

# Tender specifications



# **TENDER SPECIFICATIONS**

Reference: OC/EFSA/BIOHAW/2023/02

**Subject:** Burden of zoonoses in European Union and EEA/EFTA countries

**Procurement procedure:** Open call (Article 164(1) (a) of the Financial Regulation)

Project/Process code: (PCODE EPA04.01.19, PNAME 04.01.19 Zoonoses)

**Budget Line:** 3210

### **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 <sup>1</sup>	Comments
Launch date	26/05/2023	Date Contract Notice is sent to Official Journal
Deadline for sending request for clarification to EFSA	06/09/2023 at 14:30 (CEST)	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	08/09/2023	
"Receipt Time Limit" - Closing date and time for receipt of offers	14/09/2023 at 14:30 (CEST)	Refer to the Invitation letter and part 3 of these tender specifications regarding how to submit your offer.
Opening session	15/09/2023 at 14:30 (CEST)	Requests to attend the virtual opening session must be made not later than 3 hours in advance of the opening session. Refer to Invitation letter for details.
Notification of evaluation results	Estimated October 2023	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 November 2023	

 $<sup>^{\</sup>rm 1}$  All times are in the time zone of Italy, the country in which EFSA is based.





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

#### 1.1 BACKGROUND

The joint annual EFSA-ECDC EU One Health Zoonoses reports of which the latest was published in December 2022<sup>2</sup>, give a comprehensive overview of trends and sources of zoonoses in the EU, after each year of joint efforts to reduce the burden of food-borne disease in the EU. These reports are underpinned by data that are collected yearly by the EU Member States and submitted to EFSA and ECDC. Data collection and reporting is mandatory, in accordance with List A of Annex I of Zoonoses Directive 2003/99/EC3, for eight foodborne zoonoses: campylobacteriosis, salmonellosis, listeriosis, infection with Shiga toxin-producing Escherichia coli (STEC), zoonotic tuberculosis<sup>4</sup>, brucellosis, trichinellosis and echinococcosis. In addition, based on the epidemiological situations in the EU Member States, data must be reported on other agents and zoonoses (List B of Annex I of the Zoonoses Directive), such as Yersinia. Yersiniosis is also foodborne and was the third most commonly reported zoonosis in humans in 2021, as during previous years. The ranking and trends of identified zoonoses give an indication of which zoonoses require priority action, based on incidence (confirmed annual cases) and case fatality in humans, on foodborne outbreak reporting rates, and on prevalence of contaminated food or infected animals. However, such zoonosis-specific assessments make it difficult to get an overall assessment of zoonoses burden to society, as the zoonoses and their consequences are heterogeneous in terms of mortality and morbidity.

To remediate the caveats inherent to decision-making based on surveillance data, methodology has been developed for burden of disease estimates. Human disease burden can be quantitatively estimated in Disability Adjusted Life Years (DALYs)<sup>5</sup> <sup>6</sup> <sup>7</sup>, which is a composite health measure of overall disease burden, expressed as the number of years lost due to ill-health, disability or early death. ECDC funded the 'Burden of Communicable Disease in Europe' (BCoDE) project that was carried out from 2009 to 2013 <sup>8</sup> <sup>9</sup>. An ECDC BCoDE toolkit<sup>10</sup> allows calculation of DALYs for a selection of 117 communicable diseases and six healthcare-associated infections.

<sup>&</sup>lt;sup>2</sup> EFSA and ECDC (European Food Safety Authority and European Centre for Disease Prevention and Control), 2022. The European Union One Health 2021 Zoonoses Report. EFSA Journal 2022;20(12):7666, 273 pp. https://doi.org/10.2903/j.efsa.2022.7666

<sup>&</sup>lt;sup>3</sup> Directive 2003/99/EC of the European Parliament and of the Council of 17 November 2003 on the monitoring of zoonoses and zoonotic agents, amending Council Decision 90/424/EEC and repealing Council Directive 92/117/EEC. OJ L 325, 12.12.2003 pp. 31–40.

<sup>&</sup>lt;sup>4</sup> Infection with Mycobacterium tuberculosis complex (focussing on M. bovis and M. caprae)

<sup>&</sup>lt;sup>5</sup> Murray CJ, Acharya AK. Understanding DALYs (disability-adjusted life years). J Health Econ 1997; 16(6):703-

<sup>&</sup>lt;sup>6</sup> Murray CJ, Lopez AD. Global mortality, disability, and the contribution of risk factors: Global Burden of Disease Study. Lancet 1997; 349(9063):1436-42

<sup>&</sup>lt;sup>7</sup> WHO estimates of the global burden of foodborne diseases: foodborne diseases burden epidemiology reference group 2007-2015: https://www.who.int/publications/i/item/9789241565165

 $https://www.ecdc.europa.eu/sites/default/files/media/en/publications/Publications/1106\_TER\_Burden\_of\_disease.pdf$ 

<sup>&</sup>lt;sup>9</sup> Cassini A, Colzani E, Pini A, Mangen M-J J, Plass D, McDonald SA, Maringhini G, van Lier A, Haagsma JA, Havelaar AH, Kramarz P, Kretzschmar ME, on behalf of the BCoDE consortium, 2018. Impact of infectious diseases on population health using incidence-based disability-adjusted life years (DALYs): results from the Burden of Communicable Diseases in Europe study, European Union and European Economic Area countries, 2009 to 2013. Euro Surveill. 2018;23(16):pii=17-00454. https://doi.org/10.2807/1560-7917.ES.2018.23.16.17-00454

<sup>&</sup>lt;sup>10</sup> ECDC, 2019. BCoDE toolkit [software application]. Version 1.7 Solna: European Centre for Disease Prevention and Control; 2019. Available from: <a href="https://www.ecdc.europa.eu/en/publications-data/toolkit-application-calculate-dalys">https://www.ecdc.europa.eu/en/publications-data/toolkit-application-calculate-dalys</a>



Zoonoses can cause a substantial burden not only on human health but also on animal health. Recently, methodology was published to estimate the societal burden of zoonotic diseases, which have substantial human and animal disease burden, and which can be accommodated within the DALY framework. The zoonosis DALYs (zDALY)<sup>11</sup> <sup>12</sup> combines the DALYs and the estimated burden of zoonotic disease in animals, the Animal Loss Equivalents (ALE), which is a metric that quantifies livestock fatal outcomes (deaths, or destruction or slaughter) and non-fatal ones (production losses). According to the Global Burden of Animal Diseases (GBADs) programme, a consortium of research and academic organisations co-led by the World Organisation of Animal Health (WOAH) and the University of Liverpool, the evaluation of the burden of animal diseases must be placed in an economic context that captures livelihood and wider economy impacts as well as externalities related to the environment and human health<sup>13</sup>. The GBADs analysts are building prototype dashboards which allow the user to explore the burden of animal diseases at global, sector and local levels <sup>14</sup> <sup>15</sup>. Globally, estimates of the dual (human and animal) burden of zoonoses are scarce<sup>16</sup>.

Zoonoses DALYs do not consider wider prevention and treatment costs of ill health in people and animals. Methodologies that could be used for risk ranking of food related hazards, on the basis of human health impact have been published<sup>17</sup>. In the context of the One Health European Joint Programme, the project COHESIVE delivered a review of economic analyses conducted on foodborne zoonoses, considering tangible (direct and indirect) and intangible disease costs<sup>18</sup>. Several interventions to control zoonoses are funded by centralised government institutions such as the European Union<sup>19</sup>.

