test methods for the evaluation of endocrine disruptors, the results of which were published in a 2017 report<sup>10</sup>.

The study and the workshop resulted in a number of findings and recommendations, organised separately for human health endpoints and for the environmental endpoints. The ideas to fill the gaps for those two areas were further split based on the timeline in which the gaps could be addressed into short-, medium and long-term.

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<sup>4</sup> TMR, <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:142:0001:0739:en:PDF>

<sup>5</sup> Kortenkamp et al. (2011). [http://ec.europa.eu/environment/chemicals/endocrine/pdf/sota\\_edc\\_final\\_report.pdf](http://ec.europa.eu/environment/chemicals/endocrine/pdf/sota_edc_final_report.pdf)

<sup>6</sup> OECD (2012). [http://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=env/jm/mono\(2012\)23&doclanguage=en](http://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=env/jm/mono(2012)23&doclanguage=en)

<sup>7</sup> EFSA (2013). <http://www.efsa.europa.eu/en/efsajournal/pub/3132>

<sup>8</sup> UNEP/WHO/IOMC (2012). [http://www.unep.org/pdf/WHO\\_HSE\\_PHE\\_IHE\\_2013.1\\_eng.pdf](http://www.unep.org/pdf/WHO_HSE_PHE_IHE_2013.1_eng.pdf)

<sup>9</sup> <https://publications.europa.eu/en/publication-detail/-/publication/6b464845-4833-11e8-be1d-01aa75ed71a1>

<sup>10</sup> JRC (2017). Expert survey on identification of gaps in available test methods for evaluation of endocrine disruptors. Deliverable under administrative arrangement: ENV/07/0307/2012/641465/D3. Available at: [http://publications.jrc.ec.europa.eu/repository/bitstream/JRC106244/jrc\\_tr\\_ed\\_tm\\_prioritisation\\_survey\\_fv.pdf](http://publications.jrc.ec.europa.eu/repository/bitstream/JRC106244/jrc_tr_ed_tm_prioritisation_survey_fv.pdf)

Following the outcomes of the work, the European Commission Services have initiated activities to improve the test guidelines for detection of endocrine disrupting effects. A study on the development of a study protocol for thyroid disruptor testing in the mammalian system was recently launched. With this call for tender the European Commission Services are looking to get support for the development of (a) study protocol(s) for testing of identification of endocrine disrupting substances in non-mammalian vertebrates or invertebrates as indicators of effects on biotic systems, *i.e.* regulatory relevant endpoints for environmental hazard assessment.

## **Objectives**

The objective of this study request is to:

- Develop (a) study protocol(s) for testing of endocrine disrupting effects in biotic systems to improve the identification of substances disturbing the endocrine system, by either enhancing already existing TGs and/or developing a new TG, taking into consideration the recommendations of the prioritisation workshop and the JRC survey.

The contractor will develop (a) draft protocol(s) for the enhancement of existing TGs, or as a basis for the development of a new TG. The contractor will together with a Scientific Expert Group (see below) make recommendations on the final content of (a) draft protocol(s), based on a scoping document created by the contractor.

One or more feasibility studies shall be made on the proposed draft study protocol(s). It is expected that the feasibility study(ies) will either result in (a);

1) final draft study protocol(s) of a method ready to enter into the validation

or

2) revised draft study protocol(s) modified based on the results from the feasibility study(ies), able to be used for a second run of the feasibility study(ies) before the final draft study protocol(s) is ready. The execution of a second run of the feasibility study(ies) would be a step beyond the current contract.

## **Tasks to be performed, management of the tasks and details of how the tasks are to be carried out**

### *Study Organisation and Management:*

To manage the contract organisationally, a Steering Group will be established for steering the work under the contract. The Steering Group will be composed of representatives of the Commission Services. The group will consist of up to 6 people.

**Task 1. Set up a Scientific Expert Group which will provide scientific and technical guidance on the development of the study protocol(s)**

The contractor in cooperation with the Steering Group shall establish a Scientific Expert Group (SEG), which should provide scientific guidance on the development of the study protocol(s) for enhancement of existing TGs or the development of a new TG, including comments on the drafting, ideas and endpoints to be included, suggestions to the feasibility study(ies) etc.

The SEG should consist of up to 12 people. The members shall be internationally recognised experts in the field of ecotoxicology/endocrinology and testing of effects of chemicals in biotic systems complemented by some regulators and experts from contract laboratories. The contractor shall propose the members of the SEG. The final decision on who to invite will be made in consultation with the Steering Group. The participation of experts in the SEG shall be free of charge, *i.e.* experts will not be paid for the work done.

