TENDER SPECIFICATIONS

Reference: OC/EFSA/SCER/2021/06
Subject: Specialised training courses on certain aspects of food safety risk assessment.
LOT 1: Trainings on specific aspects of chemical risk assessment, and related tools.
LOT 2: Trainings in the area of environmental risk assessment.
LOT 3: Trainings on horizontal scientific assessment methodologies.
Procurement procedure: Open call (Article 164(1) (a) of the Financial Regulation)
Project/Process code: HUCAP-14

Tender specifications purpose:

1. specify what EFSA will buy under the contract resulting from this procurement procedure;
2. announce the criteria which EFSA will use to identify the successful contractor;
3. guide tenderers in the preparation and sending of their offer;
4. form annex 1 of the contract resulting from this procurement procedure and be binding for contract implementation.

Additional guidance:
Please read the **EFSA Guidance for tenderers** available on the EFSA website, designed to assist potential tenderers in their understanding of EFSA procurement procedures.

Provide EFSA with feedback:
If you considered applying to this call for tenders but finally decided not to, please provide **EFSAProcurement@efsa.europa.eu** with your feedback on the call and reasons for not applying. Feedback will be treated confidentially and will only be used for improving future EFSA procurement calls.

PROCEDURE TIMETABLE

Milestone	Date[1]	Comments
Launch date	07/07/2021	Date Contract Notice is sent to Official Journal.
Deadline for sending request for clarification to EFSA	07/09/2021 at 14:30	Requests for clarification may only be submitted through the e-Tendering website as described in the Invitation Letter. EFSA is not obliged to reply to clarifications received less than 6 working days before the deadline for submission of offers.
Deadline for EFSA to reply to clarification questions	09/09/2021	
"Receipt Time Limit" - Closing date and time for receipt of offers	**15/09/2021** **at 14:30**	Refer to the Invitation letter and part 3 of these tender specifications regarding how to submit your offer.
Opening session	**16/09/2021** at 14:30	Requests to attend the virtual opening session must be made 2 working days in advance of the opening session. Refer to Invitation letter for details.
Notification of evaluation results	Estimated November 2021	The outcome of the procurement procedure will be communicated to all tenderers exclusively using the e-mail address indicated in their offer. Please check regularly the inbox in question.
Contract signature	Estimated January 2022	

[1] All times are in the time zone of Italy, the country in which EFSA is based.

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

1.1 BACKGROUND

The EFSA Science Strategy 2027[2] describes three strategic objectives and associated expected operational outcomes for the implementation of its Strategic Objective 2: «Ensure preparedness for future risk analysis needs». Developing and implementing harmonised methodologies for risk assessment, across the EU and internationally, is one of these operational objectives. EFSA Guidance documents, once implemented, should be consistently used by all concerned stakeholders. 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 within the EFSA risk assessment community.

It is within the mandate and mission of the Scientific Committee and Emerging Risks (SCER) Unit to support the development and implementation of approaches of a horizontal cross-cutting nature for scientific evaluations through the organisation of the work of the EFSA 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 new and existing Guidance Documents through specialised training courses.
This call is based on EFSA's 2021 Work Programme for grants and operational procurements as presented in Annex XIa of the Programming Document 2021 – 2023, available on the EFSA's website[3].

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 risk assessment, (ii) Environmental risk assessment and (iii) Scientific assessment methodologies.

1.2 OBJECTIVES AND DIVISION IN LOTS

[2] https://www.efsa.europa.eu/sites/default/files/2021-04/draft-strategy-2027-for-public-consultation_0.pdf

[3] https://www.efsa.europa.eu/sites/default/files/corporate_publications/files/amp2123.pdf

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

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

- To enable the understanding and practical implementation of risk/benefit assessment practices amongst members of EFSA Scientific Committee/Panels, their working groups, EFSA staff and EFSA Networks and eventually other interested parties, in particular on horizontal aspects related to three main areas of risk assessment (i) Chemical risk assessment, (ii) Environmental risk assessment and (iii) Scientifc assessment methodologies.

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

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 risk assessment, (ii) Environmental risk assessment and (iii) Scientific assessment methodologies.

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

- Lot 1 –Trainings on specific aspects of chemical risk assessment, and related tools.
- Lot 2 –Trainings in the area of environmental risk assessment.
- Lot 3 –Trainings on horizontal scientific assessment methodologies.

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: Trainings on specific aspects of chemical risk assessment, and related tools.

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 combined exposure to multiple chemicals

Background

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.

The objective of this training course is to train the users on the guidance that EFSA has published on this topic:

1. "Harmonisation of risk assessment methodologies for human health and ecological risk assessment of combined exposure to multiple chemicals (MIXTOX)". https://www.efsa.europa.eu/en/efsajournal/pub/5634
The guidance document, published in 2019, addresses how to perform a risk assessment of combined exposure to multiple chemicals for the human health, animal health and ecological area taking into consideration the amount and types of data that are available and is based on the latest developments that have taken place in the field.

2. "Draft guidance document on scientific criteria for grouping chemicals into assessment groups for human risk assessment of combined exposure to multiple chemicals". https://connect.efsa.europa.eu/RM/s/publicconsultation/a0c1v00000HnXIB/pc0014 . The guidance document addresses scientific criteria (i.e. hazard-driven criteria) and prioritisation methods (i.e. risk-based and exposure-driven methods) for grouping chemicals into assessment groups for human risk assessment of combined exposure to multiple chemicals. The GD has been published for public consultation and is due to be adopted by the end of 2021.

The trainings shall also cover aspects on both guidance documents.

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 risk assessment of combined exposure to multiple chemicals as provided by the MIXTOX guidance document.
- 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.

- How to group chemicals into assessment groups for human health risk assessment of combined exposure to multiple chemicals using hazard-driven criteria.
- How to prioritise chemicals to be grouped into assessment groups for human health risk assessment of combined exposure to multiple chemicals using prioritisation methods (risk-based and exposure-driven methods).

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

Background

The tenderer/trainers are asked to train the audience on the contents of two EFSA guidances for nanoscience and nanotechnology in the agro/food/feed chain. These documents are to be published in July 2021 and any potential future update has to be taken as a basis for the course. Intermediate versions are available for both guidances:

Guidance on nano-RA (version of 2018). Full citation is available here online.

Guidance on risk assessment of the application of nanoscience and nanotechnologies in the food and feed chain: Part 1, human and animal health (available here online).

Guidance on Particle – TR (version from the public consultation in 2020):
Full title is "EFSA Guidance on technical requirements for regulated food and feed product applications to establish the presence of small particles including nanoparticles" and the draft guidance is now available here online.

These guidances are applicable to the application areas within EFSA's remit, i.e. novel foods, food and feed additives, food contact materials, and pesticides.

The objective of this training course is:

All users of these guidances must be trained to a detailed level, so that the scientific rationales behind the nano scale risk assessment are well understood. These guidances are overarching by nature. Questions and answers sessions must be built in to allow for refining information if needed (e.g. questions on specific examples that the participants may have). An interactive training set up is to be foreseen. The proposed training course should help risk assessors to implement these guidances correctly.

The training programme shall also cover aspects on:

Examples of best practices. It is to be evaluated together with EFSA in how far the information of the novel food case IHAT can be used (here online). Also specific advices from the Cross Cutting Working Group on nano in the context of cases of implementation in EFSA may complement the training in practical example sessions: After adoption and publication of the scientific opinion by the relevant Panel, the trainers can produce a case-study based on the scientific opinion and detailing how the advice from the cross-cutting working group nanotechnologies (here online) was used by the Panel. The case study is to be approved by EFSA and used as training material.

Technical Content

General information on the technical content

The training course should be divided to cover each guidance and have modules that span to entire content of both guidances (i.e. appraisal routes, characterisation of the fraction of small particles and use of existing studies (as per the technical guidance) and, the various chapters on physicochemical characterisation, exposure assessment, toxicokinetics, in vitro digestion/dissolution, in vivo and in vitro hazard characterisation, read across (as per the scientific guidance). From experiences so far, it is needed to give more focus on the following modules: assessing the information on physicochemical characterisation in line with the different purposes of such characterisation, the key parameters that should be measured, the methods and techniques that can be used, covering also the identification of a nanofraction in conventional materials and its characterisation when identified. The course should also go in depth on the nano-specific considerations relating to *in vivo/in vitro* toxicological studies (administration route, doses, dispersion, internal exposure & detection) and the criteria that are important to use existing studies to cover the hazard characterisation of a nanofraction, and the development of IATAs for complementing existing studies minimising the need for repeating in vivo studies.

