TENDER SPECIFICATIONS

Reference: OC/EFSA/SCER/2017/01
Subject: Specialised training courses on certain aspects of food safety risk assessment for members of EFSA's Scientific Committee/Panels, their working groups, members of the EFSA Networks and EFSA staff.
Procurement procedure: Open call
Project/Process code: SCER-07
Budget Line: not applicable

Tender specifications purpose:

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

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

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

Submitting your tender on time:
Follow carefully the guidance in annex 2 "E-Submission application description".
Do not wait until the last day to upload your offer. Responsibility rests with you to ensure that your tender is fully, completely and correctly uploaded before the time limit for receipt. Failure to respect the time limit for receipt will result in the rejection of your offer for non-compliance with the deadline for tenders.

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

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

INDICATIVE PROCEDURE TIMETABLE

Milestone	Date[1]	Comments
Launch date	04/07/2017	Date of publication being sent to OJ
Deadline for sending a request for clarification to EFSA	15/09/2017	***Attention:*** *Requests for clarification may only be submitted through the eTendering website as described in the Invitation Letter.*
"Receipt Time Limit" - Closing date and time for offers reception	**25/09/2017 at 14:30 (CET)[2]**	See details in the Invitation letter. Please also refer to the e-Submission application description attached in annex 2 hereto.
Opening session	26/09/2017	14:30hr, EFSA premises, Parma
Notification of the evaluation results	October 2017	Estimated. *Attention: outcome of the present procurement procedure will be communicated to all tenderers to the e-mail address indicated in their offer. Accordingly, the tenderers who have submitted offers under the present call are strongly invited to check regularly the inbox in question.*
Contract signature	November 2017	Estimated

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

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

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

1.1 BACKGROUND

The EFSA's Science Strategy 2020[3] describes different operational objectives as well as specific key activities for the implementation of its following objective: "Prepare for future risk assessment challenges".

Developing and implementing harmonised methodologies for risk assessment, across the EU and internationally, is one of these operational objectives and therefore all EFSA Guidance Documents should be fully implemented in a harmonised manner across EFSA Panels. Member States, European Commission and international agencies should also take into account the EFSA guidance documents when performing their assessments. With the help of training schemes for staff and experts, EFSA is aiming at implementing this objective through the coordination of the methodologies and the development of new capabilities to foster this framework among EFSA risk assessment community.

It is within Scientific Committee and Emerging Risk (SCER) Unit's mandate and mission to support the development and implementation of approaches of a horizontal cross-cutting nature for scientific evaluations through the organisation of the work of EFSA's Scientific Committee and its working groups. In order to fulfil its mandate, the SCER Unit should meet three main objectives: (i) developing cross-cutting guidance, (ii) developing documents methodologies for risk assessment and (iii) Implementing new Risk Assessment methodologies in a harmonised way. Written guidance documents alone are not sufficient to put procedures into practice. The contracts resulting from the present call should therefore support EFSA in the implementation of the new and existing Guidance Documents through specialised training courses.

The present Call is part of the Final work programme for grants and operational procurements 2017 as presented in Annex IX of the EFSA Programming Document 2017 – 2019, available on the EFSA's website[4]. In addition, the Programming Document has already announced the need to continue organising advanced training on risk assessment under the coordination of the SCER Unit.

The specialised courses are aimed to be structured around the body of best risk assessment practices and cross-cutting guidance documents that EFSA has developed over the past years.

In consultation with the EFSA Units and Panels, the SCER unit identifies the need of training courses aiming at covering the three main areas of expertise under the EFSA cross-cutting guidance documents developed by the EFSA Scientific Committee: (i) Chemical and Biological Risk assessment, (ii) Environmental Risk Assessment and (iii) Risk assessment Methodologies.

[3] https://www.efsa.europa.eu/sites/default/files/151008.pdf

[4] https://www.efsa.europa.eu/sites/default/files/corporate_publications/files/amp1719.pdf

1.2 OBJECTIVES AND DIVISION IN LOTS

The aim of this procurement procedure is to conclude a framework contract for four years. The framework contract will be implemented through specific contracts or order forms. Each time the framework contractor responds to a call under the framework contract, a specific contract or order form will have to be concluded between EFSA and the framework contractor. The specific contract or order form will set out the specific conditions for performing the individual assignment.

Overall Objectives:

The overall objectives of the framework contract resulting from this procurement procedure are:

- To enable the understanding and practical implementation of best risk assessment practices amongst members of EFSA's Scientific Committee/Panels, their working groups, EFSA staff and EFSA Networks, in particular on horizontal aspects related to three main areas of risk assessment (i) Chemical and Biological Risk assessment, (ii) Environmental Risk Assessment and (iii) Risk assessment Methodologies.

- To strengthen the dissemination of risk assessment Guidance Documents and modelling practises and to ensure the uptake of Guidance Documents on cross-cutting risk assessment approaches already developed by EFSA amongst members of EFSA's Scientific Committee/Panels, their working groups, the EFSA staff and the EFSA's Networks.

Specific objectives:

The objectives of the contract resulting from the present procurement procedure are to provide EFSA with a number of specialised training courses covering the following three main areas of EFSA's risk assessment (i) Chemical and Biological Risk assessment, (ii) Environmental Risk Assessment and (iii) Risk assessment Methodologies.

This call for tender is divided into the following 3 lots:

- Lot 1 –Trainings on Guidance Documents developed by the EFSA Scientific Committee/EFSA on different aspects of Chemical and Biological Risk Assessment and different related tools.

- Lot 2 –Trainings on Guidance Documents developed by the EFSA Scientific Committee/EFSA on the area of Environmental Risk Assessment.

- Lot 3 –Trainings on Risk assessment Methodologies developed by the EFSA Scientific Committee/EFSA.

Tenderers may submit an offer for one, two or three lots. Your offer should clearly indicate for which lot you are applying. In the case you decide to apply for several lots, a separate technical and financial offer for each lot must be provided. For the material composition of the offer(s) you submit, please consult Part 3 of these tender specifications.

LOT 1: Training courses on Chemical and Biological risk assessment

Trainings courses to be delivered under this lot should provide the participants with the necessary knowledge to implement and to apply, the different Guidance documents developed by the EFSA Scientific Committee/EFSA in the area of Chemical and Biological Risk assessment as well as to deepen knowledge on certain aspects of chemical and biological risk assessment that cut across the work of different Panels.

1. Harmonisation of risk assessment methodologies for human health and ecological risk assessment of combined exposure to multiple chemicals

Human and ecological risk assessment of combined exposure to multiple chemicals ("chemical mixtures") poses a number of challenges to scientists, risk assessors and risk managers, particularly because of the complexity of the problem formulation, the huge number of chemicals involved, and the toxicological profiles and exposure patterns of these chemicals in humans and species present in the environment.

EFSA is in the process of developing guidance document on "Harmonisation of risk assessment methodologies for human health and ecological risk assessment of combined exposure to multiple chemicals". The guidance document will address the different food sectors of EFSA and provide an approach on how to perform a risk assessment of combined exposure to multiple chemicals taking into consideration the amount and types of data that are available. The guidance is aimed at both human health and ecological risk assessment and is based on the latest developments that have taken place in the field.

The GD is due for publication after public consultation by the end of 2018-early 2019 with an international workshop by autumn 2019.

The tenderer/trainers will be asked to provide training on this guidance document after its publication on the EFSA website.

Technical Content

The training should be designed to build the expertise and facilitate the introduction of the guidance document and harmonised risk assessment methodologies for human health and ecological risk assessment of combined exposure to multiple chemicals in EFSA.

By the end of the course, participants should be able to understand and describe:

- The general principles and terminology of mixture risk assessment as provided by guidance documents from national and international bodies.
- Overview of tiered approaches developed in the GD and respective tools available for each step of the risk assessment process.
- How to deal with interactions within chemical mixtures and use of uncertainty factors in a mixture RA context.