During the tasks implementation, the contractor shall organise at least four 2-day face-to-face meetings of this group with the contractor and the Commission Services in Brussels. Materials to be discussed at the meetings shall be circulated to the SEG and Steering Group at least 2 weeks in advance. The contractor shall organise the logistics and cover the associated travel and accommodation costs for the members of the expert group in accordance with Annex 6. The European Commission services will provide a meeting room and refreshments.

One additional SEG meeting should be factored into the offer in case of need during the running of the feasibility study(ies) to discuss preliminary results and/or changes to the draft study protocol(s) if the contractor and/or the Steering Group find it necessary.

The contractor in consultation with the Steering Group shall decide how and at what stages they further wish to involve the SEG in the work on this project.

**The deliverables for this task will be:**

- Establishment of the Scientific Expert Group (SEG);
- At least four 2-day face-to-face meetings of the SEG in Brussels

**Task 2: Create a scoping document of possible test method(s) or endpoints to be discussed with the SEG**

Based on the proposed enhancements of already existing TGs and new TGs in the prioritisation report and the JRC survey the contractor shall make a scoping document for the SEG structuring the suggested proposals. The scoping document should contain the elements of the proposed enhanced and/or new TG(s). Based on the scoping document the SEG together with the contractor and Steering Group shall decide for which proposal(s) a feasibility study should be conducted and a draft study protocol(s) developed. The scoping document should describe as a minimum:

- Which existing TG(s) should be enhanced or replaced and which additional parameters to be included, *e.g.* inclusion of new endpoints, changing of design, etc. Deletion of non-informative endpoints should also be considered
- Which new TG(s) could be developed and which parameters to be included, *e.g.* incorporation of endpoints, design, *etc.*, in parallel with suggestions of which TG(s) could be substituted

- The proposed endpoints to be measured, and an explanation on how they relate to adverse effects (e.g. measurement of vitellogenin level, where reduction leads to a reduction of cumulative fecundity and spawning in fish)
- Considerations of practical aspects of measuring the additional parameters
- In case of practical reasons to limit the number of additional parameters, parameters to be ranked in order of priority
- Estimated timeframe for the feasibility study(ies) suggested *i.e.* possible to do within the given timeframe of this project

The scoping document shall be discussed by the SEG at a 2-day face-to-face meeting. At the meeting it shall be decided which proposal(s) to continue with and on which to make a feasibility study(ies) considering the time frame of the project. The decision will be made by the Steering Group based on the advice of the SEG members and the contractor. The proposal(s) decided on shall afterwards be revised based on the comments and ideas from the SEG members and developed into a first draft study protocol or protocols.

**The deliverables for this task will be:**

- Scoping document developed and circulated to the SEG and Steering Group 14 days in advance of the SEG meeting
- Moderating a discussion of the proposals in the scoping document and agreeing on one or more of them with the SEG and Steering Group at a face-to-face meeting
- Providing a summary record of the discussion and outcome of the SEG meeting
- Revising the agreed proposal(s) based on input from the SEG to create a first draft study protocol(s)

**Task 3: Develop (a) draft study protocol(s) and a roadmap for the feasibility study(ies)**

Based on the outcome and input from the first SEG meeting the contractor shall develop (a) draft study protocol(s) for the feasibility study(ies) on the proposals agreed on. Proposed study designs which would fall under Directive 2010/63<sup>11</sup> should at all times respect the 3Rs principles as outlined, for example, in the NC3Rs ARRIVE guidelines<sup>12</sup> and project authorisation would need to be obtained<sup>13</sup>.

In parallel the contractor shall develop (a) roadmap(s) for conducting the feasibility study(ies) with a few reference chemicals. The roadmap(s) should as a minimum include:

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<sup>11</sup> Directive 2010/63/EU of the European Parliament and of the Council of 22 September 2010 on the protection of animals used for scientific purposes

<sup>12</sup> **Kilkenny et al.** Improving Bioscience Research Reporting: The ARRIVE Guidelines for Reporting Animal Research. PLOS Biology, 2010: 8(6)

<sup>13</sup> **EC 2013**, [http://ec.europa.eu/environment/chemicals/lab\\_animals/pdf/guidance/project\\_evaluation/en.pdf](http://ec.europa.eu/environment/chemicals/lab_animals/pdf/guidance/project_evaluation/en.pdf)



- Defined list of reference chemicals to be tested in the feasibility study(ies)
- Proposal of one or more experienced laboratories able to conduct the feasibility study(ies)
- Timeline and budget
- Proposal of a "study management team" for each feasibility study to assist and support the laboratory, as necessary, in the execution of the study and data analysis, including statistical support

The first draft study protocol(s) and roadmap shall be discussed by the SEG at a 2-day face-to-face meeting. The documents shall be provided at least 14 days before the meeting of SEG. The first draft study protocol(s) and roadmap(s) shall afterwards be revised, based on the comments and ideas from the SEG members, into revised version of the study protocol(s) and roadmap.