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/nanoforms or contain 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 agri/food/feed chain.

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

Background

In 2018, EFSA and the European Chemicals Agency (ECHA) jointly developed a 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 is describing how to determine endocrine disrupting properties by focusing on the identification of endocrine adverse effects and endocrine activity through oestrogen, androgen and steroidogenesis (EAS) and thyroid (T) modalities. In determining whether pesticide/biocide active substances interact with the EATS-mediated pathways, the number and type of effects induced, and the magnitude and pattern of responses observed should be considered and, whether or not, endocrine-related responses occurred at dose(s)/concentration(s) that also resulted in overt toxicity. The guidance recommends considering all the available evidence of the potential interaction of active substances with the EAS and T signalling pathways in a weight-of-evidence analysis.

The proposed course is therefore aiming at training risk assessors on key aspects of the testing strategy proposed in the guidance both for humans and non-target organisms, as

well as in the application of the weight of evidence approach through the Mode of Action analysis.

The objective of this training course is:

- By providing an overview of the testing strategy of the ECHA/EFSA Guidance, to focus on those aspects which may facilitate interpretation of data from studies placed at different level of the OECD conceptual framework, from level 1 to 5.
- Get participants confident on the use of the OECD GD 150 for the identification of parameters that are considered "sensitive" or "diagnostic to" of an endocrine effect.
- Strengthen the ability of participants in the identification of EATS mediated adverse effects and recognise if such effects are observed at doses/concentrations already inducing signs of systemic toxicity.
- Get participants confident on how to use and interpret studies indicative of endocrine activity e.g. level 1 (including data from ToxCast (EPA's Toxicity Forecaster), 2 and 3 studies and in vivo mechanistic studies.
- Strengthen the ability of participants to develop a MOA analysis to establish the link between endocrine activity and EATS mediated adverse effects.
- Get participants aware of which studies are necessary to complete the MOA analysis when data are insufficient to conclude.
- 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 scientific information required to perform 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.

4. Principles on genotoxicity assessment

Background

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 J, 2011, available here) to provide recommendations on genotoxicity testing strategies, which could contribute to greater harmonisation between EFSA Panels on approaches to such testing. This guidance is complemented with the Scientific opinion of clarification of some aspects related to genotoxicity assessment (EFSA J. 2017, available here), Statement on genotoxicity assessment of chemical mixtures (EFSA J. 2019, available here) and Guidance on aneugenicity assessment (under development, expected to be published in July 2021; version published for public consultation available here).

The tenderer/trainers are required to provide training on the scientific opinion/statement/guidance above, taking into account the latest EFSA work on this area.

The objective of this training course is:

- To enable the understanding of the different regulatory requirements on genotoxicity assessment in the different areas covered by EFSA remit of activity.
- To build capacity on the understanding of the test batteries related to genotoxicity testing/assessment and in the interpretations of the results.
- To give an update on the available in vitro and in vivo tests and their level of reliability and relevance.

The training programme shall also cover aspects on using of non-testing methods for genotoxicity assessment.

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 Scientific Committee, including understanding of limitations and difficulties in the interpretation of genotoxicity test results
- A step-wise approach for the generation and evaluation of data on genotoxic potential recommended by the EFSA Scientific Committee.

5. Use of the benchmark dose approach in risk assessment

Background

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 a set of mathematical models to the data. Model averaging is then performed to account for model uncertainty, as the true underlaying model is unknown. To build the averaging model, a weighing

system representing the goodness of fit of the various models is used. The BMD will be the dose level, derived from the estimated average dose-response curve, associated with a specific change in the response (the BMR). The confidence/credible interval for the BMD accounts for the statistical uncertainty in the estimation of the BMD. The lower confidence limit is denoted as the BMDL and the upper confidence limit as the BMDU. The BMDL is obtained from the average model considering a bootstrapping procedure and it will be 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. 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 currently under development and to be finalised by mid-2022, introducing Bayesian model averaging as the preferred method for BMD analysis in EFSA. The training should therefore be programmed as from January 2023.

Technical Content

By mid-2022, the EFSA Scientific Committee will adopt its updated guidance on the use of the benchmark dose (BMD) approach in risk assessment. In this document, the Scientific Committee confirms that the BMD approach is a scientifically more advanced method to the No-Observed-Adverse-Effect-Level (NOAEL) approach for deriving a Reference Point, and introduces Bayesian model averaging as the preferred approach for BMD analysis in EFSA. The updated guidance is applicable to all chemicals in food, irrespective of their category or origin, e.g. pesticides, additives or contaminants. For this purpose, the Scientific Committee suggested that training is organised for members of EFSA Scientific Committee/Panels, their working groups, EFSA staff and eventually other interested parties ,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:

- The general principles of the BMD approach
- How to derive a BMD with quantal and continuous data from animal studies.
- Overview of the EFSA platform for BMD analysis.
- How to perform BMD analysis with the Bayesian model averaging approach, using the EFSA platform for BMD analysis
- How to report a BMD analysis, including the characterisation of the uncertainty around the RP
- Use of the BMD analysis outcome to derive a health-based guidance value.

6. Dietary exposure assessment

Background

The health impact of chemical hazards in food is estimated by comparing dietary exposure to toxicological levels of concern. Dietary exposure assessments combine data on concentrations of a chemical substance present in food with the consumed amount of those foods. Some guidance documents have been produced over the last ten years at international level that describe the current state-of-the-art of domain specific methodologies for dietary exposure assessment. Different methods exist ranging from pragmatic worst-case estimations to refined methods aimed at assessing dietary exposure.

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

Principles of chemical dietary exposure assessment

- Objective of chemical dietary exposure assessment:
  - Naturally present vs. intentionally added
  - Pre-regulation (prospective) vs. post-regulation (retrospective)
  - Chronic vs. acute
- High consumers
- Consumers only vs. total population
- Multinational vs. national exposure assessments
- Target populations, special groups (e.g. toddlers, children, etc.)
- Stepwise approach and screening methods
- Uncertainty and variability

Food consumption data and dietary survey methodology

- Data types and sources of food consumption data available in EFSA
- Types of dietary assessments methods (24h recall, dietary record etc.)
- the EFSA Comprehensive European Food Consumption Database
- The EU Menu Guidance and framework project
- Other international food consumption database (e.g. GEMS, CIFOCOs and GIFT)
- Main uncertainties related to food consumption data

Food classification and systems

- Basic principles of food classification and systems used at international level
- The FoodEx2 classification system
- The FoodEx2 SCA tool
- Matching food consumption with occurrence data

Occurrence data for dietary exposure assessment

- Type of occurrence data (e.g. legal limits, usage levels, experimental data, monitoring and surveillance programs, food composition, etc.)
- Data collection: Standard Sample Description ver. 2 (SSD2)
- Quality issues related to analytical results
  - Management of left censored data
  - Quality checks
  - Outliers and use of cut-off values
- Conversion factors
- Main uncertainties related to analytical results

Dietary exposure assessment methods

- Methods used in the different domains of EFSA
- Exposure for special population groups, e.g. infants below 16 weeks of age
- Methods used by other international organizations/committees (JECFA and JMPR)
- Probabilistic vs. deterministic
- Combined and cumulative exposure estimates
- EFSA exposure assessment tools (e.g. FAIM, FACE, RACE, PRIMo and DietEx)
- Methods used to quantify the exposure uncertainty

Basic principles of exposure science

- Non-dietary exposure assessment
- Biomonitoring studies and results
- Aggregated exposure

Practical sessions and case studies should be provided.

LOT 2: Training courses in the area of Environmental risk assessment

1. Training course on the ApisRAM model for risk assessment of pesticides (alone or in combination with other stressors) in honey bees

Background

EFSA has recently put forward a systems-based approach to the environmental risk assessment of multiple stressors in honey bees[4]. Such approach is composed of two core components: a monitoring system and a modelling system. The training course to be delivered under Lot 2 should provide participants with the necessary knowledge to follow and apply the modelling component of this systems-based approach.

The training will be focused on the mechanistic model to assess risks to honey bee colonies from exposure to pesticides under different scenarios of combined stressors and factors (ApisRAM model). This computer simulation is designed as a quantitative tool for regulatory risk-assessment purposes and as a predictive and explanatory tool to better understand the (relative) risks and impacts of multiple stressors on honey bee colonies, including the overall complexity of interactions.