Implementing a "One Health" approach<sup>20</sup> will require the characterisation and the quantification of the burden of zoonoses through integrated human and animal metrics. Information on this dual burden of zoonotic diseases in the EU would help setting priorities in European policy for control of zoonotic diseases. Therefore, EFSA and ECDC wish to investigate, in a One Health framework, the potential of the dual burden of zoonoses concept, estimate the zDALYs at European level and combine the dual burden of zoonoses with the economic costs that are not considered in zDALYs.

<sup>&</sup>lt;sup>11</sup> Shaw APM, Rushton J, Roth F, Torgerson PR. DALYs, dollars and dogs: how best to analyse the economics of controlling zoonoses. Rev Sci Tech. 2017 Apr;36(1):147-161. doi: 10.20506/rst.36.1.2618. PMID: 28926019.
<sup>12</sup> Torgerson Paul R., Rüegg Simon, Devleesschauwer Brecht, Abela-Ridder Bernadette, Havelaar Arie H., Shaw Alexandra P.M., Rushton Jonathan, Speybroeck Niko, 2018. zDALY: An adjusted indicator to estimate the burden of zoonotic diseases, One Health, Volume 5, 2018, Pages 40- 45, ISSN 2352-7714, https://doi.org/10.1016/j.onehlt.2017.11.003.

 $<sup>^{13}</sup>$  Global burden of animal diseases  $\underline{\text{https://animalhealthmetrics.org/}}$  and  $\underline{\text{https://bulletin.woah.org/?officiel=08-1-2-2020-2-gbads}}$ 

<sup>&</sup>lt;sup>14</sup> Rushton, J., Bruce, M., Bellet, C., Torgerson, P., Shaw, A., Marsh, T., Pigott, D., Stone, M., Pinto, J. & Mesenhowski, S. 2018. Initiation of global burden of animal diseases programme. The Lancet, 392, 538-540, available at https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(18)31472-7/fulltext <sup>15</sup> https://animalhealthmetrics.org/prototype-dashboards/

<sup>&</sup>lt;sup>16</sup> Noguera Z. LP, Charypkhan D, Hartnack S, Torgerson PR, Ruëgg SR (2022) The dual burden of animal and human zoonoses: A systematic review. PLoS Negl Trop Dis 16(10): e0010540. https://doi.org/10.1371/journal.pntd.0010540

<sup>&</sup>lt;sup>17</sup> 'H.J. van der Fels-Klerx, E.D. van Asselt, M. Raley, M. Poulsen, H. Korsgaard, L. Bredsdorff, M. Nauta,V. Flari, M. d'Agostino, D. Coles, L. Frewer. 2015. Critical review of methodology and application of risk ranking for prioritisation of food and feed related issues, on the basis of the size of anticipated health impact. EFSA supporting publication 2015:EN-710, 106 pp.' and is available online at https://www.efsa.europa.eu/en/supporting/pub/en-710.

<sup>18</sup> https://zenodo.org/record/5786027#.ZBGIKnbMKUl

<sup>&</sup>lt;sup>19</sup> EUROPEAN COMMISSION. 2021. National Veterinary Programmes [Online]. European Commission. Available: <a href="https://food.ec.europa.eu/horizontal-topics/funding-procurement-grants/food-chain-funding/funding-animal-health-measures/national-veterinary-programmes en <a href="https://ec.europa.eu/food/horizontal-topics/funding-procurement-grants/foodchain-funding/funding-animal-health-measures-1">https://ec.europa.eu/food/horizontal-topics/funding-procurement-grants/foodchain-funding/funding-animal-health-measures-1</a> en
<sup>20</sup> One Health High-Level Expert Panel (OHHLEP), Adisasmito WB, Almuhairi S, Behravesh CB, Bilivogui P,

One Health High-Level Expert Panel (OHHLEP), Adisasmito WB, Almuhairi S, Behravesh CB, Bilivogui P, Bukachi SA, et al. (2022) One Health: A new definition for a sustainable and healthy future. PLoS Pathog 18(6): e1010537. https://doi.org/10.1371/journal.ppat.1010537



This call is based on EFSA Founding regulation<sup>21</sup> and EFSA's 2023 Draft Work Programme for grants and operational procurements as presented in Annex XII of the Programming Document 2023 – 2025, available on the EFSA's website<sup>22</sup>. This procurement procedure links to the EFSA'S 2027 strategic objective 2 "Ensure preparedness for future risk analysis needs" and supports the expected operational results 2.1.3 "The quality of scientific guidance and methodologies, with the necessary risk assessment capabilities is improved to address future challenges" <sup>23</sup>.

#### 1.2 OBJECTIVES

The aim of this procurement procedure is to conclude on a four-year framework contract for the execution of specific tasks which will be requested under specific contracts as defined in these tender specifications. The objectives of the contract resulting from this procurement procedure are as follows:

- Objective 1: estimate the dual burden (zDALYs) of the following nine foodborne zoonoses in the EU Member States and EEA/EFTA countries: campylobacteriosis, salmonellosis, listeriosis, infection with Shiga toxin-producing *Escherichia coli* (STEC), zoonotic tuberculosis, brucellosis, trichinellosis, echinococcosis, and yersiniosis.
- Objective 2: estimate the possible tangible (direct and indirect costs) and intangible costs (referred to as COSTS hereafter) of human and animal disease, which are not considered in zDALYs, for the nine specified foodborne zoonoses.
- Objective 3: develop a methodological framework to combine the zDALYs and COSTS estimators into an overall estimator (referred to as OVERALL hereafter), for the specified nine foodborne zoonoses.

It is important that the developed methodology is readily understandable and of clear benefit to both public health and animal health sectors (win-win). Results should be clearly explained, and indicate the added value of the outcomes for both sectors and all stakeholders.

## 1.3 TASKS, DELIVERABLES, TIMELINE AND PAYMENTS

The contract resulting from this procurement procedure will be a framework contract. Under this framework contract, specific tasks and their deliverables will be requested under specific contracts. An <u>indicative</u> planning for the framework contract will be to issue 4 specific contracts in 4 years, where EFSA will request the contractor to carry out the below listed tasks, grouped in 7 work packages. An overview of general timelines and duration of the work packages' activities is in Figure 1.

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<sup>&</sup>lt;sup>21</sup> Regulation (EC) 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety, as amended by Regulation (EU) 2019/1381 of the European Parliament and of the Council of 20 June 2019 on the transparency and sustainability of the EU risk assessment in the food chain.

<sup>&</sup>lt;sup>22</sup> https://www.efsa.europa.eu/sites/default/files/2022-01/amp2325.pdf

https://www.efsa.europa.eu/sites/default/files/2021-07/efsa-strategy-2027.pdf



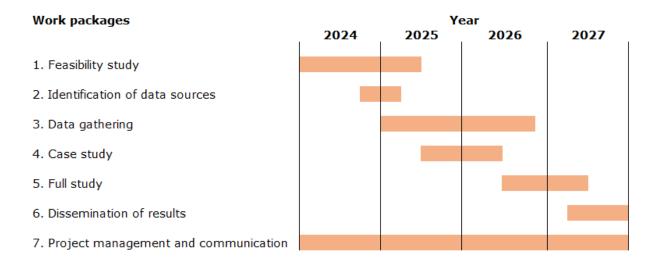


Figure 1. Overview of general timelines and duration of the work packages activities

A project manager should be nominated (see work package 7 and selection criteria). The project manager should monitor the project ensuring all tasks, milestones and deadlines are met and be responsible for internal communications, communications with EFSA and other external stakeholders/partners. The project manager is responsible for archiving all the deliverables and meeting minutes in a dedicated EFSA folder in a well-structured manner. The EFSA folder, accessible through Microsoft Teams and SharePoint will be specified at the signature of the contract.