2. Risk assessment of the application of nanoscience and nanotechnologies in agro/food/feed

The tenderer/trainers are asked to consider the following work of EFSA on nanomaterials when developing the programme for this course. The European Food Safety Authority has produced part-1 of the guidance document on human and animal health aspects of the risk assessment of nanoscience and nanotechnology applications in the food and feed chain (ref. draft for public consultation foreseen January 2018). It covers the application areas within EFSA's remit, i.e. food additives, enzymes, flavourings, food contact materials, novel foods, feed additives and pesticides. The guidance document takes account of the new developments that have taken place since publication of the previous guidance document in 2011. Aspects relating to nano-scale delivery systems, food contact materials and nanopesticides have been particularly covered because scientific literature suggests ongoing developments in these areas.

The proposed training course should help risk assessors to implement this Guidance, particularly when assessing the physicochemical properties, exposure assessment, and hazard characterisation of nanomaterials. The course should specifically elaborate on physicochemical characterisation of nanomaterials in terms of how to establish whether a material is nanomaterial, the key parameters that should be measured, the methods and techniques that can be used for characterisation of nanomaterials in complex matrices. It should also detail nano-specific considerations relating to in vivo/in vitro toxicological studies and the tiered framework for toxicological testing. Depending on the initial tier results, studies may be needed to investigate reproductive and developmental toxicity, immunotoxicity, allergenicity, neurotoxicity, effects on gut microbiome, and endocrine activity. The course should also touch upon the possible use of read across to fill data gaps, in vitro digestion, toxicokinetics, genotoxicity, as well as general issues relating to in vitro testing of nanomaterials. The potential use of integrated testing strategies and the knowledge of mode/mechanism of action will be discussed as well as uncertainty analysis for nanomaterials, in line with the EFSA guidance.

The guidance document is due for publication after public consultation by January 2018. The tenderer/trainers are required to provide training on this guidance document after its publication on the EFSA website.

The objective of this training course is:

- To enable the understanding and practical implementation of guidance on assessment of nanomaterial in the food/feed chain amongst members of EFSA's Scientific Committee/Panels, their working groups, as well as members of the EFSA scientific Networks and EFSA staff, for assessing nanomaterials in the food/feed chain.
- To strengthen the dissemination of guidance on assessment of nanomaterial in the food/feed chain amongst members EFSA's Scientific Committee/Panels, their working groups, as well as members of the EFSA scientific Networks and EFSA staff, and promote and facilitate its uptake through the participation in this course.
- To make a link between the theory and practice by including case studies with examples of nanomaterials assessed by EFSA.

Technical Content

By the end of the course, participants should be able to understand and describe:

- The scope and applicability of this guidance for materials falling within the definition of nanomaterials or other small particles that maintain characteristics of the nanoscale.

- The general scheme of this guidance and its interplay with already existing EFSA guidance per sector.
- The scientific information required to perform (1) physicochemical characterisation of nanomaterial; (2) exposure assessment and (3) step-wise hazard identification and characterisation for nanomaterials in the food/feed chain.

3. Science-based criteria for identifying endocrine disruptors in the context of EU legislation on pesticides and biocides.

Many substances released into the environment through human activity or naturally occurring in our diets are capable of interacting with the endocrine or hormone systems of animals and humans that regulate the metabolism and function of the body. These so-called endocrine active substances (EASs) occur in a variety of chemical classes including natural and synthetic drugs, pesticides, compounds used in industry and in consumer products, industrial by-products and pollutants, including some metals. If the interaction of these exogenous substances with the endocrine system leads to adverse health effect in an intact organism or its progeny or (sub) populations, these substances are referred to as 'endocrine disruptors' (EDs).

In 2016, the European Commission (EC) requested EFSA and the European Chemicals Agency (ECHA) to develop a common guidance document for the implementation of the hazard-based criteria to identify endocrine disruptors (ED) in the context of Regulations (EC) No 1107/2009 and (EU) No 528/2012. The guidance document is currently under development and its scope is limited to scientific hazard identification.

The proposed training course should help risk assessors to implement this guidance, particularly when assessing the data and information needed for ED hazard identification of plant protection products in the context of the EU legislation of pesticides taking toxicological and eco-toxicological information into account in an integrated manner.

The tenderer/trainers are required to provide training on this guidance document after its publication on the EFSA website.

The objective of this training course is:

- To enable the understanding and practical implementation of the guidance document on ED hazard identification of plant protection products in the context of the EU legislation on pesticides amongst members of EFSA's Scientific Committee/Panels, their working groups, as well as members of the EFSA scientific Networks and EFSA staff.
- To strengthen the dissemination of this guidance document amongst Panel and working group members, as well as members of the EFSA scientific Networks and EFSA staff dealing with pesticides, and promote and facilitate its uptake through the participation in this course.
- To make a link between the theory and practice by including case studies with examples of pesticides assessed by EFSA.

Technical Content

By the end of the course, participants should be able to understand and describe:

- The scope and applicability of this guidance document on ED hazard identification of plant protection products in the context of the EU legislation on pesticides.
- The general scheme of this guidance document and its interplay with already existing EFSA guidance document per sector.

- The scientific information required to perform ED hazard identification of plant protection products in the context of the EU legislation on pesticides.

4. Principles on genotoxicity on scientific assessment

Information on genotoxicity is a key component in risk assessment of chemicals in general, including those used in food and feed, consumer products, human and veterinary medicines, and industry. Genotoxicity testing of substances used or proposed for use in food and feed has been routine for many years. Genotoxicity information is also essential for risk assessment of natural and environmental contaminants in food and feed. While the strategies for different chemical sectors may differ in points of detail, the majority recommend use of a basic test battery, comprising two or more in vitro tests, or in vitro tests plus an in vivo test, to evaluate genotoxic potential. This is followed up when necessary, in cases where the results of basic testing indicate that a substance is genotoxic in vitro, by further studies to assess whether the genotoxic potential is expressed in vivo. Follow-up usually comprises one or more in vivo tests.

The EFSA SC prepared a scientific opinion (EFSA, 2011) to provide recommendations on genotoxicity testing strategies, which could contribute to greater harmonisation between EFSA Panels on approaches to such testing.

The tenderer/trainers are required to provide training on this scientific opinion taking into account the latest EFSA work on this area (Reflection on interpretation of some aspects related to genotoxicity assessment, document to be under public consultation by the 19th July 2017).

The objective of this training course is:

- To enable the understanding of the different regulatory requirements on genotoxicity.
- To build capacity on the understanding of the test batteries related to genotoxicity.
- To give an update on the available in vitro and in vivo tests and their level of reliability.

Technical Content

By the end of the course, participants should be able to understand and describe:

- The general principles of genotoxicity testing and the mechanisms of action (aneuploidy, clastogenicity, gene mutation, etc.)
- The basic battery test recommended by the EFSA SC.
- A step-wise approach for the generation and evaluation of data on genotoxic potential recommended by the EFSA SC.

5. Use of the benchmark dose approach in risk assessment. This will require a knowledge and understanding of the SC Guidance on the use of the BMD approach in Risk Assessment, and on how to use the EFSA Platform for BMD analysis

Toxicity studies are designed to identify potential critical endpoints that may be of relevance for human health. The No-Observed-Adverse-Effect-Level (NOAEL) approach aims at finding the highest experimental dose for which no adverse health effects can be (statistically) detected using the predefined (i.e. tested) doses. The BMD approach uses

the same experimental data used to derive the NOAEL but, instead of focussing on the predefined doses, it aims at finding a dose corresponding to a predefined response (the benchmark response – BMR; i.e. incidence or magnitude of an adverse health effect). Therefore it considers the dose-response information by fitting mathematical models to the data. The BMD will be the dose level, derived from the estimated dose-response curve, associated with a specific change in the response (the BMR). The confidence interval for the BMD accounts for the statistical uncertainty in the estimate of the BMD. The lower confidence limit is denoted as the BMDL and the upper confidence limit as the BMDU. Different models compatible with the data may result in different BMDLs, where the extent of such differences depends on the dose-response information in the particular dataset. For instance, designs with more dose groups tend to provide better dose-response information than designs with fewer doses; this will be reflected by smaller differences in BMDLs among different models. The BMD approach therefore does not aim to find the single statistically best estimate of the BMD but rather all plausible values that are compatible with the data. The lowest BMDL is often used as reference point (RP, also denoted point-of-departure (PoD)) to derive a health-based guidance value. The BMD approach not only provides a RP but it also evaluates the quality of the data. Discussion on the outcome and possible solution will be discussed, together with reflection and implication of selecting outcomes in the context of EFSA's work. EFSA developed a web-based platform for BMD analysis that will need to be presented in the training. The course will consider the guidance document updated by EFSA in 2017.