The objectives of this training course are to provide an overview of:

- Approaches (including the ecosystem service approach) to make policy protection goals operational for use in regulatory ERA;
- Approaches to quantify environmental risks/harm in a standardised and harmonised manner;
- Approaches that can be used for:
    - Assessing potential adverse environmental effects associated with the deployment of regulated products, including sublethal/chronic ones;
    - Extrapolating adverse effects across different levels of biological organisation (individual >> ecosystem) and relevant spatio-temporal scales (e.g. landscape);
    - Assessing risks due to combined exposure to pesticides in a context of multiple environmental stressors, including their interactions;
- type of environmental monitoring and surveillance data that could be integrated in the ERA to deliver more realistic and accurate risk estimates;
- Approaches to evaluate a range of alternative solutions (e.g. different landscape structures or land uses) and compare associated environmental risks;

Technical Content

The technical content should cover:

- Systems-based approaches for formulating ERA issues/problems holistically to address overall system impacts;

[4] https://efsa.onlinelibrary.wiley.com/doi/10.2903/j.efsa.2021.6607

- Approaches (including the ecosystem service approach) to make policy protection goals operational for use in regulatory ERA;
- Approaches to quantify environmental risks/harm in a standardised and harmonised manner;
- Approaches for assessing potential adverse environmental effects associated with the deployment of regulated products, including sublethal/chronic ones;
- Approaches for extrapolating adverse effects across different levels of biological organisation (individual >> ecosystem) and relevant spatio-temporal scales (e.g. landscape);
- Approaches for assessing risks due to combined exposure to multiple pesticides and other environmental stressors, including their interactions;
- Approaches to evaluate a range of alternative solutions and compare associated environmental risks;
- A mechanistic agent-based model to assess risks to honey bee colonies from exposure to pesticides under different scenarios of combined stressors and factors (ApisRAM). This will include: 1. Formal model describing the different model modules (colony and in-hive products, foraging, resource providing unit and Environmental drivers, beekeeping management practices, biological agents and pesticides); 2. generation of model landscapes and 3. Test runs on the ALMaSS platform (an Animal, Landscape and Man Simulation System) for the simulation of the bee colony dynamics under different environmental conditions, landscape structures and dynamics, pesticides, biological stressors (like *Varroa, Nosema*, deformed wing virus and acute bee paralysis virus) and beekeeping management practices.

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

- Understand and describe the various yet complementary aspects to consider for the development and implementation of a systems-based approach for the ERA of regulated products falling in EFSA's remit;
- Formulate ERA issues/problems more holistically;
- Understand the various approaches followed to assess potential adverse environmental effects caused by regulated products (focusing on mixtures of pesticides) in a context of environmental stressors and factors and extrapolate them across levels of biological organisation (from individual bees to the colony level) and relevant spatio-temporal scales;
- Assess which environmental monitoring and surveillance data could be used to inform ERA;
- Explore how an integrated systems-based approach could be designed for regulatory ERA.

LOT 3: Trainings on horizontal scientific 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 scientific areas below:

1. **The EFSA scientific assessment principles and process**

Background

EFSA's mandates are very diverse and pertain to areas of food and feed safety, including animal health and welfare, plant protection, plant health, chemical and biological hazard, human and animal nutrition, the environment and emerging risks. Despite the large variety of topics, the type of questions originating from EFSA's mandates and the resulting conceptual models are relatively limited and comparable across domains. The EFSA's mandates can be broadly classified into: (a) those related to applications submitted by applicants before the introduction of a new type of food, ingredient, substance/material used in the production process or a new use of an existing one. The evidence submitted by the applicants and the methodologies used to collect them is set by regulation and associated guidance documents. Therefore, it is quite standardised as it is the associated assessment process; (b) all other types of mandates conventionally named 'non application assessments'.

Recently EFSA decided to regularly implement a four steps approach when performing non-application scientific assessments. These steps include: 1. Planning the assessment upfront; 2. Implementing the plan, 3. Verifying that the assessment has been carried out according to the plan; 4. Reporting the methodological approach and results. Step 1 entails the development of a protocol that embeds the description of the "what" i.e. the problem formulation (translation of the mandate into scientifically answerable questions and sub-questions) and the "how" i.e. the upfront definition of the methods to perform the assessment (Figure 1). The implementation step entails collecting/retrieving the evidence, appraising/validating the evidence, synthetising the evidence, integrating evidence and conclusions from various sub-questions, reporting (Figure 1)

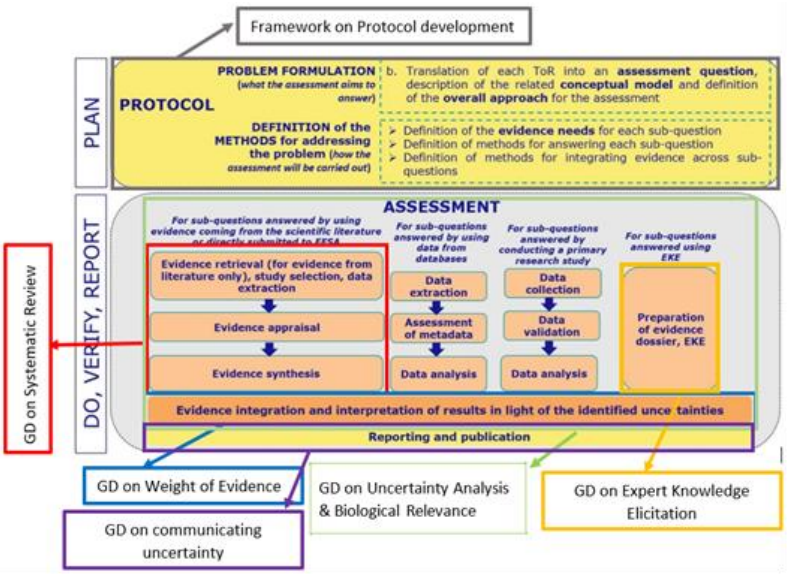

Figure 1: EFSA's scientific assessment process for non-application mandates

EFSA has issued a series of cross-cutting guidance documents and recommendations that are meant to provide recommendations on the methods to apply in various steps of the scientific assessment process. They include: 1. Framework for protocol

development[5]; 2. Guidance on systematic review[6]; 3. Guidance on biological relevance[7]; 4&5. Guidance on uncertainty analysis and communication[8,9]; 6. Guidance on expert knowledge elicitation[10]; 7. Guidance on weight of evidence[11].

The objective of this training course is:

- To provide an overview of the steps characterising the EFSA scientific assessment process and the associated cross-cutting guidance documents
- to introduce the main concepts covered in the framework for protocol development and in the cross-cutting guidance on systematic review, biological relevance, expert knowledge elicitation, weight of evidence, uncertainty analysis and communication
- to describe how the recommendations provided in the cross-cutting guidance documents fit into the EFSA scientific assessment process

The training course should also present concrete examples from previous EFSA's assessments with the purpose of illustrating the planning phase of the scientific assessment process (protocol) and, where possible, the related implementation of the methods recommended for the implementation phase.

Technical Content

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

- the EFSA scientific assessment process
- the planning phase (protocol) and, in particular:
  - ✓ what is the value of planning the assessment upfront
  - ✓ protocol development (what): the problem formulation
  - ✓ protocol development (how): planning the methods
- the main concepts that are critical for horizontal methodologies used across panels and working groups with reference to the guidance on:
  - ✓ systematic review
  - ✓ biological relevance
  - ✓ uncertainty analysis and communication
  - ✓ expert knowledge elicitation
  - ✓ weight of evidence.

The training materials need to be a mixture of theory with applied real case studies tailored to the training audience.