The following work packages and tasks should contribute to achieve the objectives:

#### Work package 1: Feasibility study, of two selected zoonoses using publicly available data from at least three countries

Specific objectives of the feasibility study are:

- Review and synthesise the state-of-the-art in research on models for measuring
   a) the human disease burden in DALYs taking account of the outcome of the ECDC
   BCoDE project, b) the disease burden in animals in ALEs, and c) the dual burden
   of zoonoses (zDALYs).
- 2) Review and synthesise the state-of-the-art in research on models for measuring the possible tangible (direct and indirect costs) and intangible economic costs of human and animal disease (COSTS), which are not considered in the zDALYs. Examples of tangible costs of interest in human illness are a) cost of disease quantified in terms of cost of illness such as general practitioner visits, hospitalisation and treatment, or b) productivity losses. Examples in animal disease are a) control and eradication costs and b) losses due to trade and movement implications. Intangible costs of interest are, for example, loss of consumer confidence.
- 3) Develop a methodological framework to combine the zDALYs and the COSTS into an OVERALL estimator.
- 4) The state-of-the-art in research on models as specified in the specific objectives 1 and 2 should address key conceptual and methodological issues related to the project, with a focus on the nine specified foodborne zoonoses.
- 5) Test the envisaged methodology and estimate zDALYs, COSTS and OVERALL;
  - o for two of the nine specified zoonoses,
  - using publicly available data from at least three EU MS and/or EEA/EFTA countries.



The experience gained and outcomes of the feasibility study should enable the comprehensive planning and description of the specific activities of work packages 2, 3, 4 and 5.

#### Task 1.1: Draft a protocol for the feasibility study

Draft a **protocol** for the feasibility study, including problem formulation, method specification, a plan for implementation, with tasks, timelines, and reporting. All criteria for selection the two zoonoses and of the at least three countries should be specified.

#### Task 1.2: Draft a preliminary report on the feasibility study

Conduct the feasibility study and draft a **preliminary report**. The preliminary report should also list all needed data variables to underpin the estimation of zDALYs and of COSTS, highlight methodological challenges, and state assumptions and extrapolations made.

For the drafting of this preliminary report as well as for other contractual reports EFSA will provide a template (for 'external scientific' or 'technical' reports). In this report and other contractual scientific reports the results should be presented in a narrative form, and through tables, figures and/or diagrams. The rationale and assumptions made should be reported.

As regards models, all model(s) developed for the feasibility study, for the case study (work package 4), and for the full study (work package 5), should be formalised by defining model variables and parameters and linking them together into mathematical equations or algorithms. The result should be (a) formal, validated model(s), which may be a set of mathematical equations or a specification of the algorithms that translates into a computer code. The variables and parameters of the formal model should be described, including their meaning and units. The most important mathematical equations and model assumptions should be clearly described and justified. The model(s) should be translated into computer code. The computer code shall be written in an open-source language (e.g., R software, Python...). The computer code should be easily readable and accessible. It should be verified whether it correctly represents the developed model(s). This verification process should be clearly described. The code/scripts should be thoroughly checked by the modeller(s) and be made available to EFSA. A written model description of the computer code in the form of a detailed **technical annex** to all reports of the feasibility study, case study and full study, should be provided by the modeller(s), to enable EFSA staff and other users (e.g., risk assessors, researchers...) who may not have a solid training in mathematics or computer science, to understand the model/code structure. An executable version of the code should be also provided, so that EFSA evaluators can check whether they can replicate reported results (estimations of zDALYs, COSTS and OVERALL). All used data need to be delivered in a simple, easy-to-use standard spreadsheet software like for example Microsoft Excel.

# Task 1.3: Draft a final report on the feasibility study

Finalise the feasibility study and draft a **final report**. This report shall update the preliminary report, revised in accordance with the feedback received from stakeholders during the first workshop (Task 7.5).

#### Task 1.4: Draft a peer-reviewed article on the feasibility study

Draft an article for a peer-reviewed journal, informing on the feasibility study, to be published together with EFSA and ECDC.

Work package 2: Identification of data sources



#### Task 2.1: Draft a protocol for identifying data sources

Draft a **protocol** for identifying, using a systematic approach, all possible data sources and sources of information whether published or informal (grey literature, websites) sources or behind pay walls. The protocol should take account of the list of needed data in the preliminary report on the feasibility study (Task 1.2.). Points to be addressed in the protocol are;

- 1) problem formulation
- 2) Survey and interview methodologies, and other envisaged potential means (for example through literature review, crowdsourcing, but not necessarily restricted to those). The design of methods must be addressed in detail (for example in case of surveys whether these are online surveys or semi-structured interviews, or a mixed approach).
- 3) Contents of questionnaires inquiring for instance about the available data including the year the data pertain to, the type and format of the available data, and whether any fee needs to be paid (data behind pay wall), data quality, and data acquisition/usage criteria.
- 4) Exhaustive list of stakeholders, owning potential useful data(bases) to be surveyed, also targeting potential data providers whose data are not publicly available. Stakeholders can be for instance academic, governmental or private (for example farmers, food business operators), whether national or international. A suggestive, non-exhaustive list of possible data sources and information hubs is: EFSA<sup>24</sup> <sup>25</sup> <sup>26</sup> <sup>27</sup>, EFSA Partners and networks on food safety cooperation <sup>28</sup>, ECDC, ECDC Partners and networks<sup>29</sup>, EUROPEAN COMMISSION<sup>30</sup> (ADIS<sup>31</sup> and TRACES<sup>32</sup>), EUROSTAT, FAOSTAT, WOAH Collaborating Centre for the Economics of Animal Health - Europe Region, WHO, European Burden of Disease Network (COST Action CA18218), UN COMTRADE, The World Bank, European Professional Agricultural and Husbandry Organisations, European farmers and other professional organisations, EU Almanac<sup>33</sup>, National public health agencies, National food safety agencies, National institutes of statistics.
- 5) plan for implementation, with tasks, timelines, and reporting (Task 2.2).

#### Task 2.2: Draft a report on the identified data sources

Conduct the identification of all possible data sources (Task 2.1) and draft a **report**, taking account of the feedback received from stakeholders during the first workshop (Task 7.5) on the protocol for identifying all possible data sources. Points to be addressed in the report are;

- 1) Present an updated exhaustive list of stakeholders, who could provide potentially useful data.
- 2) The list of identified data sources and sources of information, which should be assessed in terms of data accessibility. When the data are accessible (even partially) or when sufficient information can be retrieved, the data quality (e.g., accuracy, completeness, timeliness etc.) and format should be assessed in a systematic and predefined way. The identified data sources and all the relevant information of their assessment should be organised in an inventory. The inventory

<sup>&</sup>lt;sup>24</sup> https://efsa.onlinelibrary.wiley.com/doi/abs/10.2903/j.efsa.2022.7666

<sup>&</sup>lt;sup>25</sup> SIGMA toolbox: https://www.efsa.europa.eu/en/topics/topic/animal-health-data-collection-sigma#toolbox

<sup>&</sup>lt;sup>26</sup> Relevant EFSA scientific outputs, including Scientific Opinions

<sup>&</sup>lt;sup>27</sup> https://www.efsa.europa.eu/sites/default/files/stakeholders-registered-list.pdf