Technical Content

In May 2009, the EFSA Scientific Committee adopted its guidance on the use of the benchmark dose (BMD) approach in risk assessment (EFSA Scientific Committee, 2009). In this document, the Scientific Committee concluded that the BMD approach is a scientifically more advanced method to the No-Observed-Adverse-Effect-Level (NOAEL) approach for deriving a Reference Point. Recommendation was made that EFSA Scientific Panels and Units are adopting the BMD approach, since it is applicable to all chemicals in food, irrespective of their category or origin, e.g. pesticides, additives or contaminants. In its 2017 update of the guidance document, the EFSA's Scientific Committee confirmed the supremacy of the BMD approach for deriving the Reference Point and introduced model averaging as the best approach to perform BMD analysis For this purpose the Scientific Committee suggested that training is organised for members of EFSA's Scientific Committee/Panels, their working groups and EFSA staff to build further expertise and implement further this approach in EFSA's risk assessments.

By the end of the course, participants should be able to understand and describe:

- General principles of the BMD approach
- How to derive a BMD with quantal and continuous data from animal studies.
- Perform BMD analysis using both the single models and the model averaging approaches
- Overview of the EFSA platform for BMD analysis.
- Reporting BMD analysis.
- Use of the BMD analysis outcome to derive a health-based guidance value.

6. Computational toxicology tools

The EFSA Scientific Committee acknowledges the usefulness of computational tools and databases with toxicological information to support regulatory assessments and decision making in the field of food safety. Therefore, there is also a need for continuing training EFSA scientific staff and experts on these tools.

Computational tools and databases with toxicological information can be useful to support regulatory assessments and decision making in the field of food safety. In relation of this, there is a need for appropriate training of scientific staff and experts both in the use in the right context and critical evaluation of such tools and potentially also in the review of such information generated by these tools submitted as part of application dossiers. Training on computational tools would need to address how to prepare for, search and use such tools appropriately, correctly and reproducibly. The training will focus on the freely available tools and databases already used in-house, such as Toxtree, the OECD QSAR Toolbox and databases embedded in it, as well as an overview of the more commonly used (Q)SAR models and tools. The work already done by EFSA including outsourced projects (i.e. through a procurement paid by EFSA) should also be considered in the preparation of the training course. The training should address the usefulness of various types of computational estimation methods, with emphasis on Quantitative Structure-Activity Relationship (QSARs), Structure Activity Relationship (SARs) for prediction of toxicological endpoints and the Treshold of Toxicological Concern (TTC) approach for chemicals. The training should analyse the applicability of different models in regulatory toxicology for food and feed risk assessment with the inclusion of practical exercises on real case studies.

Technical Content

By the end of the course, participants should be able to understand and describe:

- Conceptual basis on construction of toxicity modelling tools
    - overview of principles and different types of (quantitative) statistical modelling techniques, read across ,trend analysis and various applications (e.g. OECD QSAR Toolbox, freely available tools developed by EC and US government);
    - consideration on validation;
    - chemical model applicability domains and reliability of the predictions (with examples);
    - overfitting and quality issues (with examples).

- General principles of the TTC approach and how to derive apply it to chemicals with defined structure and present at very low levels.

- How to prepare and clean data sets for screening in computational toxicology tools, how to use the tools appropriately. Case studies shall be drawn from publically available European and international resources.

- How to verify that dossiers containing information from using such tools, has been conducted appropriately. How to evaluate the relevance and the reliability of the predictions based on the documentation provided.

LOT 2: Training courses on Environmental Risk assessment

Trainings courses to be delivered under this lot should provide the participants with the necessary knowledge to implement and to apply, the different Guidance documents developed by the EFSA Scientific Committee/EFSA in the area of Environmental Risk assessment as well as to deepen knowledge on certain aspects of Environmental risk assessment that cut across the work of different Panels.

1. Environmental risk assessment under the various legislation within EFSA's remit and as a component of EFSA's risk assessments.

The course will explain the basics of how to conduct ERA with a particular focus on the deliberate release into the environment of GMOs, the use of additives in feed and the introduction and spread of invasive alien species that are harmful to plant health. This will entail looking at the different aspects of the environment and environmental compartments; practicing in problem formulation to propose options for the aspects of the environment that need to be protected from harm (specific protection goals), on the basis of the general environmental protection goals as set by EU legislation; selecting measurable endpoints for evaluation studies; and gathering relevant evidence.

It will include the application and use of statistics to the measurable endpoint results with appropriate interpretation of the biological relevance of statistically significant results.

The training programme shall also cover aspects on:

- environmental exposure assessment and life-stage analysis. Life stage analysis becomes most relevant when exposure patterns are known, and one can investigate whether exposure is likely to have a detrimental effect at a specifically sensitive life stage, with subsequent population level effects, using appropriate modelling tools,
- landscape-level environmental risk assessment and risk mapping,
- environmental scenarios and modelling approaches to address extrapolation in space and time,
- new developments/ trends in ERA,

Topics like e.g. combination toxicity and mixture toxicity could also be addressed

EFSA may request the development of a specialised ERA course to address the needs of the Plant Health Panel with respect to ERA of invasive alien species.

The EFSA guidance documents developed on ERA (link) will be considered as the basis for this training. The robustness of the scientific information used in risk assessment models is of paramount importance to ensure the reliability of the final risk estimate.

Technical content

By the end of the course, participants should be able to understand and describe:

Problem formulation: Starting with the identification of hazards of the subject matter and its use, problem formulation helps to describe in a transparent way the causes of potential adverse effects to the environment, the nature of these effects, and pathways of exposure through which the subject matter may adversely affect the environment. A

crucial step in problem formulation is to identify the aspects of the environment that need to be protected from harm, where applicable according to environmental protection goals set out by EU legislation. This includes the specification of ,the magnitude, temporal scale and spatial scale of the biologically relevant effect of invasive alien species harmful to plant health and of tolerable effects of the use of feed additives and the introduction of GMOs in the environment.
Statistical significance versus biological relevance: When applying statistics to environmental measurable endpoint results, the follow-up step is to interpret the biological relevance of statistically significant results. The recommendations from the EFSA Scientific Committee from 2011 shall be applied also in ecology. For example, the nature and size of biological changes or differences seen in studies should be defined before the study is initiated. Emphasis shall be given to statistical points estimation and associations intervals (e.g. confidence intervals).

Selection of non-target organism (NTO): Current risk assessment approaches are based on selection of functional groups and individual species within a tiered approach. This approach requires initiating the scientific risk assessment by setting testable hypotheses; criteria for appropriate selection of test species and ecological functional groups; appropriate laboratory and field studies to collect relevant NTO data; and the use of statistical techniques that shall be an integral part of experimental design. In a first tier a standard set of test species might be used, while at higher tiers, the intention would be to identify vulnerable representative species. Traits (such as a long-life cycle, time to recover, sensitivity, level of exposure due to high feeding rate or habitat exclusively in agricultural fields) and trait based grouping of NTOs in the RA will be discussed. This topic also extends into establishing and evaluating the relationship between a (pest) biomass and its impact on ecosystem functional traits and also at ecosystem service provision levels in traits-service clusters.

Environmental exposure assessment: For each of the environmental compartments, scenario models can be selected to generate data and to link environmental exposure assessment to environmental effects. What are the current methodologies and how they could help reducing uncertainties?