The revised version of the study protocol(s) and of the roadmap shall be again discussed and fine-tuned by the SEG at a 2-day face-to-face meeting. The documents shall be provided at least 14 days before the meeting of SEG. The revised version of the study protocol(s) and roadmap(s) shall afterwards be revised, based on the comments and ideas from the SEG members, into final versions used for the feasibility study(ies).

The final versions of the draft study protocol(s) and roadmap(s) shall be circulated to the SEG members and the Steering Group. After acceptance of the final versions by the Steering Group based on the advice of the SEG members the feasibility study(ies) shall be conducted.

**The deliverables for this task will be:**

- Proposal of a first draft study protocol(s) for the feasibility study(ies) circulated to the SEG and Steering Group 14 days in advance of the 2<sup>nd</sup> SEG meeting
- Proposal of a first draft roadmap(s) for conducting one or more feasibility studies circulated to the SEG and Steering Group 14 days in advance of the 2<sup>nd</sup> SEG meeting
- Discussing and revising the proposals of the first draft study protocol(s) and roadmap(s) with the SEG at a face-to-face meeting
- Providing a summary record of the discussion and outcome of the 2<sup>nd</sup> SEG meeting
- Creating a revised version of a study protocol(s) for the feasibility study(ies) circulated to the SEG and Steering Group 14 days in advance of the 3<sup>rd</sup> SEG meeting
- Creating a revised version of a roadmap(s) for conducting one or more feasibility studies circulated to the SEG and Steering Group 14 days in advance of the 3<sup>rd</sup> SEG meeting
- Discussing and revising the revised versions of study protocol(s) and roadmap(s) with the SEG at a face-to-face meeting
- Providing a summary record of the discussion and outcome of the 3<sup>rd</sup> SEG meeting
- Creating a final version of study protocol(s) and roadmap(s) for the feasibility study(ies) based on input from the SEG

**Task 4: Conduct the feasibility study(ies) and discuss results with SEG**

On acceptance of the draft study protocol(s) and roadmap(s), the feasibility study(ies) shall be conducted by a laboratory with enough experience in the type of experiments to be run. The laboratory testing can be done by the contractor itself or by using a commercial laboratory. All the cost of the feasibility study(ies) must be held by the contractor and factored into the offer. The contractor could suggest a laboratory already in their offer to be available from the commencement of the project for consultation if needed.

An additional SEG meeting (4<sup>th</sup> meeting) should be factored into the offer in case of need during the running of the feasibility study(ies) to discuss preliminary results and/or changes to the draft study protocol(s) if the contractor and/or the Steering Group find it necessary.

The final results of the feasibility study(ies) shall be presented and pre-analysed by the contractor in a draft feasibility study report. The study report shall be discussed by the SEG at a 2-day face-to-face meeting (5<sup>th</sup> meeting) for further analysis and optimisation of the draft study protocol(s). Agreed changes and recommendations provided by the SEG will be implemented by the contractor in the draft study protocol(s).

**The deliverables for this task will be:**

- Feasibility study(ies) conducted
- Draft feasibility study report(s) developed
- Discussion and analysis of the outcome of the feasibility study(ies) with the SEG at a face-to-face meeting (5<sup>th</sup> meeting)
- Provision of a summary record of the discussion and outcome of the 5<sup>th</sup> SEG meeting
- Final feasibility study report(s)

**Task 5: Final/Revised draft study protocol**

Based on the final feasibility study report(s) and recommendations from the SEG the contractor is expected to make a final/revised draft study protocol(s), including recommendations for next steps. It is expected that the final deliverable will either be (a);

1) final draft study protocol(s) of a method ready to enter into the validation

or

2) revised draft study protocol(s) modified based on the results from the feasibility study(ies), able to be used for a second run of the feasibility study(ies) before the final draft study protocol(s) is ready. The execution of a second run of the feasibility study(ies) would be a step beyond the current contract.