<sup>&</sup>lt;sup>28</sup> https://www.efsa.europa.eu/en/about/partnersnetworks

<sup>&</sup>lt;sup>29</sup> https://www.ecdc.europa.eu/en/about-us/ecdcs-partnerships-and-networks

<sup>&</sup>lt;sup>30</sup> EUROPEAN COMMISSION. 2021. National Veterinary Programmes [Online]. European Commission. Available at: https://food.ec.europa.eu/horizontal-topics/funding-procurement-grants/food-chain-funding/fundinganimal-health-measures/national-veterinary-programmes\_en

<sup>31</sup> https://food.ec.europa.eu/animals/animal-diseases/animal-disease-information-system-adis\_en

<sup>32</sup> https://food.ec.europa.eu/animals/traces\_en

<sup>33</sup> https://www.bfr.bund.de/cm/364/eu-food-safety-almanac.pdf



- should be structured according to a data model that will take into account existing standards developed by EFSA and can be adapted to specific needs by the contractor upon EFSA requirements and agreed with EFSA.
- 3) Clarification of processes and provision of recommendations for data access and data acquisition.
- 4) Evaluation of the data handling and management, and description of any need to transform available data in useable datasets, for instance through web scraping.

#### Work package 3: Data gathering

# Task 3.1: Draft protocols for a systematic literature and data review, for collecting other data, for an expert knowledge elicitation, and for a case study of one selected zoonosis

The data gathering is composed of a) a systematic literature and data review, b) collecting other data, and c) an expert knowledge elicitation.

Task 3.1 is to draft **protocols** for a) a systematic literature and data review, b) for the collection of data other than those sourced by the literature and data review, c) for an expert knowledge elicitation and d) for the case study (work package 4). Each of the four protocols should include the problem formulation, method specification, a plan for implementation, with tasks, timelines, and reporting. In a One Health approach, all information should be collected across human and animal sectors, and public health and animal health economic domains. Specific points to be addressed are;

- 1) in the **protocol for a systematic literature and data review** (scientific literature including articles, conference papers, books), which need to be conducted in a systematic way:
  - a. compliance with EFSA's guidance `Systematic review methodology and food and feed safety risk assessment'<sup>34</sup> (for example language limits)
  - addressed questions, which should be informed by the experience gained in and outcomes of work package 1 and 2 (such as review of estimates, of available data and/or any other source of information, and of zDALYs and of COSTS)
  - c. data acquisition, data storage and management, data sharing agreements (in case owner is private), and data handling (types of data, timelines)
- 2) in the **protocol for the collection of relevant data** other than those sourced by the literature and data review:
  - a) addressed questions, which should be informed by the experience gained in and outcomes of work package 1 and 2 (such as review of estimates, of available data and/or any other source of information, and of zDALYs and of COSTS)
  - b) data acquisition, data storage and management, data sharing agreements (in case owner is private), and data handling (types of data, timelines)
- 3) in the protocol for an expert knowledge elicitation:
  - addressed questions should be informed by the results of a) the systematic literature and data review, and b) the collection of data other than those sourced by the literature and data review. It is anticipated that expert knowledge elicitation may be useful for weighing evidence related to health parameters, whether public or animal health.
- 4) in the **protocol for the case study**: the selection of one of the nine specified foodborne zoonoses. The criteria for the selected zoonosis should be specified

#### Task 3.2: Conduct the systematic literature and data review and draft a report

<sup>&</sup>lt;sup>34</sup> European Food Safety Authority; Application of systematic review methodology to food and feed safety assessments to support decision making. EFSA Journal 2010; 8(6):1637. [90 pp.]. doi:10.2903/j.efsa.2010.1637. Available online: www.efsa.europa.eu



Conduct the systematic literature and data review and draft a **report**, which should include an assessment of the suitability of the collected data and information. Moreover, the results will be collected in a flexible/searchable database with easy external access to retrieve the numerical information needed. This inventory should be structured according to a data model that will take into account existing standards developed by EFSA and can be adapted to specific needs by the contractor upon EFSA requirements and agreed with EFSA. It will include separate tables for the defined data. These tables should be linked to the original report/paper or data source using appropriate metadata (title, author, publication year etc.).

# **Task 3.3: Conduct the expert knowledge elicitation and draft a report** Conduct the expert knowledge elicitation and draft a **report**.

#### Task 3.4: Gather all needed data and draft a report

Gather all data (Task 3.1) focussing firstly on the zoonosis selected for the case study. In a second phase all data need to be gathered for the eight zoonoses for the full study (work package 5). Draft a **report**, which should detail the correspondence with stakeholders, list data agreements with private entities as appropriate, discuss and interpret the available data and their limitations, identify key knowledge gaps related to measuring the zDALYs and COSTS in the EU MS and EEA/EFTA countries and make suggestions for how best to overcome them.

 Work package 4: Case study of one selected zoonosis using all gathered data from all countries

#### Task 4.1: Draft a preliminary report on the case study

Conduct the case study, taking into account the information and experience gained in WP1, WP2 and WP3 as well as the feedback received from stakeholders during the second workshop (Task 7.6) on the protocol for the case study. Findings from the literature and data review should be formatted to inform the methodology development. Draft a **preliminary report**, including the detailed **technical annex** with the used, validated model(s) in accordance with requirements spelled out in Task 1.2.

#### Task 4.2: Draft a final report on the case study

Finalise the case study and draft a **final report**, taking into account the feedback received from stakeholders during the third workshop (Task 7.7) on the preliminary report on the case study. The estimations of zDALYs, COSTS and OVERALL for the selected zoonosis using all gathered data from for all countries (EU MS or EEA/EFTA countries) should be final. This report should highlight methodological challenges, state assumptions and extrapolations made, and address uncertainty from limitations in the case study using appropriate analyses (scenario analysis, sensitivity analysis to identify sub-sets of parameters that have relatively large effects on the model, other). The detailed **technical** annex with the used, validated model(s) in accordance with requirements spelled out in Task 1.2 should be updated. Moreover, this report must also include a proposal for **protocol for the full study** of the eight zoonoses not addressed in the case study, including problem formulation, method specification, a plan for implementation, with tasks, timelines, and reporting. The full study ought to take into account the finetuned methodology of the case study, and should be based on all gathered data from for all countries (EU MS or EEA/EFTA countries) on the eight zoonoses not addressed by the case study.

 Work package 5: Full study of eight zoonoses using all gathered data from all countries



#### Task 5.1: Draft a preliminary report on the full study

Conduct the full study of the eight zoonoses not addressed in the case study estimating zDALYs, COSTS and OVERALL, taking into account the information and experience gained in work packages 1, 2, 3 and 4, and draft a **preliminary report**, including the detailed **technical annex** with the used, validated model(s) in accordance with requirements spelled out in Task 1.2.

#### Task 5.2: Draft a final report on the full study

Finalise the full study, taking into account the feedback received from stakeholders during the fourth workshop (Task 7.8) on the preliminary report on the full study, and draft a **final report**. This report should highlight methodological challenges, state assumptions and extrapolations made, and address uncertainty from limitations in the full study using appropriate analyses (scenario analysis, sensitivity analysis, other). It should further include recommendations for future research and action, also based on the outcome of the case study. It moreover needs to include the detailed **technical annex** with the used, validated model(s) in accordance with requirements spelled out in Task 1.2.