Life-stage analysis: The developmental stages of wildlife are linked with their temporal and spatial distribution. Life stage analysis becomes most relevant when exposure patterns are known, and one can investigate whether exposure is likely at a specifically sensitive life stage. For animals with well-defined life stages, life stage analysis may inform about the number of individuals that enter the stage, the mean time spent in a life stage, the probability of surviving for each life stage, the mean time to enter each life stage, or the unit time survival rate. Population survival and mortality can be tabled, either age specific or time specific, in life tables. For a reproducing population in one t-period of time, matrix population models can be used for estimating the numbers in each life stage during a next period of time

LOT 3: Training courses on Risk assessment Methodologies

Trainings courses to be delivered under this lot should provide the participants with the necessary knowledge to implement and to apply, the different Risk Assessment Methodologies developed by the EFSA Scientific Committee as well as to deepen knowledge on certain aspects of risk assessment that cut across the work of different Panels.

By the end of the different training courses, participants should be able to understand, describe and apply general principles on at least the topic below:

1. **How to identify and characterise uncertainties in in EFSA's scientific assessments.**

As part of EFSA's commitment to transparency and to provide EU risk managers with objective and reliable scientific advice identifying and characterising uncertainties, and explaining their implications for assessment conclusions, is an important element of EFSA's risk assessment process.

EFSA initiated a WG on Uncertainty in Scientific Assessment in fall 2013 to provide guidance to its Panels on how to characterise, document and communicate uncertainties in the risk assessment process. A comprehensive draft guidance document was published for public consultation during summer 2015. After public consultation EFSA published a revised draft guidance document in March 2016 (link). A technical report on the public consultation details how the feedback was systematically evaluated and used to strengthen the revised draft was also published (link). The draft guidance document has been tested by 10 EFSA Panels on 12 specific case studies from May 2016 to May 2017. After finalisation of the trial phase, each WG having trialled the guidance document has participated to a survey on impact analysis. This survey evaluated (1) applicability of guidance document to EFSA's risk assessment and (2) impact on resources. This feedback has provided the basis to plan an EFSA internal workshop 22-23 June to discuss the feedback on the trial phase. The workshop report is planned to be published by end of October 2017. The outcome of the trial phase will help to shape the final guidance document planned to be presented at the November Scientific Committee plenary in November 2017 for adoption.

The final guidance document is planned to be published in early 2018.

The ongoing and planned EFSA work would need to be considered by the trainers when developing the programme for this course.

The objective of the training courses is:

- To enable the understanding and practical implementation of the guidance document on uncertainty analysis in scientific assessments amongst members of EFSA's Scientific Committee/Panels, their working groups, members of the EFSA Networks, EFSA staff and risk managers.
- To strengthen the dissemination of the guidance document on uncertainty analysis in scientific assessments amongst members of EFSA's Scientific Committee/Panels, their working groups, members of the EFSA Networks, EFSA staff and risk managers and promote and facilitate its uptake through the participation in tailored courses
- To make a link between the theory and practice by including case studies other than those to be published already in the revised guidance document demonstrating how the uncertainty analysis can be applied across the various EFSA scientific areas and across various conditions (e.g. emergency versus non-emergency assessments)

Technical Content

By the end of the course, participants should be able to understand and describe:

- Why uncertainty analysis is helpful in scientific assessments
- The general principles of uncertainty analysis
- Terminology used in uncertainty analysis
- Main steps in uncertainty analysis and, in particular:
    - Planning the assessment strategy
    - Identification of sources of uncertainty
    - Evaluation of individual sources of uncertainty, both in qualitative and quantitative ways
    - Evaluation of combined uncertainty, both in qualitative and quantitative ways
    - Describe the unquantified uncertainties

- Various application domains within EFSA's remit across the regulatory and non-regulatory assessments.

2. The weight of evidence on scientific assessments and to be able to consider and document the approach used to weight the evidence

The weight of evidence (WoE) has been defined by the WHO as "a process in which all of the evidence considered relevant for a risk assessment is evaluated and weighted" (WHO/IPCS, 2009). The Scientific Committee (SC) of EFSA used the WHO definition and pointed out that evidence can be derived from several sources such as white literature (peer reviewed scientific publications), grey literature (reports on websites of governmental, non-governmental, intra-governmental agencies etc.) and black literature (confidential reports). In order to increase transparency in the risk and other scientific assessment processes, it is important to provide a methodology to select, weigh and integrate the evidence in a systematic, consistent and transparent way to reach the final conclusions and to identify related uncertainties (SCENIHR, 2012; EFSA, 2013). In addition, the SC of EFSA noted that part of the overall weighing of the evidence deals with the evaluation of equivalent or similar questions performed by other international bodies and the adequacy of such evaluations should be judged by EFSA before taking them into account. This is particularly helpful in cases for which the information available is so extensive that it is beyond the capability of a single evaluation to judge each individual study, report, publication by itself. In addition, systematic reviews (SRs) may be very useful, however, the adequacy of the process, the pertinence to the risk assessment, the nature of the question and the inclusion and exclusion criteria should be transparently evaluated by EFSA before taking SRs into account (EFSA, 2013). Considering the example of chemical risk assessment, the WoE approach requires expert judgment of distinct lines of evidence (in vivo, in vitro, in silico, population studies, modelled and measured exposure data etc.) which may come from studies conducted according to official guidelines (e.g. OECD) or from non-standardised methodologies. In this context, data from all sources and categories of literature should be considered for the risk assessment processes, as appropriate to determine their quality and relevance. These considerations should then be reflected in the relative weight given to the evidence in the scientific assessment and transparently taken into account in the overall evaluation of uncertainty (EFSA, 2013).

It is therefore proposed that the SC of EFSA develop guidance on the use of the WoE approach in scientific assessments.

The tenderer/trainers are required to provide training on this guidance document after its publication on the EFSA website.

The objective of this training course is:

- To enable the understanding and practical implementation of a methodological approach to combine scientific evidence in a consistent, harmonised and transparent way by means of the SC guidance document on the use of the weight of evidence approach in scientific assessments amongst members of EFSA's Scientific Committee/Panels, their working groups, as well as members of the EFSA scientific Networks and EFSA staff.

- To strengthen the dissemination of guidance on the use of the WoE approach in scientific assessments amongst members of EFSA's Scientific Committee/Panels, their working groups, as well as members of the EFSA scientific Networks and EFSA staff and promote and facilitate its uptake through the participation in this course.

- To make a link between the theory and practice by including case studies with examples of the use of the WoE approach in scientific assessments from the work of EFSA.

- To enable the improvement of the overall quality of available information and data used for EFSA's outputs.

Technical Content

By the end of the course, participants should be able to understand and describe:

- The proposed general framework and principles for WoE assessment as described in the guidance document.
- The current qualitative and quantitative methods for WoE assessment and the criteria used for choosing the most appropriated.
- The basic steps for conducting a WoE assessment.
- The proposed way to report a WoE assessment.

3. How to consider biological relevance in relation to evidence used in scientific assessments.

EFSA's Science Strategy 2012-2016 identified four strategic objectives: 1. further develop excellence of EFSA's scientific advice, 2. optimise the use of risk assessment capacity in the EU, 3. develop and harmonise methodologies and approaches to assess risks associated with the food chain, 4. strengthen the scientific evidence for risk assessment and risk monitoring. In this context, the harmonisation and development of new methodologies for risk assessment and scientific assessments is of critical importance to deliver EFSA's science strategy. For this purpose, EFSA addressed individual and cross-cutting methodological issues for the whole scientific assessment landscape. All these activities aim to contribute to producing more robust, transparent and open scientific assessments in line with the recent discussion paper on Transformation to an "Open EFSA" as a means of consulting on how it will achieve two strategic goals within the next five years. These are (i) to improve the overall quality of available information and data used for its outputs and (ii) to comply with normative and societal expectations of openness (EFSA, 2014).
In July 2013, the Scientific Committee (SC) of EFSA published an opinion on "priority topics for the development of risk assessment guidance by EFSA's SC" which used a number of criteria to make recommendations for the preparation of new or the revision of existing guidance documents as follows:

- Across panel relevance
- Critical importance including urgency of topic to be addressed for several Panels

- Topic not being addressed by an individual Panel
- Sufficient information available to develop meaningful guidance
- International dimension

From this prioritisation exercise, the SC opinion identified three priority topics for 2014: uncertainty analysis, biological relevance, and finally the use of the weight of evidence (WoE) in scientific assessments as the subject of this project (EFSA, 2013).