The contractor may be asked to present the final/revised draft study protocol(s) at the OECD EDTA meeting.

**The deliverables for this task will be:**

- The final/revised draft study protocol(s) delivered
- The final/revised draft study protocol(s) presented at an OECD EDTA meeting

## **Meetings**

In summary, the contractor should envisage the following meetings during the course of the study:

- A **kick off meeting** with the Steering Group in Brussels lasting for one day. It should take place within 1 month from the signature of the contract. The kick off meeting will be dedicated to the discussion of the details of the work plan proposed in the offer. The contractor is expected to present the offer *e.g.* by use of PowerPoint presentation at the meeting. The contractor will write minutes from the meeting and distribute to the Steering Group for comments within 1 week after the meeting.
- At least **four 2-day meetings with the Scientific Expert Group** to discuss and get expert input on the study protocol. **One additional meeting with the Scientific Expert Group** shall be factored into the offer in case of need during the running of the feasibility study(ies). These meetings will be held at the EU Commission premises in Brussels. The contractor is expected to write minutes from the meetings and distribute to the SEG for comments within 1 week after the meeting.
- Up to **four 1-day Study Progress meetings** with the Steering Group to be held at the EU Commission premises in Brussels. The contractor will write minutes from the meeting and distribute to the Steering Group for comments within 1 week after the meeting.
- Presentation of the revised draft study protocol to the OECD EDTA group.

## Summary of contract indicative milestones

Milestones	Months																							
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24
Kick-off meeting	X																							
SEG established		X																						
Scoping document created			X																					
1 <sup>st</sup> SEG meeting			X																					
Study Progress meeting			X																					
1 <sup>st</sup> draft protocol developed					X																			
1 <sup>st</sup> draft roadmap developed					X																			
2 <sup>nd</sup> SEG meeting						X																		
Study Progress meeting						X																		
Revised version of protocol developed							X																	
Revised version of roadmap developed							X																	
3 <sup>rd</sup> SEG meeting								X																
Final version of protocol accepted										X														
Final version of roadmap accepted										X														
Feasibility study started											X													
4 <sup>th</sup> SEG meeting*																X*								
Study Progress meeting																X								
5 <sup>th</sup> SEG meeting																						X		
Study Progress meeting																						X		
Final/Revised draft study protocol delivered																								X
Presentation of the protocol to OECD EDTA																								X

\* An additional SEG meeting should be factored into the offer in case of need during the running of the feasibility study(ies) to discuss preliminary results and/or changes to the draft study protocol(s) if the contractor and/or the steering group find it necessary.

## **Duration of the tasks**

The tasks should be completed within **25** months of the signature of the contract. The execution of the tasks may not start before the contract has been signed.

## **Place of performance**

The place of performance of the tasks shall be the contractor's premises or any other place indicated in the tender, with the exception of the Commission's premises.

## **4. CONTENT, STRUCTURE AND GRAPHIC REQUIREMENTS OF THE FINAL DELIVERABLES**

The contractor must deliver the study and other deliverables as indicated below.

### **4.1. Content**

#### **4.1.1. Final study report**

The final study report must include:

- an abstract of no more than 200 words and an executive summary of maximum 6 pages, both in English;
- specific identifiers which must be incorporated on the cover page provided by the Contracting Authority;
- the following disclaimer:

*“The information and views set out in this [report/study/article/publication...] are those of the author(s) and do not necessarily reflect the official opinion of the Commission. The Commission does not guarantee the accuracy of the data included in this study. Neither the Commission nor any person acting on the Commission's behalf may be held responsible for the use which may be made of the information contained therein.”*

#### **4.1.2. Requirements for publication on Internet**

The Commission is committed to making online information as accessible as possible to the largest possible number of users including those with visual, auditory, cognitive or physical disabilities, and those not having the latest technologies. The Commission supports the Web Content Accessibility Guidelines 2.0 of the W3C.

For full details on the Commission policy on accessibility for information providers, see: [http://ec.europa.eu/ipg/standards/accessibility/index\\_en.htm](http://ec.europa.eu/ipg/standards/accessibility/index_en.htm)

For the publishable versions of the study, abstract and executive summary, the contractor must respect the W3C guidelines for accessible pdf documents as provided at: <http://www.w3.org/WAI/>.