#### Task 5.3: Toolkit and documentation

All final, validated models, developed under work package 1 and finetuned under work packages 3 and 4 should be documented in the detailed technical annexes of the reports. They should be delivered as a stand-alone software application (toolkit) that allows estimations of all parameters (zDALYs, COSTS and OVERALL) for the nine specified foodborne zoonoses. Together with the toolkit also a user friendly manual on how to run the model(s) should be provided. All used data need to be delivered in a simple, easy-to-use standard spreadsheet software like for example Microsoft Excel.

The toolkit, data and user manual will be made available on the EFSA's Knowledge Junction<sup>35</sup> platform.

# Task 5.4: Draft a peer-reviewed article on final merged results of the case study and of the full study

Draft an article for a peer-reviewed journal, informing on the final results for the nine zoonoses, to be published together with EFSA and ECDC.

#### Work package 6: Dissemination of results

The results of the burden of zoonoses project should be disseminated to all stakeholders and to the public. To this end, one or more online data visualisation products need be developed and a webinar organised.

The online data visualisation products, for example story maps, should present general and specific information on all project parameters (zDALYs, COSTS, and OVERALL) and results. It is further important to inform the general public in these data visualisation products on the underlying principles of the One Health approach<sup>36</sup> while referencing authoritative sources. Benefits to both public health and animal health sectors should be clearly explained. All displayed information should be readily understandable to the general public.

Examples of data visualisation products are EFSA zoonoses story maps, some of which that can be found at : <a href="https://www.efsa.europa.eu/en/news/zoonotic-diseases-and-foodborne-outbreaks-rise-still-below-pre-pandemic-levels">https://www.efsa.europa.eu/en/news/zoonotic-diseases-and-foodborne-outbreaks-rise-still-below-pre-pandemic-levels</a>. The EFSA zoonoses story maps

<sup>35</sup> https://zenodo.org/communities/efsa-kj/about/

<sup>&</sup>lt;sup>36</sup> One Health High Level Expert Panel (OHHLEP) has developed an over-arching Theory of Change (https://www.who.int/publications/m/item/one-health-theory-of-change)



are built using the ArcGIS StoryMaps software, which is part of the ArcGIS Online cloud platform provided by ESRI, and they have the same layout used in 'ESRI products – ArcGIS StoryMaps' (available at https://storymaps.arcgis.com).

# Task 6.1: Requirements analysis for one or more interactive data visualisation product(s)

Conduct and deliver a requirements analysis for one or more interactive data visualisation product(s) to be built presenting the burden of zoonoses project results. This plan shall include formal and technical checking and testing in order to ensure global consistency and coherence as well as proper functioning on the relevant platform(s).

# Tasks 6.2, 6.3, 6.4 and 6.5: First, second, third and final versions of the online data visualisation product(s)

Provide respectively the first, second, third and final versions of interactive data visualisation product(s) for review.

# Task 6.6: Organise the webinar to present the project results and demonstrate the toolkit

Present the project and the toolkit in a webinar to train the users. The contractor will take care of preparing the training materials, which should be shared at the latest three weeks prior to the webinar with EFSA. A video tutorial should be made based on the recorded webinar.

# • Work package 7: Project management and communication

#### Task 7.1: Project management and project communication

Monitor the project ensuring all tasks, milestones and deadlines are met, taking care of internal communications, communication with EFSA, ECDC and other external stakeholders/partners. Archive all the deliverables and meeting minutes on the dedicated EFSA SharePoint folder, well-structured per Service Contract. EFSA will create a MS TEAM for internal communication and a SharePoint folder to archive the deliverables.

The Project Leader will make sure at the start of every year of contract that the policies for operation (e.g. use of document management system of EFSA for archiving documents, data, data visualisations, codes, other) are agreed by all parties involved.

#### **Task 7.2: Organise management web-meetings**

Organise monthly management web-meetings with EFSA and ECDC staff, and with relevant consortium members (if applicable) to discuss the project progress, the draft and final deliverables and discuss and agree on possible problems and solutions.

These meetings will last maximum 4 hours. The contractor will take care of setting the meeting appointment, uploading a draft agenda (Word file to be uploaded on the EFSA SharePoint folder one week prior to the meeting) and drafting brief minutes of maximum 3 pages latest 3 working days after the meeting.

## Task 7.3. Organise technical web-meetings

Organise technical web-meetings with EFSA and ECDC staff, relevant consortium members (if applicable) and possibly external experts (identified after agreement with EFSA) to discuss the **protocols** and other methodological issues, as well as preliminary and/or final reports. These meetings will last maximum 4 hours. The contractor will take care of setting the meeting appointment, uploading a draft agenda (Word file to be uploaded on the EFSA SharePoint folder one week prior to the meeting) and drafting minutes of maximum 5 pages, latest 3 working days after the meeting.

#### Task 7.4. Organise on-site, technical meetings



Organise an on-site, technical meeting with EFSA and ECDC staff, relevant consortium members (if applicable) and possibly external experts (identified after agreement with EFSA) to discuss the **protocols** and other methodological issues, as well as preliminary and/or final reports.

These meetings will last maximum 8 hours, in a location that requires the least traveling for all participants. The first on-site, technical meeting issued under the specific contract will be the **kick-off meeting**. The contractor will take care of setting the meeting appointment, uploading a draft agenda (Word file to be uploaded on the EFSA SharePoint folder two weeks prior to the meeting) and drafting brief minutes of maximum 8 pages, latest 3 working days after the meeting. The meeting room should be booked and paid by the contractor. Hotel, indemnities and travel costs should be covered by the contractor (except for staff working for EU or UN institutions) for maximum 5 persons.

#### Task 7.5: Organise the first workshop

Organise the first workshop for EU Members States and EEA/EFTA countries and other stakeholders to present and discuss: a) the preliminary report on feasibility study (Task 1.2) and b) the protocol for identification of data sources study (Task 2.1). Collect the preferences of stakeholders for the various criteria.

### Task 7.6: Organise the second workshop

Organise the second workshop for EU Members States and EEA/EFTA countries and other stakeholders to present and discuss a) the report on the identified data sources (Task 2.2, and b) the protocols for a systematic literature and data review, for gathering other data, for an expert knowledge elicitation, and for a case study (Task 3.1). Collect the preferences of stakeholders for the various criteria.

#### Task 7.7: Organise the third workshop

Organise the third workshop for EU Members States and EEA/EFTA countries and other stakeholders to present and discuss the preliminary report on the case study (Task 4.1). The reports on the systematic literature and data review (Task 3.2) and on the expert knowledge elicitation (Task 3.3) should be presented. Collect the preferences of stakeholders for the various criteria.

#### Task 7.8: Organise the fourth workshop

Organise the fourth workshop for EU Members States and EEA/EFTA countries and other stakeholders to present and discuss a) the preliminary report on the full study (Task 5.1), and the first versions of the data visualisation product(s) (Task 6.2). The report on the data gathering (Task 3.4) should be presented. Collect the preferences of stakeholders for the various criteria.