In the EFSA opinion on the hazard assessment of endocrine disruptors (EFSA Scientific Committee, 2013), the concept of biological relevance assumes that a "normal" biological state can be defined and the definition of normality is closely linked to adversity of an effect observed during toxicity testing or in epidemiological studies. Distinguishing adverse effects from physiological adaptive effects is not only crucial in identifying a No Observed Adverse Effect Level (NOAEL) from experimental toxicity studies but also when using the benchmark dose (BMD) approach as recommended by the SC (EFSA Scientific Committee, 2017).
In its opinion on biological relevance versus statistical significance, the EFSA Scientific Committee gave a wider definition of biological relevance than just a modification of a physiological system, making it more applicable to the various EFSA working areas. In this opinion, biological relevance is defined as an effect considered by expert judgement as important and meaningful enough for human, animal, plant or environmental health. It implies a change that may alter how decisions for a specific problem are taken (EFSA Scientific Committee, 2011).
The above definition implies that guidance is provided to the various EFSA panels on what "harm" means, and to define a number of related concepts such as "effect size". When a particular risk assessment considers several effects, the overall picture, using a multivariate approach, should be considered to decide whether the available body of knowledge allows to conclude on an effect to be adverse or not. Given the broad remit of activity of EFSA, the purpose of this self-task mandate is to provide the Scientific Panels with a list of generic issues to consider when discussing on biological relevance, i.e. being adverse (or showing a positive health effect) or not.

The tenderer/trainers are required to provide training on this guidance document after its publication on the EFSA website.

The objective of this training course is:

- To enable the understanding and practical implementation of a framework to assess biological relevance by means of the SC guidance document on biological relevance in scientific assessments.

- To strengthen the dissemination of guidance on the biological relevance amongst members of EFSA's Scientific Committee/Panels, their working groups and EFSA staff, and promotes and facilitates its uptake through the participation in this course.

- To make a link between the theory and practice by including case studies with examples of the use of proposed framework in scientific assessments from the work of EFSA.

- To enable the improvement of the overall quality of available information and data used for EFSA's outputs.

Technical Content

By the end of the course, participants should be able to understand and describe:

- The proposed general framework and principles for assessing biological relevance as described in the guidance document.

- Concepts about:

o Responses of a biological system to exposure
o Mode of Action and Adverse Outcome Pathway
o Thresholds
o Critical effect
o Modelling approaches
o Biomarkers

- How to establish an assessment strategy by specifying the agents, the subjects, the effects and the conditions.

- How to identify potentially biologically relevant evidence/data as specified in the Assessment strategy.

- How to integrate and appraise the relevance of the agents, the subjects, the effects and the conditions.

1.3 TASKS, DELIVERABLES, TIMELINE AND PAYMENTS

General Requirements

These specialised training courses are intended to deepen knowledge on certain aspects of risk assessment that cut across the work of different Panels. As with the ongoing EFSA training courses, the intention is to avoid duplication of specialised courses already available elsewhere, and to offer a structured way to go through critical aspects of risk assessment. The courses will be hands-on, using case-studies from EFSA scientific opinions and other scientific outputs.

There will be approximately 5-6 courses per year between 2018 and 2021 and therefore a total of at least 24 courses for the entire duration of the Framework contract.

The training courses will be designed by the contractor in order to fully meet the objectives indicated in these Technical Specifications. The training courses shall include a balanced mix of theoretical and practical activities, with emphasis on the use of EFSA based case-studies and guidance documents (if available). Discussions shall be organised to allow the exchange of views and the collection of feedback from participants.

The implementation of each specific contract will be based on EFSA needs as well as on the state of development of the Guidance documents and Methodologies.

Table 1. Training courses summary

Training courses		Number of courses per year (2018-2021)
Lot 1	1. Harmonization of risk assessment methodologies for human health and ecological risk assessment of combined exposure to multiple chemicals	
	2. Risk assessment of the application of nanoscience and nanotechnologies in	

	agro/food/feed	Approximately 5-6 training courses **per year** among the 3 Lots
	3. Science-based criteria for identifying endocrine disruptors in the context of EU legislation on pesticides and biocides	
	4. Principles on genotoxicity on scientific assessment	
	5. The use of the benchmark dose approach in risk assessment	
	6. Computational toxicology tools	
Lot 2	1. Environmental Risk Assessment	
Lot 3	1. How to identify and characterise uncertainties in EFSA's scientific assessments	
	2. Principles on weight of evidence on scientific assessments	
	3. Principles on biological relevance on scientific assessments	

In addition to the subjects listed on the table 1, EFSA may request additional training courses under each lot on other aspects of scientific assessments, methodologies and related tools falling under the remit of Guidance Documents developed by the EFSA Scientific Committee/EFSA.

During the specific contract implementation, EFSA reserves the right to propose to the contractor the introduction of adaptations to the course content, the pool of tutors or the setting of the training courses (if needed). The purpose of these adaptations is not to modify the contractor's offer. The all-inclusive price offer should include the cost of possible adaptations.

EFSA reserve the right to request to the contractor different modalities of training courses. These modalities may include: Webinars, e-learning modules, EFSA Scientific Panel specific training sessions (e.g. two hours module) or Info sessions (e.g. 2 hours recorded /life info session). The requirements for these additional trainings modalities will be detailed in the relevant specific contracts/order forms, based on the below training courses conduct.

Training courses conduct:

Agreement on dates, facilities and participants quotas of training courses at EFSA's premises.

The successful contractor has to:

- Agree with EFSA on the dates, available facilities and quotas of participation for the training courses.
- Support EFSA in advertising the course by preparing abstracts, time lines and list of trainers.

Venue of the training courses

Training courses will take place at EFSA premises (Parma, Italy). In order to meet the highest standards for training courses, the contractor shall list in the offer all venue-related needs to be provided by EFSA (in particular, the type of meeting rooms, provision of a copy machine, laptop, beamer, flip charts, WI-FI internet connection,

telephone, fax and audio equipment). EFSA will, as far as possible, accommodate such needs, and, in particular, agree with the contractor on the availability of meeting rooms according to the planned calendar for the training courses. The provision of catering services and the organisation of special events is excluded.

Accommodation and travel

EFSA takes care of the logistical arrangements for the travelling (including flights and shuttle to/from Parma) and accommodation of external participants.

The contractor shall be responsible for the logistical arrangements for its own staff and those of tutors.

Recruitment and management of participants.

The successful contractor has to:

- Process all contacts with the participants once they register to the course or were nominated by EFSA, including the distribution of information, questionnaire on pre-requisite knowledge, individualized training material, exercises, etc.
- Support EFSA in taking appropriate measures that all places are filled as much as possible.
- Provide EFSA with the list of participants at least two weeks before each training session to identify places left unfilled.

Identification and registration of participants

The participants of the training courses are members of EFSA's Scientific Committee/Panels and their working groups, preferably the newly designated ones. Members of the EFSA Networks as well as EFSA scientific staff may also participate in the training courses. Each training session shall be suitable for up to 15 Scientific Committee/Panel/Network or working group members and up to 10 EFSA scientific staff.

The contractor has the overall responsibility to identify the participants for the training courses so to meet the requested participation quotas. As for the participation of EFSA staff, the list with expression of interest to attend the trainings will be provided by EFSA. To this purpose the contractor takes appropriate measures that all places are filled.

The contractor is requested to set a deadline for submission of applications for participation in each training course. Where there are places left unfilled, these may be offered to other candidates. Should the contractor be unable to ensure the required number of participants due to factors not attributable to its own performance, it shall inform EFSA immediately. In such scenario, EFSA will agree with the contractor a revised list of participants so to fill the maximum number of seats for each training course. The final list of participants to each training session shall be provided to EFSA at least two weeks before each training session. The knowledge of participants on the subject of the training course may vary from beginner to advanced/knowledgeable. In general, it is preferable that course participants have at least a basic knowledge of the subject presented in the trainings.