## **4.2. Graphic requirements**

The contractor must deliver the study and all publishable deliverables in full compliance with the corporate visual identity of the European Commission, by applying the graphic rules set out in the European Commission's Visual Identity Manual, including its logo. The graphic rules, the Manual and further information are available at:

[http://ec.europa.eu/dgs/communication/services/visual\\_identity/index\\_en.htm](http://ec.europa.eu/dgs/communication/services/visual_identity/index_en.htm)

A simple Word template will be provided to the contractor after contract signature. The contractor must fill in the cover page in accordance with the instructions provided in the template. The use of templates for studies is exclusive to European Commission's contractors. No template will be provided to tenderers while preparing their tenders.

## **ANNEX 1 - ADMINISTRATIVE INFORMATION FORM**

*(To be signed by the tenderer only or the lead tenderer in the case of joint bids)*

**Organisation or individual:**

**NAME:** .....

**ADDRESS:** .....

**Address where contract should be sent to (if different from above):**

.....

### **PERSON AUTHORISED TO SIGN CONTRACT:**

**Name and position:** .....

### **PERSON FOR ROUTINE CONTACT:**

**Name and position:** .....

**ADDRESS:** .....

**Telephone and E-mail:** .....

**Signature of Tenderer** .....

## **ANNEX 2 – QUESTIONNAIRE FOR JOINT BIDS AND SUBCONTRACTING**

*(To be completed and signed by the lead tenderer)*

### **Joint bid (refer to paragraph 1.4)**

1. Does your bid involve more than one tenderer? Yes ☐ No ☐

Questions 2 - 4 shall be answered only if you have answered yes to question 1.

2. Please fill in the name of the company having power of attorney for the group of tenderers and acting as a co-ordinator:

---

3. Please fill in the names of the other companies taking part in the joint offer:

---

---

---

4. If a consortium or similar entity exists, please fill in the name and the legal status of the entity:

---

### **Subcontracting (refer to paragraph 1.5)**

5. Does your bid involve subcontracting? Yes ☐ No ☐

If the answer is yes, please complete question 6, and the next page per sub-contractor.

6.

List of sub-contractors:

Percentage of subcontracting:

.....

.....

.....

.....



**Reasons, roles, activities and responsibilities of sub-contractors.**

*Please complete this page for each sub-contractor (one page per sub-contractor):*

Name of the sub-contractor:

.....

Official legal form:

.....

Country of registration:

.....

Statutory registration number:

.....

(Internet address, if applicable):

.....

Official address in full:

.....

.....

Contact person:

.....

Telephone number:

.....

Reasons for subcontracting:

.....

Role, activities and responsibilities of the sub-contractor:

.....

The volume or the proportion of the sub-contracting:

.....

Do you intend to rely on capacities from the sub-contractor in order to fulfil the selection criteria? If yes, specify which selection criterion - financial and economic capacity or technical and professional capacity - and be aware that the tenderer must provide the documents which make it possible to assess the selection criteria.

.....

**Tenderer:**

**Date:**

**Signature:**

### **ANNEX 3 – FINANCIAL OFFER TEMPLATE**

*(To be completed and signed by the tenderer only or the lead tenderer in the case of joint bids)*

**(for guidance purposes only)**

#### **Price and Estimated budget breakdown**

**Calculation of the costs (incl. travel, overheads, consumables and any other related costs)**

Type of service provider	Position within the project team	Number of working days	Allocation of tasks	Proportion of the contract in %	Costs in €
Lead contractor					
	.....	.....	.....	.....	.....
	.....	.....	.....	.....	.....
	.....	.....	.....	.....	.....
	<i>Sub-total</i>	.....		.....	.....
Sub-contractor 1					
	.....	.....	.....	.....	.....
	.....	.....	.....	.....	.....
	<i>Sub-total</i>	.....		.....	.....
Sub-contractor 2					
	.....	.....	.....	.....	.....
	.....	.....	.....	.....	.....
	<i>Sub-total</i>	.....		.....	.....
Sub-contractor 3					
	.....	.....	.....	.....	.....
	.....	.....	.....	.....	.....
	<i>Sub-total</i>	.....		.....	.....
Travel/other costs <sup>1</sup> (if applicable)					
	Total	.....		.....	.....

**Signature of Tenderer**

.....

**Date**

.....

<sup>1</sup> Will be reimbursed on a lump-sum basis.