INDICATIVE PLANNING			
Work Package	Tasks	Deliverables	Indicative deadline
First year of cor	ntract		
WP 1 feasibility study	Task 1.1: Draft a protocol for the feasibility study	<b>Deliverable 1.1</b> : The draft protocol for feasibility study sent for approval by email to EFSA	3 months after entry into force of first specific contract



WP 1 feasibility study	<b>Task 1.2:</b> Draft a preliminary report on the feasibility study	<b>Deliverable 1.2</b> : The preliminary report on feasibility study sent for approval by email to EFSA	9 months after entry into force of first specific contract
WP 2 identification of data sources	Task 2.1: Draft a protocol for identifying data sources	<b>Deliverable 2.1</b> : The draft protocol for identifying data sources sent for approval by email to EFSA	10 months after entry into force of first specific contract
WP 7 Project management	Task 7.5: Organise the first workshop	<b>Deliverable 7.5</b> : The first workshop report sent for approval by email to EFSA	11 months after entry into force of first specific contract
WP 7 project management	Task 7.1: Project management and communication	Deliverable <b>7.1</b> : Project management and communication activities performed, report on executed tasks	Continuous activity
WP 7 project management	<b>Task 7.2:</b> Organise management webmeetings	Deliverable <b>7.2</b> : Management web-meetings organised	Every month after entry into force of specific contract, until the end of the specific contract
WP 7 project management	Task 7.3: Organise technical web- meetings	Deliverable <b>7.3</b> : Technical web-meetings organised	Ad-hoc, exact deadline depending on the specific contract
WP 7 project management	<b>Task 7.4:</b> Organise on-site, technical meetings	Deliverable <b>7.4</b> : On-site, technical meetings organised	Ad-hoc, exact deadline depending on the specific contract
Second year of	contract		
WP 2 identification of data sources	Task 2.2: Draft a report on the identified data sources	<b>Deliverable 2.2</b> : The report on identified data sources sent for approval by email to EFSA	2 months after entry into force of second specific contract
WP 3 data gathering	Task 3.1: Draft protocols for a systematic literature and data review, for collecting other data, for an expert knowledge elicitation, and for a case study	<b>Deliverable 3.1</b> : The draft protocols for a systematic literature and data review, for collecting other data, for an expert knowledge elicitation, and for a case study sent for approval by email to EFSA	2 months after entry into force of second specific contract



WP 7 Project management	Task 7.6: Organise the second workshop	<b>Deliverable 7.6</b> : The second workshop report sent for approval by email to EFSA	3 months after entry into force
management		sent for approval by email to Li SA	of second specific contract
WP 1 feasibility study	Task 1.3: Draft a final report on the feasibility study	<b>Deliverable 1.3</b> : The final report on feasibility study sent for approval by email to EFSA	4 months after entry into force of second specific contract
WP 1 feasibility study	<b>Task 1.4</b> : Draft a peer-reviewed article on the feasibility study	<b>Deliverable 1.4</b> : The draft article for a peer-reviewed journal sent for approval by email to EFSA	6 months after entry into force of second specific contract
WP 3 data gathering	<b>Task 3.2</b> : Conduct a systematic literature and data review and draft a report	<b>Deliverable 3.2</b> : The report on systematic literature review sent for approval by email to EFSA	9 months after entry into force of second specific contract
WP 3 data gathering	<b>Task 3.3</b> : Conduct an expert knowledge elicitation and draft a report	<b>Deliverable 3.3</b> : The report on expert knowledge elicitation sent for approval by email to EFSA	12 months after entry into force of second specific contract
WP 7 project management	<b>Task 7.1:</b> Project management and communication	Deliverable <b>7.1</b> : Project management and communication activities performed, report on executed tasks	Continuous activity
WP 7 project management	<b>Task 7.2:</b> Organise management webmeetings	Deliverable <b>7.2</b> : Management web-meetings organised	Every month after entry into force of specific contract, until the end of the specific contract
WP 7 project management	<b>Task 7.3:</b> Organise technical webmeetings	Deliverable <b>7.3</b> : Technical web-meetings organised	Ad-hoc, exact deadline depending on the specific contract
WP 7 project management	<b>Task 7.4:</b> Organise on-site, technical meetings	Deliverable <b>7.4</b> : On-site, technical meetings organised	Ad-hoc, exact deadline depending on the specific contract
Third year of co.	ntract		



WP 4 case study of one selected zoonosis	Task 4.1: Draft a preliminary report on the case study	<b>Deliverable 4.1:</b> The preliminary report on the case study sent for approval by email to EFSA	2 months after entry into force of third specific contract
WP 7 Project management	Task 7.7: Organise the third workshop	<b>Deliverable 7.7</b> : The third workshop report sent for approval by email to EFSA	3 months after entry into force of third specific contract
WP 4 case study of one selected zoonosis	Task 4.2: Draft a final report on the case study	<b>Deliverable 4.2</b> : The final report on case study sent for approval by email to EFSA	7 months after entry into force of third specific contract
WP 6 dissemination of results	Task 6.1: Requirements analysis for one or more interactive data visualisation product(s)	<b>Deliverable 6.1</b> : The report on requirements analysis sent for approval by email to EFSA	10 months after entry into force of third specific contract
WP 3 data gathering	Task 3.4: Gather all needed data and draft a report	<b>Deliverable 3.4</b> : The report on data gathering sent for approval by email to EFSA	11 months after entry into force of third specific contract
WP 7 project management	Task 7.1: Project management and communication	Deliverable <b>7.1</b> : Project management and communication activities performed, report on executed tasks	Continuous activity
WP 7 project management	Task 7.2: Organise management web- meetings	Deliverable <b>7.2</b> : Management web-meetings organised	Every month after entry into force of specific contract, until the end of the specific contract
WP 7 project management	Task 7.3: Organise technical web- meetings	Deliverable <b>7.3</b> : Technical web-meetings organised	Ad-hoc, exact deadline depending on the specific contract
WP 7 project management	Task 7.4: Organise on-site, technical meetings	Deliverable <b>7.4</b> : On-site, technical meetings organised	Ad-hoc, exact deadline depending on the specific contract
Fourth year of o	contract		



WP 5 full	Task 5.1: Draft a preliminary report on	<b>Deliverable 5.1</b> : The preliminary report on the	2 months after
study of eight zoonoses	the full study	full study sent for approval by email to EFSA	entry into force of fourth specific contract
WP 6 dissemination of results	Task 6.2: First versions of online data visualisation product(s)	<b>Deliverable 6.2</b> : The first versions of online data visualisation product(s) provided for approval to EFSA	2 months after entry into force of fourth specific contract
WP 7 Project management	Task 7.8: Organise the fourth workshop	<b>Deliverable 7.8</b> : The fourth workshop report sent for approval by email to EFSA	4 months after entry into force of fourth specific contract
WP 6 dissemination of results	<b>Task 6.3:</b> Second versions of online data visualisation product(s)	<b>Deliverable 6.3</b> : The second versions of online data visualisation product(s) provided for approval to EFSA	5 months after entry into force of fourth specific contract
WP 5 full study of eight zoonoses	Task 5.2: Draft a final report on the full study	<b>Deliverable 5.2</b> : The final report on the full study sent for approval by email to EFSA	7 months after entry into force of fourth specific contract
WP 6 dissemination of results	<b>Task 6.4:</b> Third versions of online data visualisation product(s)	<b>Deliverable 6.4</b> : The third versions of online data visualisation product(s) provided for approval to EFSA	7 months after entry into force of fourth specific contract
WP 5 full study of eight zoonoses	Task 5.3: Provide toolkit	<b>Deliverable 5.3</b> : The toolkit provided for approval by email to EFSA	8 months after entry into force of fourth specific contract
WP 6 dissemination of results	Task 6.5: Final versions of online data visualisation product(s)	<b>Deliverable 6.5</b> : The final versions of online data visualisation product(s) provided for approval to EFSA	8 months after entry into force of fourth specific contract
WP 5 full study of eight zoonoses	<b>Task 5.4</b> : Draft a peer-reviewed article on final merged results of the case study and of the full study	<b>Deliverable 5.4</b> : The draft article for a peer-reviewed journal on final results for the nine zoonoses sent for comments and review by email to EFSA	9 months after entry into force of fourth specific contract
WP 7 project management	<b>Task 6.6:</b> Organise the webinar to present the project results and demonstrate the toolkit	Deliverable <b>6.6</b> : Webinar organised and video tutorial produced	11 months after entry into force of fourth specific contract