The contractor is requested to provide (in electronic format) to each participant a training package to be used as supporting material for the courses (including presentations from tutors, a syllabus (i.e. an outline and summary of topics to be

covered in training course) with not more than 25 pages, a description of the training content, additional references for further study, and any other documentation considered relevant.

Conduct the training course.

The successful contractor has to:

- Conduct the training according to the agreed curriculum.

The successful contractor has to prepare a complete curriculum for the trainings, including the content, learning tasks, didactical methods, timeline, as well as examples, exercises, case studies etc. covering the range of applications in EFSA. This also includes the ways to evaluate the learning success, enhance motivation by individualizing the training, and giving feedback. The successful contractor has to prepare presentations, examples, exercises, case studies, handouts, further readings, supporting material etc. in the final format of the training session.

Provide the material (in electronic format) to EFSA at least 4 weeks before the date of the corresponding training session to be validated by EFSA.

- Provide electronically to each participant a training package to be used as supporting material for the courses (including presentations from tutors, a syllabus, i.e. an outline and summary of topics to be covered in training courses), a description of the training content, additional references for further study, and any other documentation considered relevant.
- Provide certificates of attendance to each participant.
- Collect registration lists and feedback from trainers, participants (preferable by a questionnaire), EFSA and perform an evaluation on each training.
- Discuss the training session with EFSA in a meeting directly after the training session, to identify possible improvements and an action plan for revision.

Tasks of the contractor during training courses

- To ensure registration and provide information and assistance to participants and tutors.
- To provide all administrative work related to the training courses.
- To provide information packs to all participants containing all training material (e.g. manuals, documentation needed for the training, etc.).The information packs should be available in English and take the form of a comprehensive stand-alone set of documents covering all the issues dealt with during previous training courses (if applicable).
- To deliver a course attendance certificate to all those participants (at the end of the course) who have successfully completed the training. The format of the certificate shall be agreed with EFSA beforehand.
- To assess the level of satisfaction of participants with the training and services received. In particular, each participant shall be requested to provide individual feedback concerning the quality and utility of the training course. The contractor shall analyse the results and report any recommendations for improvement at the evaluation teleconferences/meetings. A summary of these assessments/recommendations shall be included in the Final Report.

Revision of the training curriculum and summary report.

For each course delivered, the successful contractor has to evaluate the training and improve the curriculum and training material for future courses based on the participants' feedback concerning the quality and utility of the training course.

On the basis of the above, the contractor has to provide a short report summarising the outcomes of this analysis.
Final report for each lot under the FWC At the end of the FWC implementation, the successful contractor has to: • Prepare the final report including a summary of the project, a technical description of the training(s), the final curriculum (a), training material(s) and overall evaluation and recommendations. This report will be published on EFSA's website.

Language of the training courses

The training courses shall be held in English. The deliverables shall be delivered to EFSA both in MS Word (.doc) and Adobe Acrobat Reader (pdf) format.

No	Deliverables – applicable to each lot	Can be subcontracted?	Deadline for finalisation
1	**Provide a training course** as indicated in the tender specifications under section 1.3.	Yes	To be defined in the specific contract/ Order Form
2	**Provide a summary report** as indicated in the tender specifications under section 1.3	Yes	To be defined in the specific contract/ Order Form
3	**Provide Webinars, e-learning modules, EFSA Scientific Panel specific training sessions** (e.g. two hours module) **or Info sessions** (e.g. 2 hours recorded /life info session).	Yes	To be defined in the specific contract/ Order Form
4	**Provide a final report for each lot under the FWC** as indicated in the tender specifications under section 1.3.	Yes	To be defined in the specific contract/ Order Form
No	**Meetings – applicable to each lot**		**Deadline for finalisation**
1	**Kick off meeting** One day physical meeting in Parma between EFSA and the successful contractor of each lot. The meeting should be attended at least by the project coordinator of each lot. At the kick-off meeting the following objectives will be discussed and fine-tuned: • **Draft training programme** • **Estimated calendar of the courses** • **Criteria and procedures to select**		Within one month from Framework Contract signature

	participants for the different courses. • **Evaluation methodology** for each course, as well as of the respective assessment questionnaires; • **Tutors of the training courses**	
2	Ad hoc teleconferences during the contract implementation between EFSA and the contractor.	To be defined in each specific contract/order form
No	**Payments**	**Linked to approval by EFSA of deliverable No**
NA	The payment modalities applicable to each order form or specific contract are detailed in the draft framework contract.	Will be defined further in the context of each specific contract/order form

1.4 INFORMATION ON THE CONTRACT

Type of contract: framework contract (FWC)

Type of FWC: single FWC

Nature of expense: services

Duration of FWC: one year + automatic renewal up to 3 times for an overall maximum duration of four consecutive years.

Budget information:
The financial ceilings available for lots for specific contracts/order forms under the framework contract are set as follows (a contingency of 10% and possible price indexations are already included in this ceiling):

- Lot 1: €200.000 (for a maximum duration of 4 consecutive years)
- Lot 2: €50.000 (for a maximum duration of 4 consecutive years)
- Lot 3: €150.000 (for a maximum duration of 4 consecutive years)

Price indexations:

Indexation will be applicable to consultancy services daily rates: the daily rates proposed in the offer of the winning tenderer will be allowed for indexation as of the second contract year following the rules stipulated in the draft FWC.

Possible increase of FWC envelope:

By virtue of article 134 (1)(e) and article 134 (4) 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. The increase will not go beyond 50% of the original envelope of each lot.

As regards the mechanism of implementation of the FWC please refer to the **EFSA Guidance for tenderers** available at EFSA website.

1.5 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

PARTS OF RESULTS PRE-EXISTING THE CONTRACT

If the results are not fully created for the purpose of the contract this should be clearly pointed out in the tender. Information should be provided about the scope of pre-existing materials, their source and when and how the rights to these materials have been or will be acquired.

EFSA does not acquire ownership or any license of pre-existing rights not incorporated in the deliverables. The full ownership is limited to the deliverables, which might include licensed pre-existing rights on excerpts, parts, texts etc., if fully or partially incorporated in the final deliverables.

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

PART 2 EVALUATION - HOW WILL YOUR OFFER BE ASSESSED?

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

2.1 OPENING OF OFFERS

The main aim of the public opening session is to check whether the offer received was dispatched within the closing date for tender receipt[5] and that the tenders are electronically protected until the official opening.

2.2 ORDER OF EVALUATION

Tenderers should note that the content of their offers will be assessed in the following pre-defined order: Exclusion criteria (Access to EU Market); Selection criteria (Technical & Professional capacity); Compliance with tender specifications; Award Criteria (Quality and Price).

Following the above assessment and identification of the winning tender, the following will be assessed only for the tenderer proposed for contract award: Selection criteria (Professional Conflict of Interest – Institutional and Individual Declarations of Interest); Exclusion criteria (Declaration on Honour on exclusion criteria); Selection criteria (Declaration on Honour on selection criteria).

2.3 GROUNDS FOR EXCLUSION

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

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

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

Evidence requested in the offer for each Lot:

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

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

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

2.4 SELECTION CRITERIA

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

A) ECONOMIC AND FINANCIAL CAPACITY:

The tenderer must have the following economic and financial capacity to perform the contract, in particular the tenderer must have generated an overall annual turnover of:

- LOT1 at least 100.000 € in each of the last 2 closed financial years (2015,2016)
- LOT2 at least 25.000 € in each of the last 2 closed financial years (2015,2016)
- LOT3 at least 75.000 € in each of the last 2 closed financial years (2015,2016)

Evidence requested in the offer:

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

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

B) TECHNICAL AND PROFESSIONAL CAPACITY:

The tenderer must have the technical and professional capacity to perform the contract in accordance with the specifications below. In accordance with article 148(6) RAP, if EFSA, based on the assessment of the technical and professional capacity evidence, concludes that the tenderer has a professional conflicting interest and therefore does not possess the professional capacity to perform the contract to an appropriate quality standard, the tenderer may be rejected.