2. How to identify, characterise and communicate uncertainties in in EFSA's scientific assessments.

[5] Draft framework for protocol development for EFSA's scientific assessments. https://efsa.onlinelibrary.wiley.com/doi/abs/10.2903/sp.efsa.2020.EN-1843
[6] Application of systematic review methodology to food and feed safety assessments to support decision making. http://www.efsa.europa.eu/en/efsajournal/pub/1637.htm
[7] Guidance on the assessment of the biological relevance of data in scientific assessments. http://onlinelibrary.wiley.com/doi/10.2903/j.efsa.2017.4970/full
[8] Guidance on Uncertainty Analysis in Scientific Assessments. https://efsa.onlinelibrary.wiley.com/doi/abs/10.2903/j.efsa.2018.5123
[9] Guidance on Communication of Uncertainty in Scientific Assessments. https://efsa.onlinelibrary.wiley.com/doi/abs/10.2903/j.efsa.2019.5520
[10] Guidance on expert knowledge elicitation in food and feed safety risk assessment. https://efsa.onlinelibrary.wiley.com/doi/10.2903/j.efsa.2014.3734
[11] Guidance on the use of the weight of evidence approach in scientific assessments. https://efsa.onlinelibrary.wiley.com/doi/full/10.2903/j.efsa.2017.4971

Background

As part of EFSA's commitment to transparency, identifying and characterising uncertainties and explaining their implications for assessment conclusions is an important element of EFSA's risk assessment process. Uncertainty analysis is not new as consideration of scientific uncertainty has always been a part of EFSA's assessments. The EFSA guidance brings more clarity on how it can be performed in a structured, transparent and unambiguous way. EFSA Scientific Committee has adopted in the November 2017 plenary a guidance document (GD) on Uncertainty Analysis in Scientific Assessments[12] and its companion opinion on The principles and methods behind EFSA's Guidance on Uncertainty Analysis in Scientific Assessment[13]. During the development of the main guidance document on uncertainty three dedicated meetings were organised with the risk managers at DG SANTE between 2014 -2016. In addition, prior to the SC adoption of the GD a workshop was held in June 2017[14] on the outcome of the 1-year trial of the uncertainty GD across all the EFSA panels. On that occasion the risk managers were given the opportunity to provide feedback on the guidance document by providing suggestions for revisions and to express their concerns regarding the implementation of the guidance document. To address the concerns expressed by the risk managers at that workshop an implementation plan has been agreed between EFSA and DG SANTE in autumn 2017: It was agreed to start the implementation of the uncertainty GD after the renewal of all the EFSA Panels in mid-2018. Although the overall aim for the long term is to have the guidance document applied across all EFSA Panels, the roll out of the implementation will not be aligned across the regulated and non-regulated areas to account for the specific needs of the former. First, from July 2018 onwards in a first implementation phase until mid-2022 the guidance document on uncertainty will be fully implementable across all Risk Assessment and Scientific Assistance (RASA)'s units. Each Panel and supporting EFSA unit should decide on the appropriate level of uncertainty analysis to be implemented, based on the scientific content, available resources, and sensitivity of the topic.

In parallel, to support risk assessors, managers and communicators in the implementation of the uncertainty GD a Guidance on Communication of Uncertainty in Scientific Assessments has been developed and published in early 2019[15]. Various additional capacity building activities were provided to support this first implementation phase: an EFSA cross cutting working group on uncertainty[16] supporting ad hoc requests for assistance on various EFSA mandates since 2018 and ongoing, and supporting further methodological development on uncertainty; tailor made trainings on uncertainty for the animal health and welfare (in 2018), the biological hazards and the chemical contaminants (in 2019) and plant heath panel (in 2021); an e-learning course on uncertainty analysis in non-chemical risk assessment (2020); and a Joint EFSA-BfR international conference on uncertainty in risk analysis (2019)[17].

In a follow up 3-year implementation phase it is an opportune moment to help building capacity and experience in the more sensitive area of regulated products.

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:

[12] https://www.efsa.europa.eu/en/efsajournal/pub/5123
[13] https://www.efsa.europa.eu/en/efsajournal/pub/5122
[14] https://www.efsa.europa.eu/en/supporting/pub/en-1313
[15] https://www.efsa.europa.eu/en/efsajournal/pub/5520
[16] https://www.efsa.europa.eu/sites/default/files/wgs/cross-cutting-science/wg-uncertainty.pdf
[17] https://efsa.onlinelibrary.wiley.com/doi/pdf/10.2903/sp.efsa.2019.EN-1689

- To enable the understanding and practical implementation of the guidance document on uncertainty analysis in scientific assessments amongst members of EFSA 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 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)

- The training programme shall also cover aspects on uncertainty communication and impact of uncertainty information on decision making for risk managers.

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
    - Communicate the uncertainty information to their main target audience
  - The content needs to be tailor made according to the needs of the training audience.
  - The training materials need to be a mixture of theory with applied real case studies tailored to the training audience.

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

3. Use of New Approach Methodologies (e.g. in silico and in vitro tools) in chemical risk assessment

Background

Most EFSA chemical risk assessments are based on the paradigm developed in the 1950s. Animal models are considered as gold standard for the derivation of Health Based Guidance Values (HBGV), through the application of safety factors to cover for

uncertainties. These are then compared with generic exposure assessments in the characterisation of consumer's risk.

In the 21st century, the risk assessment community is increasingly generating information using alternative approaches to move away from the use of animal experiments. The concept of alternative (to in vivo) methods has been extended to New Approach Methodologies (NAM) including not only in vitro methods, read-across, QSAR, other in silico tools, IVIVE but also the integration of in vivo and alternative methods through TKTD, AOPs, in vivo exposure plus -omics, etc. Various organisations have joined efforts in and outside the EU to develop, validate and integrate these new tools in the chemical risk assessment process. These efforts have not yet explored the capacity of these methods to provide information that would allow a better understanding of the mode of action of the chemical substance which are relevant for the identification of susceptible groups.

The development of High-Throughput Screening (HTS) and High-Content Screening (HCS) tools is offering additional possibilities for regulatory assessments, not only for reducing animal testing, but also for assessing directly human physiological characteristics and addressing individual differences (e.g. consumers with specific needs due to chronic diseases, genetic pre-disposition, dietary requirements and patterns, etc.). Currently, information generated by these new approaches have become available for many substances (to be) assessed by EFSA, e.g. in USEPA ToxCast, and even included in the dossiers. However, references in current EFSA guidance documents on how to validate/verify and include the information in the WoE are very scarce.

The experience has demonstrated that the incorporation of these approaches, and its regulatory acceptance, would require evolved hazard and risk characterisation models, providing risk managers with new sets of information, allowing them to address the new societal needs. The identified priority for EFSA is to minimise request for additional animal testing in case of inconclusive risk assessments, exploring and, when feasible, demonstrating that NAM-based IATAs can be used for fulling the identified data gaps and finalising the risk assessment. EFSA is running a project covering the different food and feed sectors with "Proof of Concept" case studies, the results will be integrated in the NAMs roadmap currently under development through SPIDO.

Technical Content

The technical content should cover:

- *in silico* and modelling approaches (e.g. QSAR, read-across, TKTD, QIVIVE)
- experimental *in vitro* studies for hazard identification and characterisation relevant in the food and feed area, including the verification of results and their integration in the risk assessment
- Use of data from HTS/HCS databases (e.g. ToxCast)
- AOP and approaches for using mechanistic understanding for risk assessment.
- Integrate NAMs and standard *in vivo* methods in IATA strategies, focusing on the use of NAMs for addressing data gaps identified during the assessment of *in vivo* studies.

By the end of the course, participants should be able to understand the different types of methodological approaches covered by the term "NAMs", describe the process for appraising the validity of NAM-based results, and propose alternatives for integrating NAMs data with standard in vivo results during the risk assessment process.