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WP 7 project management	Task 7.1: Project management and communication	Deliverable <b>7.1</b> : Project management and communication activities performed, report on executed tasks	Continuous activity
WP 7 project management	Task 7.2: Organise management web- meetings	Deliverable <b>7.2</b> : Management web-meetings organised	Every month after entry into force of specific contract, until the end of the specific contract
WP 7 project management	Task 7.3: Organise technical web- meetings	Deliverable <b>7.3</b> : Technical web-meetings organised	Ad-hoc, exact deadline depending on the specific contract
WP 7 project management	<b>Task 7.4:</b> Organise on-site, technical meetings	Deliverable <b>7.4</b> : On-site, technical meetings organised	Ad-hoc, exact deadline depending on the specific contract

Subcontracting is allowed for all tasks.

No.	Meetings	Deadline for finalisation
1	FWC Kick-off meeting, after FWC signature A first kick off meeting (teleconference) must be held within 1 month after the entry into force of the FWC. The aim of this meeting is to have a first discussion between the contractor and EFSA for a clear understanding of the objectives of the project, the tasks to be performed, the deliverables, timeframe, scope, etc. In addition, administrative and financial matters related to contract implementation will also be discussed. The minutes of the kick off meeting shall be taken and provided to EFSA by the contractor at the latest 2 weeks after the meeting. Expenses linked to this kick off meeting will be borne by the contractor.	Within 1 month after entry into force of FWC
2	Management web-meetings: Discuss the progress and agree on solutions for problems that occurred during the implementation of the project	Every month after entry into force of specific contract, until the end of the specific contract
3	Technical web-meetings: Discuss the protocols and other methodological issues, as well as preliminary and/or final reports. EFSA estimates 3 technical web meetings per year.	Ad-hoc, depending on the specific contract
4	On-site, technical meeting: Discuss the protocols and other methodological issues, as well as preliminary and/or final reports.  EFSA estimates 3 on-site technical web meetings per year (the 1st one being the specific contract kick-off meeting to be held within 3 weeks from entry into force of specific contract).	Ad-hoc, depending on the specific contract
No.	Payments	Linked to EFSA approval of deliverable No.
	The payment modalities applicable to each specific contract / order form are detailed in the draft framework contract.	NA



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

Tenderers should note that the draft contract is published with the call for tenders. In the event that any tenderer should have specific comments on the provisions of the draft contract, these must be raised in a clarification, prior to the deadline for receipt of tenders so that a clear and transparent reply may be published for the benefit and information of all tenderers.

**Nature of expense** services

**Type of contract** framework (FWC)

**Type of FWC** single FWC

<u>Place of performance</u> contractor's premises

#### **Duration of FWC**

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

The financial ceiling available for specific contracts/order forms under the framework contract during an overall maximum period of 4 consecutive years is **2.200.000 €.** A contingency of 10% and possible price indexations are already included in this ceiling.

#### 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 of  $2.200.000 \, \text{€}$ .

#### **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 / Order Forms. The specific contract/order form will be placed according to Article 1.4.3 of the draft FWC (Annex 2)

#### 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

In the specific case of literature reviews, should the entirety or partial texts covered by pre-existing rights be used in the final deliverables for EFSA the Contractor shall consult with copyright licensing authorities (i.e. at national level) for guidance on purchasing copyright licenses to reproduce any publications provided to EFSA. The contractor remains solely responsible and liable for obtaining all necessary authorizations and rights to use, reproduce and share the publications provided to EFSA".

In practical terms in the context of systematic reviews, EFSA requires a list of references to be provided as part of the deliverables that does not entail any copyright issues. In addition in case of systematic reviews full texts may be shared with EFSA for the sole purpose of assessing the completeness of deliverables. Full texts will not be part of final deliverables

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 <a href="Knowledge Junction37">Knowledge Junction37</a> 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.

<sup>&</sup>lt;sup>37</sup> http://www.efsa.europa.eu/en/press/news/190117 and https://zenodo.org/communities/efsa-ki/?page=1&size=20





#### 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')<sup>38</sup>. 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 sub-processor.

<u>Processing of personal data by EFSA as contracting authority (controller)</u>

Information on the processing of personal data by EFSA as contracting authority in charge of the present procurement procedure is available in the <u>Privacy Statement</u> 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 webinar and workshop participants, for the conduct of the webinars and workshops 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 IT tool or e-learning platform and/or publication or hosting platform proposed by the contractor or subcontractor, including 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 centers 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

<sup>38</sup> https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32018R1725



Court of Justice of the European Union, i.e. the so-called 'Schrems II' case <u>C-311/18</u> and <u>the Recommendations 01/2020 on measures that supplement transfer tools to ensure compliance with the EU level of protection of personal data</u>, issued by the European Data Protection Board;

- IT systems used should be certified for information security ISO 27001 or SOC 2 certification or equivalent.
- 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 predefined order: Exclusion criteria (Access to EU Market); Selection criteria (Technical & Professional capacity); Compliance with tender specifications; Award Criteria (Quality and Price).

Following the above assessment and identification of the winning tenderer, the following will be assessed only for the tenderer proposed for contract award: Selection criteria (Professional Conflict of Interest – Institutional and Individual Declarations of Interest); Exclusion criteria (Declaration on Honour, section A); Selection criteria (Economic and financial capacity-Declaration on Honour, section B).

Evidence under sections 2.3.2 and 2.4(A) will be requested in the award letter for the winning tenderer and assessed prior to contract signature. Such evidence 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

Criterion No. 2.3	Requirements and requested evidence
1	Eligibility – access to EU Market
	Requirements:
	Only offers from <b>tenderers</b> established in eligible countries will be allowed to the next step of the evaluation. Please refer to the <b>EFSA Guidance for tenderers</b> for further details <sup>39</sup> .
	By submitting an offer, tenderers (including partners and/or subcontractors) confirm that they are not subject to EU restrictive measures adopted under Article 29 of the Treaty on the European Union (TEU) or Article 215 of the Treaty on the Functioning of the EU (TFEU) <sup>40</sup> . EFSA reserves the right to refer

<sup>&</sup>lt;sup>39</sup> Please note that Procurement procedures of EFSA are not covered by the WTO Multilateral Government Procurement Agreement (GPA).

<sup>&</sup>lt;sup>40</sup> The EU Official Journal contains the list of entities subject to restrictive measures and is regularly updated.





Administrative data forms (including LEF and BAF): available here
Requested evidence:
to publicly available information to check whether an organization is subject to EU restrictive measure. The prohibition of being subject to EU restrictive measures applies throughout the whole performance of the contract.

Criterion No. 2.3	Requirements and requested evidence
2	Exclusion
	Requirements:
	Tenderers must not be in one of the exclusion situations listed in article 136 of the Financial Regulation, explained in the <u>EFSA Guidance for tenderers</u> .
	Requested evidence:
	<b>Declaration on Honour (section A):</b> Tenderers must declare that they are not in one of the exclusion situations by providing a signed and dated <b>Declaration on Honour</b> , available <a href="here">here</a> . 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 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

# A) Economic and financial capacity

Criterion No. <b>2.4.A</b>	Requirements and requested evidence
1	Minimum economic and financial capacity
	Requirements:
	The tenderer must have generated an overall annual turnover of at least 600.000 € in each of the last 3 closed financial years (2021 and 2020).