The tenderer must have the following **minimum professional capacity** to perform the contract for **each lot.**

a) The tenderer must have extensive and demonstrable experience in organising and providing scientific training courses in the area of food and feed safety, including risk assessment.

b) Ability to provide a team of experts compliant with these minimum expertise requirements:

Tutors:

The contractor is required to provide for each course qualified and experienced tutor(s) (a minimum of 1 tutor/training course), with an academic background (university degree or PhD) in life sciences and with at least 5 years of experience in the field of the given training course and experience in teaching in English and developing specific examples (case studies) on the subject matter of the different courses. Experience with the scientific areas within EFSA's remit is an added value. To this purpose, the *Curriculum vitae* of potential tutor(s) for each different training course should be provided with the

offer (see section 2.4.B of these Tender Specifications). The pool of tutors may include current and former EFSA Scientific Committee/Panel/Working Group members. Depending on the technical content for each training course, EFSA may indicate a staff member as Assistant Coordinator, who will liaise with the tutors before, during or after the training sessions for the optimal delivery of the programme. The latter, will not imply any additional cost for the contractor.

In addition, the pool of tutors shall overall have knowledge and experience:

Lot 1:

- on using relevant tools and models (e.g. exposure models, toxicological databases, TTC, PB-PK models, QSAR, OMICS etc.) in the context of human and ecological risk assessment of chemical mixtures
- on the new *in vivo* and *in vitro* developments on the genotoxicy testing

Lot 2:

- on the models used in quantitative environmental risk assessment in the plant health, GMO and feed additives domains as well as on ecosystem services and how to use them to support decision making.

Lot 3:

- on the various methodologies (shown in the annexes of the uncertainty guidance document) to assess individual and combined uncertainty;
- on freely available software for benchmark dose analysis, e.g. BMDS (www.epa.gov/ncea), and/or PROAST (www.rivm.nl/proast), as well as on the EFSA BMD platform (https://doi.org/10.5281/zenodo.801416)
- as well as knowledge and experience with the following freely available tools and databases: Toxtree (developed under the auspices of the EC JRC), the OECD QSAR Toolbox, and an overview of the more commonly used (Q)SAR models and tools.

Training Coordinator

The contractor is required to appoint a Training Coordinator (Project Leader) for each lot with an academic background (university degree) and with at least 5 years of professional experience and proven record in organising training courses. The Training Coordinator shall be responsible for the overall contact, management and coordination of the implementation of all services requested by EFSA in each specific contract and shall be a staff member of the tenderer or the consortium leader. The Training Coordinator will be the interface for all commercial and contractual matters and the overall contact point for the services requested by EFSA. The Training Coordinator can also be involved in the implementation of the courses as a tutor. In this case the Training Coordinator needs to comply with the minimum expertise requirements set for tutors.

c) The tutors and the Training Coordinators shall be able to organise the tasks requested and to write reports in English. For non-English mother tongues, the knowledge of English shall be proven by: (i) extensive experience (of at least 3 years) in international projects where English is the working language; or (ii) at least 1 year of work/study in

an English speaking environment; or (iii) certificate of English proving at least a C1 level (Effective Operational Proficiency).

Evidence requested:

For requirement **a)**: A list of previous scientific training courses (at least two courses) delivered in the course of the past 5 years, within the remit of EFSA. This list should include: (i) the title of the training course; (ii) the subject of the training course in the form of a brief description of the course content; (iii) the duration and date(s) of the training course; and (iv) the name of the entity (private or public) requesting the training course (provided its disclosure is not bound by any confidentiality agreement).

For requirements **b)** and **c):** Detailed CVs of all team members proposed for the assignment, taking into account the minimum expertise requirements detailed above; EFSA strongly recommends submitting the CVs in the EU CV format which can be accessed here.

Institutional declaration of interests available here *In case of a group of economic operators and/or in case of subcontracting, such declaration should be completed separately and submitted for each partner and for each identified subcontractor.*
Individual declarations of interests available here *A separate form to be completed by each member of the proposed team.*

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.

GENERIC EVIDENCE COMMON FOR ALL SELECTION CRITERIA(applicable for all lot):

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

Please note that you do not have to submit any of the above-mentioned evidence if already submitted to EFSA in response to any previous EFSA call, provided the evidence is exactly the same as requested in these tender specifications. If you avail yourself of this possibility, you have to specify the reference of the EFSA call for tenders under which you have already submitted the evidence to EFSA.

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

2.5 COMPLIANCE WITH TENDER SPECIFICATION AND MINIMUM REQUIREMENTS (applicable for all lots)

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

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

- do not comply with minimum requirements laid down in the tender specifications (non-compliance);
- propose a solution different from the one that is imposed;
- propose a price above the fixed maximum set in the specifications;
- are submitted as variants, when the specifications do not authorise them;
- do not comply with applicable obligations under environmental, social and labour law established by Union law, national law and collective agreements or by the international environmental, social and labour law provisions listed in Annex X to Directive 2014/24/EU[6].

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

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

2.6 AWARD CRITERIA (applicable for all LOTS)

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

A) QUALITY AWARD CRITERIA

1. **METHODOLOGY PROPOSED FOR THE DEVELOPMENT, DESIGN OF A CURRICULUM AND FOR THE CONDUCTION OF THE TRAININGS (max. 70 points)**

   This is to assess the degree to which the methodology proposed is in conformity with the technical specifications.

   - Proposed methodology in **outlining a curriculum of a training session on one of the topics under the scope of a specific Lot of this call for tender** (i.e. course outline, content, learning tasks, exercises, timetable, allocation of the trainers. Including, clearness and structure of the reasoning given in the offer for the proposed draft curriculum. (**30 points maximum**)
   - Proposed methodology of **teaching methods**, esp. didactical methods, involvement of the learners, practical relevance, training materials for the course, justifications and measures to enhance motivation and ensuring learning success (**20 points maximum**)
   - Proposed methodology for tailored-made **examples, exercises and case studies** on one of the topics under the scope of a specific Lot of this call for tender (**20 points maximum**)

2. **PROJECT ORGANISATION (max 15 points)**
   This is to assess the extent to which the team set-up is suitable for the implementation of the assignment, and to assess the mechanisms put in place in order to guarantee availability of contractor for this assignment and to meet the agreed deadlines for deliverables. Attention has to be drawn to:

   I. **Project management methodology** to be used, including the draft project plan with responsibilities of the team members, esp. contact persons for EFSA (**10 points maximum**)
   II. **Project management measures** to be used to **ensure project deadlines** are met. (**5 points maximum**)

3. **MEASURES TO GUARANTEE QUALITY OF DELIVERABLES (max 15 points)**
   This is to assess the quality assurance mechanisms put in place to guarantee the high quality of deliverables:
   I. Description of the proposed specific **quality assurance system** put in place to ensure high-quality delivery of the requested training courses, training materials and reports (**5 points maximum**)
   II. In addition, the identification of **risks and mitigation measures** proposed to overcome/remedy them throughout the implementation of the services requested, esp. availability of trainers, including back-up persons (**10 points maximum**)

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

Tenderer has to 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 these minimum quality thresholds will be eliminated from the subsequent stages of the evaluation process.

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

B) PRICE AWARD CRITERION:

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

I. the price offer is made within the maximum budget for each lot for financial offers indicated in the tender specifications and;
II. the financial offer satisfies the formal requirements of the tender specifications.

C) THE BEST PRICE-QUALITY RATIO:

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

FWC:

TOTAL SCORE OF THE EVALUATED OFFER (C) =

40 * Cheapest price offer/price of tender X

+

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

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

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

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

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

How to Submit your Tender in e-Submission

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

In order to have access to e-Submission, you will need to "Subscribe to call for tenders" on TED e-Tendering first. To subscribe, you will need to login with your an EU Login[7]. In case you don't have an EU Login, you can create an account at any moment. For more information see the EU login help. After logging in with your EU Login password, the e-Tendering will then display a button 'submit your tender' and you will be able to access the e-Submission.

Information to be filled in

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

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

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

For detailed instructions on how to submit your tender, consult the Quick Reference Guide for Economic Operators available in the e-Submission help page, under the section "Quick Guide", where you will find:

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

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

Documents to be signed and dated while creating your Tender

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

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

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

Re-submission or alternative tender

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

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

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

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

Withdrawal of tenders

If after submitting a tender, you wish to completely withdraw your tender, you must formally notify that you wish to withdraw your submitted Tender(s).This notification must be signed by the same authorised legal representative(s) who previously signed the tender(s) in question.