## **ANNEX 4 - LEGAL ENTITY AND FINANCIAL IDENTIFICATION FORMS**

These forms can be downloaded from

[http://ec.europa.eu/budget/contracts\\_grants/info\\_contracts/legal\\_entities/legal\\_entities\\_en.cfm](http://ec.europa.eu/budget/contracts_grants/info_contracts/legal_entities/legal_entities_en.cfm)  
m (Legal entity form)

*(To be signed by the tenderer and all members of the group in the case of joint tender (not necessary for subcontractors))*

[http://ec.europa.eu/budget/contracts\\_grants/info\\_contracts/financial\\_id/financial\\_id\\_en.cfm](http://ec.europa.eu/budget/contracts_grants/info_contracts/financial_id/financial_id_en.cfm)  
(financial identification form)

*(One form per offer to be signed by the tenderer or lead tender in the case the of joint tender)*

## **ANNEX 5 - DECLARATION ON HONOUR ON EXCLUSION CRITERIA AND SELECTION CRITERIA**

*(To be completed by the tenderer, all members of a joint tender and any subcontractor whose capacity is necessary to fulfil the selection criteria)*

*Comments [in grey italics in square brackets] are to be deleted and/or replaced by appropriate data.*

The undersigned [insert name of the signatory of this form], representing:

<i>(only for natural persons)</i> himself or herself	<i>(only for legal persons)</i> the following legal person:
ID or passport number:   ('the person')	Full official name:  Official legal form:  Statutory registration number:  Full official address:  VAT registration number:  ('the person')

### **I – SITUATION OF EXCLUSION CONCERNING THE PERSON**

	YES	NO
➤ declares that the above-mentioned person is in one of the following situations:		
a) it is bankrupt, subject to insolvency or winding up procedures, its assets are being administered by a liquidator or by a court, it is in an arrangement with creditors, its business activities are suspended or it is in any analogous situation arising from a similar procedure provided for under national legislation or regulations;	<input type="checkbox"/>	<input type="checkbox"/>
b) it has been established by a final judgement or a final administrative decision that the person is in breach of its obligations relating to the payment of taxes or social security contributions in accordance with the law of the country in which it is established, with those of the country in which the contracting authority is located or those of the country of the performance of the contract;	<input type="checkbox"/>	<input type="checkbox"/>
c) it has been established by a final judgement or a final administrative decision that the person is guilty of grave professional misconduct by having violated applicable laws or regulations or ethical standards of the profession to which the person belongs, or by having engaged in any wrongful conduct which has an impact on its professional credibility where such conduct denotes wrongful intent or gross negligence, including, in particular, any of the following:		

(i) fraudulently or negligently misrepresenting information required for the verification of the absence of grounds for exclusion or the fulfilment of selection criteria or in the performance of a contract;	<input type="checkbox"/>	<input type="checkbox"/>
(ii) entering into agreement with other persons with the aim of distorting competition;	<input type="checkbox"/>	<input type="checkbox"/>
(iii) violating intellectual property rights;	<input type="checkbox"/>	<input type="checkbox"/>
(iv) attempting to influence the decision-making process of the contracting authority during the award procedure;	<input type="checkbox"/>	<input type="checkbox"/>
(v) attempting to obtain confidential information that may confer upon it undue advantages in the award procedure;	<input type="checkbox"/>	<input type="checkbox"/>
d) it has been established by a final judgement that the person is guilty of the following:		
(i) fraud, within the meaning of Article 1 of the Convention on the protection of the European Communities' financial interests, drawn up by the Council Act of 26 July 1995;	<input type="checkbox"/>	<input type="checkbox"/>
(ii) corruption, as defined in Article 3 of the Convention on the fight against corruption involving officials of the European Communities or officials of EU Member States, drawn up by the Council Act of 26 May 1997, and in Article 2(1) of Council Framework Decision 2003/568/JHA, as well as corruption as defined in the legal provisions of the country where the contracting authority is located, the country in which the person is established or the country of the performance of the contract;	<input type="checkbox"/>	<input type="checkbox"/>
(iii) participation in a criminal organisation, as defined in Article 2 of Council Framework Decision 2008/841/JHA;	<input type="checkbox"/>	<input type="checkbox"/>
(iv) money laundering or terrorist financing, as defined in Article 1 of Directive 2005/60/EC of the European Parliament and of the Council;	<input type="checkbox"/>	<input type="checkbox"/>
(v) terrorist-related offences or offences linked to terrorist activities, as defined in Articles 1 and 3 of Council Framework Decision 2002/475/JHA, respectively, or inciting, aiding, abetting or attempting to commit such offences, as referred to in Article 4 of that Decision;	<input type="checkbox"/>	<input type="checkbox"/>
(vi) child labour or other forms of trafficking in human beings as defined in Article 2 of Directive 2011/36/EU of the European Parliament and of the Council;	<input type="checkbox"/>	<input type="checkbox"/>
e) the person has shown significant deficiencies in complying with the main obligations in the performance of a contract financed by the Union's budget, which has led to its early termination or to the application of liquidated damages or other contractual penalties, or which has been discovered following checks, audits or investigations by an Authorising Officer, OLAF or the Court of Auditors;	<input type="checkbox"/>	<input type="checkbox"/>
f) it has been established by a final judgment or final administrative decision that the person has committed an irregularity within the meaning of Article 1(2) of Council Regulation (EC, Euratom) No 2988/95;	<input type="checkbox"/>	<input type="checkbox"/>
g) for the situations of grave professional misconduct, fraud, corruption, other criminal offences, significant deficiencies in the performance of the contract or	<input type="checkbox"/>	<input type="checkbox"/>