4. Principles of human health risk-benefit assessment of foods

Background

In the last two decades, several national and international organisations proposed approaches for risk-benefit assessments of food. The EFSA Scientific Committee published a general guidance on human health risk-benefit assessment of foods in 2010[18]. The document focuses on human health risks and human health benefits, and does not address social, economic, or other considerations such as "cost-effectiveness". It is considered essential that formulation of the problem precedes the risk-benefit assessment. In that context, agreement between the risk-benefit assessor and the risk-benefit manager on the terms of reference should be reached to ensure that the outcome of the assessment is useful and relevant for the risk-benefit manager goals. A stepwise approach is recommended for the risk-benefit assessment, i.e. i) initial assessment, addressing the question whether the health risks clearly outweigh the health benefits or vice versa, ii) refined assessment, aiming at providing semi-quantitative or quantitative estimates of risks and benefits at relevant exposures by using common metrics, and iii) comparison of risks and benefits using a composite metric such as DALYs or QALYs to express the outcome of the risk-benefit assessment as a single net health impact value. The outcome of each step should also include a narrative of the strengths and weaknesses of the evidence base and its associated uncertainties. After each step of the risk-benefit assessment, discussion should take place between the risk-benefit assessor and the risk-benefit manager on whether sufficient information has been provided or whether the terms of reference should be refined in order to proceed with the next step of the assessment.
In 2011, FAO/WHO[19] published a report of a Joint Expert Consultation on the Risks and Benefits of Fish Consumption from 25 to 29 January 2010. The tasks of the Expert Consultation were to review data on levels of nutrients (long-chain omega-3 fatty acids) and specific chemical contaminants (methylmercury and dioxins) in a range of fish species and to compare the health benefits of fish consumption associated to nutrient intakes with the health risks associated with contaminants present in fish. The Expert Consultation drew a number of conclusions regarding the health benefits and health risks associated with fish consumption and recommended a series of steps that Member States should take to better assess and manage the risks and benefits of fish consumption and more effectively communicate these risks and benefits to their citizens. The output of the Expert Consultation is a framework for assessing the net health benefits or risks of fish consumption that will provide guidance to national food safety authorities and the Codex Alimentarius Commission in their work of managing risks, taking into account the existing data on the benefits of eating fish.
With the increasing knowledge about the human health benefits of individual nutrient and non-nutrient components of foods and the potential adverse health effects of other substances contained in the same foods such as contaminants, residues of pesticides and veterinary drugs, the number of questions from risk managers about weighing health benefits and risks of eating these foods grew

[18] EFSA Scientific Committee (2010). Guidance on human health risk-benefit assessment of foods. EFSA Journal 2010; 8(7):1673. https://doi.org/10.2903/j.efsa.2010.1673 (available at https://www.efsa.europa.eu/en/efsajournal/pub/1673)
[19] FAO/WHO (2011). Report of the Joint FAO/WHO Expert Consultation on the Risks and Benefits of Fish Consumption. Rome, Food and Agriculture Organization of the United Nations; Geneva, World Health Organization, 50 pp.

The objective of this training course is to understand and apply the general principles of the human health risk-benefit assessment of food consumption and to understand trends and developments in the application of novel approaches as proposed by the EFSA Scientific Committee on an update of its 2010 guidance to be released in 2024 and in EU research projects.

The training programme shall cover aspects on:

- Understanding the principles of the guidance prepared by the EFSA Scientific Committee in 2010
- Examples of risk-benefit assessments of fish consumption in relation to nutrients and contaminants in fish
- Introduction to the updated guidance of the EFSA Scientific Committee (2024-)

Technical Content

By the end of the course, participants should be able to understand and describe the principles of risk-benefit approaches as proposed by EFSA and FAO/WHO and recent developments in the application of novel approaches for risk-benefit assessments in EU Research projects and by EFSA.

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 2-6 training courses per year under lot 1 and lot 3 and approximately 1-3 training courses under lot 2[20].

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.

The training courses will be designed by the contractor 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.

[20] The number of trainings courses are an estimation.

Table 1. Scientific areas for training courses divided by lots.

Scientific areas for training courses		Estimated courses per year (2022-2025)
Lot 1	1. Harmonisation of risk assessment methodologies for combined exposure to multiple chemicals.	approximately 2-6 training courses per year under lot 1 and lot 3 and approximately 1-3 training courses under lot 2 (the number may vary depending on the needs of EFSA)
	2. Risk assessment of the application of nanoscience and nanotechnologies in agro/food/feed.	
	3. Science-based criteria for identifying endocrine disruptors in the context of EU legislation on pesticides and biocides.	
	4. Principles on genotoxicity assessment.	
	5. Use of the benchmark dose approach in risk assessment.	
	6. Dietary exposure assessment.	
Lot 2	1. Training on the Apis RAM model (incorporating effects on bees as part of the environmental risk assessment).	
Lot 3	1. The EFSA scientific assessment principles and process.	
	2. How to identify, characterise and communicate uncertainties in in EFSA's scientific assessments.	
	3. Use of New Approach Methodologies (e.g. in silico and invitro tools) in chemical risk assessment.	
	4. Principles of human health risk-benefit assessment of foods.	

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

The tenderer should be able to provide following **training courses:**

- **Modality 1**: (**Classroom**) **instructor-led** training = physical training (e.g. Scientific Panel tailor-made trainings, info sessions, training workshops);
- **Modality 2**: (**Virtual**) **instructor-led** training = live online, using Teams or similar platforms (e.g. Scientific Panel tailor-made trainings, webinars, training workshops);
- **Modality 3**: (**Virtual**) **recorded** training = online tutorials
- **Modality 4**: **E-Learning** (asynchronous self-paced online modules).

Please note that Classroom training could include remote participation (few virtual participants in order to augment participation and avoid travel disruptions). Pedagogical requirements might also lead to a "blended training" approach, combining any of the four above described modalities. Training registration, access and hosting (when applicable) will be using EFSA's Learning Management System (LMS) as soon as the system will be available (estimated to be launched in January 2022). Training materials

and training records shall be stored in LMS for future use by EFSA. In case the LMS will not be available at the time of FWC implementation, EFSA reserves the right to request the successful contractor to facilitate suitable systems to perform the training registration, access and hosting in compliance with personal data protection (as outlined under section 1.6 of this tender specifications), with the highest level of information security and user experience available. These solutions will need to be previously agreed with EFSA.

Training courses conduct:

During the Framework contract implementation, EFSA will interact with the contractor and reserves the right to propose the introduction of adaptations to the course content, the pool of tutors or the setting of the training courses proposed by the contractor. The need for adaptation of a course previously delivered will be agreed by the contractor and EFSA.

Agreement on dates, facilities and participants quotas of training courses

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, timelines and list of trainers.

Physical training at EFSA's premises (modality 1)

Venue of the training courses

Physical 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 e.g. WI-FI internet connection 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.

Virtual Instructor-led Trainings (modality 2)
The contractor shall provide a suitable solution to deliver interactive webinars, including whiteboard, polling, break-out rooms, screensharing and recording capabilities (examples include MS Teams, Webex, Zoom, etc). These solutions should not require the training participants to create an account (login/password).

Virtual recorded trainings and e-learning (modalities 3 and 4)
In order for EFSA to host the course material on its LMS, the contractor shall provide files compatible with the following requirements:

Learning Cloud Service System Requirements:

Video Type Supported:
h.264 with AAC
Maximum File Size supported is 1GB

SCORM/ AICC Supported:
SCORM 1.2 and 2004 (3rd Edition)
AICC Level 1 Versions 2.2 or 4.0
Maximum File Size supported is 1GB
zip

Image Types Support:
gif, jpeg, png
Maximum File Size supported is 50MB

PDF Supported:
Maximum File Size supported is 1GB

In case of an electronic tool is required for the purpose of delivering of synchronous trainings, it should be available to the training participant in the form of a web tool with no need to be downloaded in the participants' personal PC. These tools should be clearly described by the tenderer in their offer. Exceptions to this are tools already in use at EFSA, specifically Microsoft Teams, Zoom, Adobe Connect and Cisco Webex.

Additionally, any electronic system or platform proposed by the contractor or any subcontractor for the instructor-led virtual trainings, virtual recorded trainings and E-Learning (training course modalities 2 to 4 described above), shall comply with specific data protection compliance requirements concerning storage location and data access outlined in Part 1.6 of these specifications.

EFSA is committed to ensure high standards of inclusion in learning. Any learning technologies and tools shall be inclusive in terms of accessibility and usability for the learners.

Identification and management of training 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 eligible participants at least two weeks before each training session to identify places left unfilled.

<u>Registration and identification of participants</u>

The participants of the training courses are members of the EFSA Scientific Committee/Panels and their working groups, preferably the newly designated ones. Members of the EFSA Networks, EFSA scientific staff and eventually other interested parties may also participate in the training courses. 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.

Each training session shall be suitable for a number of participants under each category (Scientific Committee/Panel/working group members, EFSA scientific staff, Network members and other EFSA groups of interest) to be agreed for each delivery.

The contractor must ensure the timely registration of participants.

Panel/Working Group members and EFSA staff will self-register in EFSA LMS.

The contractor should facilitate the identification of eligible training participants other than Panel/Working Group members and EFSA staff, identified here as external participants (e.g. with the help of an alternative registration tool and pre-screening).

After identification of all eligible learners, and in consultation with EFSA, the contractor finalises the list of training participants at least three weeks before each training session.