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

Deadline for receipt of tenders

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

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

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

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

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

CONTACT

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

  When communicating state the reference to the call for tenders and, if applicable, the Tender ID.
- For technical support on e-Submission, please contact support as described in the help page:

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

ANNEX 1 - FINANCIAL OFFER TEMPLATE

FINANCIAL OFFER for LOT 1

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

- As referred to in part 1.4, the maximum budget EFSA has available for this assignment is **200,000 € for LOT1**. Any offer exceeding this maximum will not be retained for contract award.
- Prices must be quoted in Euro using the conversion rates published in the C series of the Official Journal of the European Union on the day when the invitation to tender was issued. This information is also available on the website of the European Central Bank at the following URL: http://www.ecb.int/stats/eurofxref/.
- Pursuant to the provisions of Article 9 of the Italian Law n. 17 dated 10/01/2006 and under Article 151 of Council Directive 2006/112/EC, EFSA is exempt from all duties, taxes and other charges, including VAT. For this reason, all prices given in the financial breakdown should be free of VAT and other taxes or duties.
- The price offered below is understood to be all inclusive. For example any additional costs which can be incurred by the contractor in performing the contract, such as overheads, travelling and subsistence/accommodation expenses, etc. should also be factored in to the all-inclusive price. In addition, if the deliverables incorporate pre-existing rights, the tenderer should factor into their total price the cost of licensing those pre-existing rights to EFSA.

FINANCIAL OFFER			
Type of service	**Estimated volume for 4 years**	**Unit prices to be used in EFSA specific contracts/ order forms (prices in Euros without VAT)**	**Total costs**
A) Fee for one day training course, including the travel expenses, subsistence and accommodation of 2 trainers and 1 coordinator. Cost should be all inclusive covering all the tasks indicated in tender specifications.	13	A (1).....€	A(2)=A(1)*13 .....€
B) Fee for additional day of training course as indicated in point A (without travel expenses)	13	B (1).....€	B(2)=B(1)*13 .....€
B) Hourly rate for a tutor for Webinars, e-learning modules, EFSA Scientific Panel specific training sessions (e.g. two hours module) or Info sessions (e.g. 2 hours recorded /life info session).	26	C (1).....€	C(2)=C(1)*26 .....€
C) Final report for each lot under the FWC	1	D (1).....€	D(2)=D(1)*1 .....€

E) TOTAL price offer to be taken into account for contract evaluation	The total price is calculated as follows	E= A(2)+ B(2)+ C(2)+ D(2)= .....€

Tenderer name: .....

Date: ……..

Name of person signing the financial offer: …….

His/her position in the company: ……

His/her signature: ……

ANNEX 1 - FINANCIAL OFFER TEMPLATE

FINANCIAL OFFER for LOT 2

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

- As referred to in part 1.4, the maximum budget EFSA has available for this assignment is **50,000 € for LOT2**. Any offer exceeding this maximum will not be retained for contract award.
- Prices must be quoted in Euro using the conversion rates published in the C series of the Official Journal of the European Union on the day when the invitation to tender was issued. This information is also available on the website of the European Central Bank at the following URL: http://www.ecb.int/stats/eurofxref/.
- Pursuant to the provisions of Article 9 of the Italian Law n. 17 dated 10/01/2006 and under Article 151 of Council Directive 2006/112/EC, EFSA is exempt from all duties, taxes and other charges, including VAT. For this reason, all prices given in the financial breakdown should be free of VAT and other taxes or duties.
- The price offered below is understood to be all inclusive. For example any additional costs which can be incurred by the contractor in performing the contract, such as overheads, travelling and subsistence/accommodation expenses, etc. should also be factored in to the all-inclusive price. In addition, if the deliverables incorporate pre-existing rights, the tenderer should factor into their total price the cost of licensing those pre-existing rights to EFSA.

FINANCIAL OFFER			
Type of service	**Estimated volume for 4 years**	**Unit prices to be used in EFSA specific contracts/ order forms (prices in Euros without VAT)**	**Total costs**
A) Fee for one day training course, including the travel expenses, subsistence and accommodation of 2 trainers and 1 coordinator. Cost should be all inclusive covering all the tasks indicated in tender specifications.	3	A (1).....€	A(2)=A(1)*3 .....€
B) Fee for additional day of training course as indicated in point A (without travel expenses)	3	B (1).....€	B(2)=B(1)*3 .....€
D) Hourly rate for a tutor for Webinars, e-learning modules, EFSA Scientific Panel specific training sessions (e.g. two hours module) or Info sessions (e.g. 2 hours recorded /life info session).	6	C (1).....€	C(2)=C(1)*6 .....€
E) Final report for each lot under the FWC	1	D (1).....€	D(2)=D(1)*1 .....€

E) TOTAL price offer to be taken into account for contract evaluation	The total price is calculated as follows	E= A(2)+ B(2)+ C(2)+ D(2)= .....€

Tenderer name: .....

Date: ……..

Name of person signing the financial offer: …….

His/her position in the company: ……

His/her signature: ……

ANNEX 1 - FINANCIAL OFFER TEMPLATE

FINANCIAL OFFER for LOT 3

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

- As referred to in part 1.4, the maximum budget EFSA has available for this assignment is **150,000 € for LOT3**. Any offer exceeding this maximum will not be retained for contract award.
- Prices must be quoted in Euro using the conversion rates published in the C series of the Official Journal of the European Union on the day when the invitation to tender was issued. This information is also available on the website of the European Central Bank at the following URL: http://www.ecb.int/stats/eurofxref/.
- Pursuant to the provisions of Article 9 of the Italian Law n. 17 dated 10/01/2006 and under Article 151 of Council Directive 2006/112/EC, EFSA is exempt from all duties, taxes and other charges, including VAT. For this reason, all prices given in the financial breakdown should be free of VAT and other taxes or duties.
- The price offered below is understood to be all inclusive. For example any additional costs which can be incurred by the contractor in performing the contract, such as overheads, travelling and subsistence/accommodation expenses, etc. should also be factored in to the all-inclusive price. In addition, if the deliverables incorporate pre-existing rights, the tenderer should factor into their total price the cost of licensing those pre-existing rights to EFSA.

FINANCIAL OFFER			
Type of service	**Estimated volume for 4 years**	**Unit prices to be used in EFSA specific contracts/ order forms (prices in Euros without VAT)**	**Total costs**
A) Fee for one day training course, including the travel expenses, subsistence and accommodation of 2 trainers and 1 coordinator. Cost should be all inclusive covering all the tasks indicated in tender specifications.	10	A (1).....€	A(2)=A(1)*10 .....€
B) Fee for additional day of training course as indicated in point A (without travel expenses)	10	B (1).....€	B(2)=B(1)*10 .....€
C) Hourly rate for a tutor for Webinars, e-learning modules, EFSA Scientific Panel specific training sessions (e.g. two hours module) or Info sessions (e.g. 2 hours recorded /life info session).	20	C (1).....€	C(2)=C(1)*20 .....€
D) Final report for each lot under the FWC	1	D (1).....€	D(2)=D(1)*1 .....€

E) TOTAL price offer to be taken into account for contract evaluation	The total price is calculated as follows	E= A(2)+ B(2)+ C(2)+ D(2)= .....€

Tenderer name: .....

Date: ……..

Name of person signing the financial offer: …….

His/her position in the company: ……

His/her signature: ……

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

The guide can be viewed here.

ANNEX 3 - DRAFT CONTRACT

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

ANNEX 4 - DECLARATION ON HONOUR ON EXCLUSION CRITERIA

ANNEX 5 - DECLARATION ON HONOUR ON SELECTION CRITERIA

ANNEX 6 – ADMINISTRATIVE DATA FORM

ANNEX 7 – not applicable

ANNEX 8 – INSTITUTIONAL DECLARATION OF INTERESTS

ANNEX 9 – INDIVIDUAL DECLARATION OF INTERESTS

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