irregularity, the applicant is subject to: i.facts established in the context of audits or investigations carried out by the Court of Auditors, OLAF or internal audit, or any other check, audit or control performed under the responsibility of an authorising officer of an EU institution, of a European office or of an EU agency or body; ii.non-final administrative decisions which may include disciplinary measures taken by the competent supervisory body responsible for the verification of the application of standards of professional ethics; iii.decisions of the ECB, the EIB, the European Investment Fund or international organisations; iv.decisions of the Commission relating to the infringement of the Union's competition rules or of a national competent authority relating to the infringement of Union or national competition law; or v.decisions of exclusion by an authorising officer of an EU institution, of a European office or of an EU agency or body.		
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## II – SITUATIONS OF EXCLUSION CONCERNING NATURAL PERSONS WITH POWER OF REPRESENTATION, DECISION-MAKING OR CONTROL OVER THE LEGAL PERSON

### *Not applicable to natural persons, Member States and local authorities*

➤ declares that a natural person who is a member of the administrative, management or supervisory body of the above-mentioned legal person, or who has powers of representation, decision or control with regard to the above-mentioned legal person (this covers company directors, members of management or supervisory bodies, and cases where one natural person holds a majority of shares) is in one of the following situations:	YES	NO	N/A
Situation (c) above (grave professional misconduct)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Situation (d) above (fraud, corruption or other criminal offence)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Situation (e) above (significant deficiencies in performance of a contract )	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Situation (f) above (irregularity)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

## III – SITUATIONS OF EXCLUSION CONCERNING NATURAL OR LEGAL PERSONS ASSUMING UNLIMITED LIABILITY FOR THE DEBTS OF THE LEGAL PERSON

➤ declares that a natural or legal person that assumes unlimited liability for the debts of the above-mentioned legal person is in one of the following situations:	YES	NO	N/A
Situation (a) above (bankruptcy)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Situation (b) above (breach in payment of taxes or social security contributions)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
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#### IV – GROUNDS FOR REJECTION FROM THIS PROCEDURE

➤ declares that the above-mentioned person:	YES	NO
h) has distorted competition by being previously involved in the preparation of procurement documents for this procurement procedure.	<input type="checkbox"/>	<input type="checkbox"/>

#### V – REMEDIAL MEASURES

If the person declares one of the situations of exclusion listed above, it must indicate measures it has taken to remedy the exclusion situation, thus demonstrating its reliability. This may include e.g. technical, organisational and personnel measures to prevent further occurrence, compensation of damage or payment of fines. The relevant documentary evidence which illustrates the remedial measures taken must be provided in annex to this declaration. This does not apply for situations referred in point (d) of this declaration.

#### VI – EVIDENCE UPON REQUEST

Upon request and within the time limit set by the contracting authority the person must provide information on the persons that are members of the administrative, management or supervisory body. It must also provide the following evidence concerning the person itself and concerning the natural or legal persons which assume unlimited liability for the debt of the person:

For situations described in (a), (c), (d) or (f), production of a recent extract from the judicial record is required or, failing that, an equivalent document recently issued by a judicial or administrative authority in the country of establishment of the person showing that those requirements are satisfied.

For the situation described in point (a) or (b), production of recent certificates issued by the competent authorities of the State concerned are required. These documents must provide evidence covering all taxes and social security contributions for which the person is liable, including for example, VAT, income tax (natural persons only), company tax (legal persons only) and social security contributions. Where any document described above is not issued in the country concerned, it may be replaced by a sworn statement made before a judicial authority or notary or, failing that, a solemn statement made before an administrative authority or a qualified professional body in its country of establishment.