The contractor should collect the necessary details from confirmed external participants to create their individual LMS account (if accessing LMS for the first time). These details should be communicated to EFSA at least three weeks before each training session.

Conduct the training course.

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 contractor is requested to provide to EFSA (in electronic format) a participant training package to be used as supporting material for the courses (including a syllabus (i.e. an outline and summary of scientific areas to be covered in training course) a description of the training content, additional references for further study, presentations from tutors, examples, exercises, case studies, handouts, and any other documentation considered relevant in the final format of the training session. The material (in electronic format) should be submitted at least 4 weeks before the date of the corresponding training session to be validated by EFSA. These will be uploaded on the LMS (see system requirements above).

The successful contractor should

- Ensure that each participant receive a training package (in electronic format) to be used as supporting material for the courses
- 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. The format of the feedback form shall be agreed with EFSA beforehand. 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.
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.

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
2	**Provide a summary report at the end of each training course** as indicated in the tender specifications under section 1.3.	Yes	To be defined in the specific contract
3	**Provide a final report for each lot at the end of the FWC implementation** as indicated in the tender specifications under section 1.3.	Yes	To be defined in the specific contract
No	**Meetings – applicable to each lot**		**Deadline for finalisation**
1	**Kick off meeting** Virtual meeting 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:		Within one month from Framework Contract signature

	• Draft training programme; • Estimated calendar of the courses; • Criteria and procedures to select 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 virtual meetings 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 specific contract are detailed in the draft framework contract.	Will be defined further in the context of each specific contract

The working language for contract implementation including execution of tasks, meetings and deliverables shall be English. Any written deliverables must be to a high standard of English which does not require proof reading.

1.4 INFORMATION ON THE CONTRACT

Nature of expense services

Type of contract framework (FWC)

Type of FWC single FWC

Maximum number of contractors in each lot

Lot 1 - 1
Lot 2 - 1
Lot 3 - 1

Place of performance: EFSA premises/contractor's premises

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

- Lot 1: €330.000 (for a maximum duration of 4 consecutive years)
- Lot 2: €50.000 (for a maximum duration of 4 consecutive years)
- Lot 3: €220.000 (for a maximum duration of 4 consecutive years)

Any offer exceeding these maximums will be excluded from further assessment during evaluation.

Duration of FWC

One year + automatic renewal up to 3 times for an overall maximum duration of four consecutive years.

Possible increase of FWC envelope
In accordance with Annex I, Section 2, article 11.1 e) of the Financial Regulation, EFSA reserves the right to launch a future negotiated procedure with the contractor chosen as a result of this call for tender, for new services consisting in the repetition of similar services during the three years following the signature of the original framework contract. The increase will not go beyond 50% of the original envelope for each lot.

Price indexation
The mechanism for the indexation of prices is set out in the draft framework contract.

Framework contract implementation modalities
The framework contract will be implemented using Specific Contracts. The contracting authority orders services by sending the contractor a Specific Contract by e-mail.

1.5 OWNERSHIP, INTELLECTUAL PROPERTY RIGHTS, USE OF RESULTS

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

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 in Annex 2 contains further provisions on ownership of intellectual property rights. All quotations or information the tenderer provides in the technical and financial offer for EFSA which originates from other sources to which third parties may claim rights, have to be clearly marked in the offer in a way allowing easy identification (source publications, including date & place, creator, number, full title etc.). The

tenderer shall take account of the above specification on ownership and copyrights in their technical and financial offer.

Use of results
EFSA is committed to the publication of contract deliverables - such as supporting evidence in the form of datasets, raw data, protocols etc. in the Knowledge Junction in order to improve transparency, reproducibility and evidence reuse. The Knowledge Junction[21] repository of EFSA runs on the EU-funded Zenodo research-sharing platform where uploaded items receive a unique Digital Object Identifier to make them citable. Any part of the output resulting from this contract may be published (at EFSA's discretion) on the Knowledge Junction repository, with attribution to the contractor, and several deliverables can be cross-linked among them and to the published final Report on Wiley Online Library.

1.6 PERSONAL DATA PROTECTION AND CONFIDENTIALITY

Processing of personal data in the context of this contract shall comply with Regulation (EU) 2018/1725 ('the EDPR')[22]. The EDPR constitutes the specific data protection legal framework applicable to EU institutions, bodies, offices and agencies, including EFSA and is aligned with the rules and principles under the General Data Protection Regulation (EU) 2016/679 (GDPR), applicable in the European Union.

In terms of the EDPR, EFSA acts as the controller for processing of personal data under the contract and the selected contractor, any consortium partner and subcontractor, as the processor or subprocessor.

Processing of personal data by EFSA as contracting authority (controller)
Information on the processing of personal data by EFSA as contracting authority in charge of the present procurement procedure is available in the Privacy Statement on the EFSA website as well as in Article II.9.1 of the draft contract in Annex 2.

Please note that your personal data as a tenderer or selected contractor may be registered in the Early Detection and Exclusion System (EDES) if you are in one of the situations mentioned in Article 136 of the Financial Regulation. The relevant Privacy Statement is available on the European Commission's website, here: http://ec.europa.eu/budget/explained/management/protecting/protect_en.cfm#BDCE.

Processing of personal data by the selected contractor (processor/sub-processor)
Personal data processing by the selected contractor, any consortium partner and/or subcontractor in the execution of the framework contract shall comply with Article II.9.2 of the draft contract (Annex 2), making the processor obligations in Article 29 of the EDPR applicable under the framework contract. In particular, the selected contractor shall ensure:

- For what concerns the personal data handling required in the context of this contract and related to the identification, selection and registration of training

[21] http://www.efsa.europa.eu/en/press/news/190117 and https://zenodo.org/communities/efsa-kj/?page=1&size=20
[22] Regulation (EU) 2018/1725 of the European Parliament and of the Council of 23 October 2018 on the protection of individuals with regard to the processing of personal data by the Union institutions, bodies, offices and agencies and on the free movement of such data and repealing Regulation (EC) No 45/2001 and Decision No 1247/2002/EC, OJ L 295/39 21.11.2018, https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32018R1725&from=EN

participants, for the conduct of the training courses and for *ex post* collection of participants' feedback and level of satisfaction, to ensure full compliance with the principles relating to the processing of personal data laid down in Article 4 of the EDPR, especially the principles of purpose limitation, data minimisation, storage limitation and confidentiality;

- To implement appropriate technical and organisational measures to ensure a level of security appropriate to the risks, in particular the risk of accidental or unlawful destruction, loss, alteration, unauthorised disclosure of, or access to the personal data, processed or stored;
- To ensure compliance with the specific **storage location and data access requirements**. This extends but is not limited to any electronic system or platform proposed by the contractor or subcontractor for instructor-led virtual trainings, virtual recorded trainings and E-Learning modality, any online learning management system or registration system for training participants. The specific requirements at issue are laid down in Article I.9.2(b) of the draft contract (Annex 2) and can be summarized as follows:
    - the personal data shall solely be processed and held in data centres located within the territory of the European Union and the European Economic Area ((EU-27 + Norway, Iceland, Liechtenstein) + Switzerland) and will not leave that territory;
    - any transfer of personal data to third countries or international organisations shall comply with the requirements laid down in Chapter V, Articles 46-51 of the EDPR, as well as the relevant case law of the Court of Justice of the European Union, i.e. the so-called 'Schrems II' case C-311/18 and the Recommendations 01/2020 on measures that supplement transfer tools to ensure compliance with the EU level of protection of personal data, issued by the European Data Protection Board.

- To assist EFSA as the controller in the fulfilment of its obligation to respond to requests of data subjects exercising their rights laid down in Chapter III of the EDPR;
- To assist EFSA as the controller with its obligation with regard to security of processing, the notification obligations in case of a personal data breach, cooperation in data protection impact assessments (DPIAs) and prior consultations with the European Data Protection Supervisor (the EDPS), outlined in Art. 33 to 40 EDPR;
- To make available to EFSA all information to demonstrate compliance with the obligations laid down in the EDPR and to allow for and to contribute to audits, including inspections, conducted by EFSA, the EDPS or another audit or control body mandated by EFSA.

For further information on data protection, please refer to the **EFSA guidance for tenderers** on the EFSA website, page 13.

Confidentiality

Tender bids will be treated confidentially in accordance with the case law of the European Courts, which confirms the existence of a presumption of non-disclosure in case of a request for public access to documents in accordance with Regulation (EC) No 1049/2001. This does not prevent that specific parts of the submitted tender may be subject to disclosure when applicable law so requires. Unless there is an overriding public interest in disclosure, EFSA will refuse full access to the submitted tender, redacting the parts that contain confidential information, the disclosure of which would undermine the protection of commercial interests and intellectual property of the tenderer.
Accordingly, EFSA will disregard general statements that the whole tender or substantial parts thereof are confidential information. Tenderers need to mark clearly the specific parts of their tender bid they consider confidential providing an explanation why the information should not be disclosed, which may be subject to EFSA's further assessment in accordance with applicable law.

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 refer to the **EFSA Guidance for tenderers**.

2.1 OPENING OFFERS

The aim of the public opening session is to check whether the offer received was dispatched by the deadline for tender receipt 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); Exclusion criteria (Declaration on Honour on exclusion criteria); Selection criteria (Declaration on Honour on selection criteria); Selection criteria (Economic & Financial capacity); 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).

Evidence under sections 2.3 and 2.4 does not have to be submitted to EFSA if it has already been submitted in response to a previous EFSA call. In such case the evidence must be exactly the same as requested in these tender specifications and not older than 12 months. Please specify the reference of the EFSA call for tenders under which you have already submitted the evidence to EFSA if you chose to rely on such evidence.

2.3 GROUNDS FOR EXCLUSION

Eligibility – access to EU Market

Only offers from tenderers established in eligible countries will be allowed to the next step of the evaluation. Please refer to the **EFSA Guidance for tenderers** for further details.

> ***Evidence requested in your offer:***
> Tenderers must submit the Administrative data forms (including LEF and BAF) available here.

Exclusion

Tenderers must not be in one of the exclusion situations listed in article 136 of the Financial Regulation, explained in the **EFSA Guidance for tenderers**.

> ***Evidence requested in your offer:***
> Tenderers must declare that they are not in one of the exclusion situations by providing a signed and dated Declaration on Honour on exclusion criteria, available here. In case of a joint offer from a group of economic operators, or in case of subcontracting, such declaration should be submitted for each member of the group and for each identified subcontractor.

Further supporting evidence in support of this declaration may be requested from the successful tenderer prior to signature of the contract. Such requested evidence will be specified in the award letter and may have to be provided to EFSA before the contract is signed.

2.4 SELECTION CRITERIA

In addition to the evidence requested below, 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.

A) Economic and financial capacity

The tenderer must have generated an overall annual turnover for each lot as follows:

- LOT1 at least 150.000€ in each of the last 2 closed financial years (2019, 2020)
- LOT2 at least 20.000€ in each of the last 2 closed financial years (2019, 2020)
- LOT3 at least 100.000€ in each of the last 2 closed financial years (2019, 2020)

Evidence requested in the offer:

Tenderers must declare they fulfil the economic and financial capacity by providing a signed and dated Declaration on Honour on selection criteria, available here. In case of a joint offer from a group of economic operators, such declaration should be completed by the leading partner only.

EFSA will request proof of annual turnover from the successful tenderer prior to signature of the contract. Such requested evidence will be specified in the award letter and must be provided to EFSA before the contract is signed. This evidence will be evaluated on a consolidated basis.

During contract implementation, in case of request for the addition of new subcontracting or assignment of the contract to a new legal entity, the economic and financial capacity will be checked for the last 2 most recent closed financial years and not necessarily the financial years published with the call.

B) Technical and professional capacity

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 scientific risk assessment **in EFSA's remit**. The tenderer must have demonstrable experience in developing, organising and delivering **classroom, virtual and eLearning scientific training courses**.

b) The tenderer must have the ability to provide a **team of experts** compliant with these **minimum expertise requirements**:

Tutors under Lot 1:

At least one qualified and experienced tutor with at least 5 years experience in one or more scientific areas of lot 1 (specified in Table 1 section 1.3 of the tender specifications); university degree or PhD in life sciences in the field of the given scientific area; experience in teaching in English and developing specific examples (case studies)

on the subject matter of the different courses. To this purpose, the *Curriculum vitae* of potential tutor(s) should be provided with the offer. 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 staff members as additional tutors for the optimal delivery of the programme. The latter will not imply any additional cost for the contractor.
In particular, tutors proposed for **Lot 1** shall have knowledge and experience on**:**

1. Tiered approaches and respective tools available for each step of the chemical risk assessment process for **mixtures** and on the use of uncertainty factors in a mixture RA context.
2. Physicochemical characterisation of **nanomaterial**, exposure assessment and stepwise hazard identification and characterisation for nanomaterials in the agri/food/feed chain including particle toxicology.
3. ECHA/EFSA Guidance and OECD Guidance 150; knowledge of the testing batter for the identification of **Endocrine Disruptors** (ED); experience on relevant ED in vitro data interpretation; experience on ToxCast data interpretation; experience on relevant in vivo data interpretation; Knowledge on Weight of Evidence and MoA analysis.
4. Test batteries related to **genotoxicity** testing/assessment and in the interpretations of the results, available *in vitro* and *in vivo* tests and their level of reliability and relevance and non-testing methods for genotoxicity assessment. Excellent knowledge of EFSA guidance documents related with genotoxicity testing/assessment (EFSA, 2011, 2017 and 2019).
5. The EFSA platform for **BMD** analysis (documentation about the WEB app: https://doi.org/10.5281/zenodo.801416, EFSA BMD WEB app URL: https://r4eu.efsa.europa.eu/app/bmd) which performs dose-response modelling, the use of Bayesian statistics and how to derive a BMD and its confidence/credible interval for quantal and continuous data from animal studies.
6. Principles, data, methods and tools for chemical dietary **exposure assessment** at international level.

Tutors under Lot 2:
At least one qualified and experienced tutor with at least 5 years experience in one or more scientific areas of lot 2 (specified in Table 1 section 1.3 of the tender specifications); university degree or PhD in life sciences in the field of the given scientific area; experience in teaching in English and developing specific examples (case studies) on the subject matter of the different courses. To this purpose, the *Curriculum vitae* of potential tutor(s) should be provided with the offer. 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 staff members as additional tutors for the optimal delivery of the programme. The latter will not imply any additional cost for the contractor.

In particular, tutors proposed for **Lot 2** shall have knowledge and experience on the mechanistic agent-based model to assess risks to honeybee colonies from exposure to pesticides under different scenarios of combined stressors and factors (**ApisRAM**). Risk assessment in areas in the remit of EFSA. Agent based modelling to assess risks to honeybee colonies from exposure to pesticides under different scenarios of combined stressors and factors at landscape scale.

Tutors under Lot 3:
At least one qualified and experienced tutor with at least 5 years experience in one or more scientific areas of lot 3 (specified in Table 1 section 1.3 of the tender specifications); university degree or PhD in life sciences in the field of the given scientific area; experience in teaching in English and developing specific examples (case studies) on the subject matter of the different courses. To this purpose, the *Curriculum vitae* of potential tutor(s) should be provided with the offer. 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 staff members as additional tutors for the optimal delivery of the programme. The latter will not imply any additional cost for the contractor.

In particular, tutors proposed for **Lot 3** shall have knowledge and experience on:

1. **Planning scientific assessment protocols** and knowledge on the planning phase (protocol) for EFSA scientific assessment process and on the horizontal methodologies used across EFSA panels and working groups with reference to the guidance on systematic review, biological relevance, uncertainty analysis and communication, expert knowledge elicitation, weight of evidence.
2. The various methodologies (shown in the annexes of the **uncertainty** guidance document[23]) to assess individual and combined uncertainty.
3. *In silico and* modelling approaches (e.g. QSAR, read-across, TKTD, QIVIVE), HTS/HCS databases (e.g. ToxCast), verification of experimental results from *in vitro* studies and their integration in the risk assessment, AOP and approaches for using mechanistic understanding for risk assessment, integration of NAMs and standard *in vivo* methods in IATA strategies, on the use of **NAMs** for addressing data gaps identified during the assessment of *in vivo* studies.
4. The principles of **risk-benefit approaches** as proposed by EFSA and FAO/WHO and recent developments in the application of novel approaches for risk-benefit assessments in EU Research projects and by EFSA.

Training Coordinator for each lot
The contractor is required to appoint a Training Coordinator (Project Leader) for each lot with an academic background (university degree) and with at least 3 years of professional experience and proven record in organising training courses and in managing e-learning projects. 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.