The person is not required to submit the evidence if it has already been submitted for another procurement procedure. The documents must have been issued no more than one year before the date of their request by the contracting authority and must still be valid at that date.

The signatory declares that the person has already provided the documentary evidence for a previous procedure and confirms that there has been no change in its situation:

Document	Full reference to previous procedure
<i>Insert as many lines as necessary.</i>	

## VII – SELECTION CRITERIA

➤ declares that the above-mentioned person complies with the selection criteria applicable to it individually as provided in the tender specifications:	YES	NO	N/A
(a) It has the legal and regulatory capacity to pursue the professional activity needed for performing the contract as required in section 2.3.2 of the tender specifications;	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
(b) It fulfills the applicable economic and financial criteria indicated in section 2.3.3 of the tender specifications;	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
(c) It fulfills the applicable technical and professional criteria indicated in section 2.3.4 of the tender specifications.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

➤ if the above-mentioned person is the <b>sole tenderer</b> or the <b>leader in case of joint tender</b> , declares that:	YES	NO	N/A
(d) the tenderer, including all members of the group in case of joint tender and including subcontractors if applicable, complies with all the selection criteria for which a consolidated assessment will be made as provided in the tender specifications.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

## VII – EVIDENCE FOR SELECTION

The signatory declares that the above-mentioned person is able to provide the necessary supporting documents listed in the relevant sections of the tender specifications and which are not available electronically upon request and without delay.

The person is not required to submit the evidence if it has already been submitted for another procurement procedure. The documents must have been issued no more than one year before the date of their request by the contracting authority and must still be valid at that date.

The signatory declares that the person has already provided the documentary evidence for a previous procedure and confirms that there has been no change in its situation:

Document	Full reference to previous procedure
<i>Insert as many lines as necessary.</i>	

***The above-mentioned person may be subject to rejection from this procedure and to administrative sanctions (exclusion or financial penalty) if any of the declarations or information provided as a condition for participating in this procedure prove to be false.***

Full name

Date

Signature



## **ANNEX 6**

### **Travel and subsistence costs**

(Only applicable if the organisation of workshops/conferences is specified in the tender specifications –  
Not applicable to contractor's own staff)

Travel costs must be based on the following:

- **Train**: first-class rail travel for journeys less than 400 km (one way).
- **Flight**: economy class air travel for distances of more than 400 km. Business class is allowed for a flight of 4 hours or more without stopovers.
- **Private car**: the travel shall be reimbursed at the same rate as the first-class rail ticket, or by default at the rate of 0.22 € per km.

Different travel options will not be accepted and will entail the refusal of the offer. Amounts must be quoted in EURO. Prices must be fixed amounts and be calculated exclusive of all duties and taxes.

#### **Maximum rates for accommodation and meals.**

Destination	Hotel ceiling in euros	Daily allowance in euros
Belgium	148	102
Bulgaria	135	57
Czech Republic	124	70
Denmark	173	124
Germany	128	97
Estonia	105	80
Ireland	159	108
Greece	112	82
Spain	128	88
France	180	102
Croatia	110	75
Italy	148	98
Cyprus	140	88
Latvia	116	73
Lithuania	117	69
Luxembourg	148	98
Hungary	120	64
Malta	138	88
Netherlands	166	103
Austria	132	102
Poland	116	67
Portugal	101	83
Romania	136	62
Slovenia	117	84
Slovak Republic	100	74
Finland	142	113
Sweden	187	117
United Kingdom	209	125

Rates for hotel and subsistence for countries not included in the above table will be provided by the Commission services if necessary.

## **ANNEX 7 - ACKNOWLEDGEMENT OF RECEIPT**



**EUROPEAN COMMISSION**  
DIRECTORATES-GENERAL ENVIRONMENT  
Directorate ENV. A – POLICY  
A.5 - Finance

*(Please fill in your address)*

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## **ACKNOWLEDGEMENT OF YOUR TENDER**

**Our reference: ENV.B.2/ETU/2018/0009**

**Your reference:**

We wish to confirm the receipt and opening of your offer<sup>1</sup>. Your offer will now be evaluated by the Commission and its experts. You will be informed of the result in due course.

We thank you for your interest.

MarketsTeam  
ENV.A5

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<sup>1</sup> Your personal contact data has been recorded in a database used by the Markets Team of unit ENV.A5 for the administrative management of offers. The Commission is bound by Regulation 45/2001 on the protection of individuals with regard to the processing of personal data by the Union institutions and bodies. For more information, and to exercise your rights to access and eventually correct data concerning you, please don't hesitate to contact us.