[23] https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2018.5122

c) The team of experts must have individually an excellent level **of spoken and written standard UK English**. For non-native speakers, this should be demonstrated by an Official certificate of English proving a C1 level OR at least 3 years of work in an English-speaking environment.

Evidence requested in the offer:

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 (tutors and training coordinator), taking into account the minimum expertise requirements detailed for each in section 2.4B b) above; EFSA strongly recommends submitting the CVs in the EU CV format which can be accessed here; tenderers should also provide a one page summary of the names of the individual Project team members.

□ **Declaration on Honour on selection criteria** available here. To be signed by the tenderer (in case of joint offer signed by the leading partner only).

□ **Confirmatory statement of resources** (*only applicable for joint offers or offers with subcontracting*): a statement signed by each partner/subcontractor confirming they will provide the necessary resources for the performance of the contract.

C) Professional conflicting interest

In accordance with article 167(1)(c) of the Financial Regulation and paragraph 104 of the recitals, 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.

Evidence requested:

The tenderer proposed for contract award will be requested, prior to and as a condition of contract signature, to provide:

Institutional declaration of interests available here In case of a group of economic operators and/or in case of subcontracting, such declaration will need to be completed separately and submitted for each partner and for each identified subcontractor and;

Individual declarations of interests available here for each member of the proposed project team.

Institutional and Individual DoIs do not need to be provided with your offer. The requirement to submit Institutional and Individual DoIs will be specified in the award letter and will have to be provided and assessed by the EFSA Authorising Officer before and as a condition of contract signature. Please refer to EFSA's policy on independence and the Decision of the Executive Director on Competing Interest Management for detailed information.

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

If any of the declarations or information provided proves to be false, EFSA may impose administrative sanctions (exclusion or financial penalties) on the entity providing the false declarations/information.

For the purposes of the evaluation related to exclusion and selection criteria EFSA may also refer to publicly available information, in particular evidence that it can access on a national database free of charge.

2.5 COMPLIANCE WITH TENDER SPECIFICATION AND MINIMUM REQUIREMENTS

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

Tenders do not comply with the tender specifications and will be rejected if they:

- do not comply with minimum requirements laid down in the tender specifications;
- propose a solution different from the one 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[24] and compliance with data protection obligations resulting from Regulation (EU) 2016/679 and Regulation (EU) 2018/1725[25].

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

2.6 AWARD CRITERIA

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

A) QUALITY AWARD CRITERIA FOR ALL LOTS

1. **METHODOLOGY PROPOSED FOR THE DEVELOPMENT, DESIGN AND FOR THE CONDUCTION OF THE TRAININGS (max. 70 points, minimum threshold 50 %)**
   This is to assess the degree to which the methodology proposed is in conformity with the technical specifications:

[24] OJ L 94 of 28.03.2014, p. 65
[25] Regulation (EU) 2018/1725 of the European Parliament and of the Council of 23 October 2018 on the protection of individuals with regard to the processing of personal data by the Union institutions, bodies, offices and agencies and on the free movement of such data and repealing Regulation (EC) No 45/2001 and Decision No 1247/2002/EC, OJ L 295/39 21.11.2018, https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32018R1725&from=EN

- Proposed methodology in outlining the curriculum of a training session on one of the scientific areas 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 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 scientific areas under the scope of a specific Lot of this call for tender (**20 points maximum**).

2. **PROJECT ORGANISATION (max 10 points, minimum threshold 50%)**
   This is 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:

   - Project management methodology to be used, including the draft project plan with responsibilities of the team members, internal communication and regular and effective communication with EFSA. In case of joint offer & subcontractors, clarity on who does what, when and why (justify why the partner/subcontractor is proposed to do the particular task/work-package) (**10 points maximum**).

3. **MEASURES TO GUARANTEE QUALITY OF DELIVERABLES (max 10 points)**
   This is to assess the quality assurance mechanisms put in place to guarantee the high quality of deliverables:

   - 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 (**10 points maximum**).

4. **MEASURES TO MEET DEADLINES TO GUARANTEE ON TIME DELIVERABLES (max 10 points)**
   This is to assess the mechanisms put in place in order to guarantee availability of contractor for assignment and to meet the agreed deadlines for deliverables:

   - Measures to ensure availability of proposed team members and mitigation strategies to cover absences; **(5 points maximum)**
   - Measures proposed to ensure the meeting of the deadlines; **(5 points maximum)**

The sum of all quality award criteria gives a maximum possible total of 100 points.
Tenderers must provide a detailed technical offer for one, two or three lots addressing all points in the technical specifications and each of the quality award criteria. Repetition of mandatory requirements in the technical specifications without providing detail in the technical offer will only result in a very low score.

Offers must score at least **50% for criteria 1 and 2 and 70% of maximum possible total points** against the quality award criteria.

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

B) PRICE AWARD CRITERION

Tenders which passed the quality thresholds will be further assessed to ensure:

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

C) THE BEST PRICE-QUALITY RATIO

Tenders for which financial offers were made within the maximum budget 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 following formula:

TOTAL SCORE OF THE EVALUATED OFFER (C) =

30 * Cheapest price offer/price of tender X

+

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

PART 3 - HOW TO SUBMIT YOUR OFFER USING e-SUBMISSION

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. It is not possible to submit a tender through eSubmission after the time-limit for receipt of tenders indicated in the contract notice and/or the TED eTendering website.

Registration in the Participant Register

Any economic operator willing to submit a tender must be registered in the Participant Register - an online register of organisations and natural persons participating in European Commission's calls for tenders or proposals.

On registering each participant obtains a Participant Identification Code (PIC, 9 - digit number) which acts as its unique identifier in the Participant Register. A participant needs to register only once – the information provided can be further updated or re-used by the participant in other European Commission's calls for tenders or calls for proposals.

At any moment during the procurement procedure the Research Executive Agency Validation Services (hereafter *the EU Validation Services)* may contact the participant and ask for supporting documents on legal existence and status [and financial capacity].

The requests will be made through the register's messaging system to the e-mail address of the participant's contact person indicated in the register. It is the responsibility of the participant to provide a valid e-mail address and to check it regularly.

The documents that may be requested by *the EU Validation Services* are listed in the EU Grants and Tenders Rules on Legal Entity Validation, LEAR appointment and Financial Capacity assessment.

Please note that a request for supporting documents by the *EU Validation Services* in no way implies that the tenderer has been successful.

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[26]. 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.

The e-Submission "quick guide for economic operators" is available after logging in with your EU Login password.

Information to be filled in

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

- **Signed declaration on Honour on Exclusion criteria.** All members of a joint tender, including subcontractors – if applicable – must upload the signed and dated declaration on honour on exclusion criteria using the template available here.
- **Signed declaration on Honour on Selection criteria.** In case of a joint offer from a group of economic operators, such declaration should be completed by the leading partner using the template available here.
- **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.

For detailed instructions on how to submit your tender, consult the Quick Reference Guide for Economic Operators where you will find:

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

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

Documents to be signed and dated while creating your Tender

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

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

- **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.

Re-submission of a tender

After submitting a tender, but within the time limit for receipt of tenders, you may still submit a new version of your tender. **If you submit a new Tender you must include all your Tender documents, including the Qualification and Tender documents.**

You must formally notify EFSA that the previous tender is withdrawn. The notification letter must be signed by the legal representative who signed the original tender stating the call reference and the Tender ID you wish to withdraw. The notification must be uploaded in e-submission together with the new version of all tender documents. You are kindly requested to also e-mail the notification letter to EFSAProcurement@efsa.europa.eu.

Withdrawal of tenders

If after submitting a tender, you wish to completely withdraw your tender, you must formally notify EFSA that you wish to withdraw your submitted Tender(s) as indicated above.

Alternative tender

You are entitled to send several tenders to one call for tenders.

Deadline for receipt of tenders

The tender (including all documents) must be fully uploaded and received before the deadline for receipt of tenders indicated in the invitation to tender. It is not possible to submit a tender through eSubmission after the time-limit for receipt of tenders indicated in the contract notice and/or the TED eTendering website.

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

- 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.

ANNEX 1 - FINANCIAL OFFER TEMPLATE – SEPARATE EXCEL FILE

The template to be used for preparing your financial offer is available as an Excel file and is uploaded in e-Tendering with all other procurement documents.

ANNEX 2 - DRAFT CONTRACT

The contract which results from this procurement procedure will be based on the model annexed to these tender specifications.