Requested evidence:
<b>Declaration on Honour (economic and financial capacity section B):</b> Tenderers must declare they fulfil the economic and financial capacity by providing a signed and dated <b>Declaration on Honour</b> , available <a href="here">here</a> . In case of a joint offer from a group of economic operators, such declaration should be completed by the leading partner only.

In addition to the evidence requested above, 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.

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.

In the event of partners in a joint offer or subcontractors providing the financial capacity, if during contract implementation, there is a request to change a subcontractor or to assign 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) Professional and Technical professional capacity

Criterion No. <b>2.4.B</b>	Requirements and requested evidence
1	Professional capacity: overall at organisational level
	Requirements:
	The tenderer overall must have extensive and demonstrable experience in a. international project management of multidisciplinary b. epidemiology of foodborne zoonoses c. development of epidemiological models d. development of public health and animal health economic models e. data collection, data management and summary report production f. development of online data visualisation products, for example story maps g. communication, notably the ability to communicate complex epidemiological and economic concepts and results to a variety of stakeholders
	Requested evidence:
	A list of major projects or publications related to the subject matter of this contract, carried out in the course of the past 5 years
2	Professional capacity: Ability to provide a team of experts compliant with these specific expertise requirements
	Requirements:



One expert can cover more than one of the profiles below, but the minimum number of team experts is 10.

a) 1 senior expert with at least 5 years of experience in **burden of disease estimation**, who will act as project manager. The project manager will be responsible for the overall contact, management, and coordination of the implementation of all tasks and deliverables requested by EFSA in this call for tender. He/she should have experience in the coordination of at least 2 large-scale projects (≥100.000 €) and in the management of teams of at least 5 people;

The project manager shall be available for monthly progress management meetings/teleconference with EFSA. A back up shall also be nominated. The project manager is assisted by the work package leaders.

- b) 1 expert with at least 3 years of experience in **One Health**<sup>41</sup> research/implementation.
- c) 3 experts with at least 2 years of experience in the epidemiology of the foodborne **zoonoses** mentioned in Objective 1. The combined experience should cover all the nine foodborne zoonoses.
- d) 2 experts, whereof one junior, with respectively at least 5 and 2 years of experience in **quantitative epidemiologic modelling**, notably the ability to develop and use models to estimate disease burden (human disease burden, animal disease burden), with their combined experience covering the public health, food safety and animal health domain; one of both experts shall demonstrate knowledge and experience (at least 2 years) of relevant programming languages used in EFSA, such as R software or Python;
- e) 2 experts, whereof one junior, with respectively at least 5 and 2 years of experience in **quantitative economic modelling**, notably the ability to develop and use models to estimate costs of impacts of diseases in humans and in animals, with their combined experience covering public health, food safety and animal health domain; one of both experts shall demonstrate knowledge and experience (at least 2 years) of relevant programming languages used in EFSA, such as R software or Python;
- f) 1 expert with at least 3 years of experience in carrying out consultation activities (design and conduct of interviews, surveys, etc.);
- g) 1 expert with at least 3 years of experience in **social science**; for example in the areas of public/health economics or microeconomics.
- 2 experts, whereof one junior, with respectively at least 5 and 2 years of experience in collecting and managing data relevant for burden of disease in humans or burden of disease in animals, with their

<sup>&</sup>lt;sup>41</sup> One Health High-Level Expert Panel (OHHLEP), Adisasmito WB, Almuhairi S, Behravesh CB, Bilivogui P, Bukachi SA, et al. (2022) One Health: A new definition for a sustainable and healthy future. PLoS Pathog 18(6): e1010537. <a href="https://doi.org/10.1371/journal.ppat.1010537">https://doi.org/10.1371/journal.ppat.1010537</a>





	combined experience covering the handling of large amounts of information, research and work programmes, and producing summary reports;
	<ul> <li>i) 2 experts, whereof one junior, with respectively at least 5 and 2 years of experience in collecting and managing data relevant for health economics in humans or animal health economics, with their combined experience covering the handling of large amounts of information, research and work programmes, and producing summary reports;</li> </ul>
	<ul> <li>j) 1 expert with at least 3 years of experience in working with information sources and experts /networks in relation to the subjects covered by the present contract;</li> </ul>
	k) 1 expert with at least 3 years of experience in <b>information technology</b> .
	Requested evidence:
	<ul> <li>Detailed CVs of the Project team members proposed for the assignment. EFSA strongly recommends submitting the CVs in the EU CV format which can be accessed <a href="here">here</a>.</li> <li>Tenderers should also provide a one-page summary of the names of the individual Project team members and the profiles covered, highlighting the evidence of the experience requested in each profile. The one-page summary should follow the template provided by EFSA in Annex 3.</li> </ul>
3	Professional capacity: English language capacity of the team overall
	Requirements:
	a) The team of experts must have overall an excellent level of spoken and written standard UK English. For non-native speakers, this should be demonstrated by an Official certificate of English proving a C1 level OR at least 3 years of work in an English-speaking environment, OR participation in at least two international projects using English as main language;
	Requested evidence:
	Detailed CVs of the Project team members proposed for the assignment.  EFSA strongly recommends submitting the CVs in the EU CV format which can be accessed <a href="here">here</a> .
4	Technical capacity: overall at organisational level
	Requirements:



	<ul> <li>a) The tenderer must have access to statistical/mathematical packages (notably the R free software for statistical computing and graphics) needed for the completion of the tasks/subjects covered by the present contract,</li> <li>b) The tenderer must have access to any data management tool necessary to define data models, terminologies, manage, process and structure the data analysed during the project. The said tool(s) must be compatible with MS Office programs or produce outputs that can be imported by MS Office programs without loss of structure, format or functionality.</li> <li>c) The tenderer must have access to relevant databases for performing literature searches (for example Web of science, PubMed, Scopus, Scielo);</li> <li>d) The tenderer must have an architecture for digital collaboration, including video/tele-meeting facilities for progress meetings, and a common document management system such as Office 365 for simultaneous handling of documents.</li> </ul>
	Requested evidence:
	A statement confirming that the tenderer has access to the tools and facilities mentioned in the above points a) to d)
5	Declaration on Honour
5	Declaration on Honour  Requirements:
5	
5	Requirements:
5	Requirements:  a) Signed declaration on honour.
6	Requirements:  a) Signed declaration on honour.  Requested evidence:  • Declaration on Honour (Professional and Technical capacity-section B), available here. To be completed by the tenderer (in case of joint offer
	Requirements:  a) Signed declaration on honour.  Requested evidence:  • Declaration on Honour (Professional and Technical capacity-section B), available here. To be completed by the tenderer (in case of joint offer by the leading partner only);
	Requirements:  a) Signed declaration on honour.  Requested evidence:  • Declaration on Honour (Professional and Technical capacity-section B), available here. To be completed by the tenderer (in case of joint offer by the leading partner only);  Confirmatory statement of resources
	Requirements:  a) Signed declaration on honour.  Requested evidence:  • Declaration on Honour (Professional and Technical capacity-section B), available here. To be completed by the tenderer (in case of joint offer by the leading partner only);  Confirmatory statement of resources  Requirements:

# 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 <a href="here">here</a> 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 <a href="here">here</a> may be requested for members of the project team having influence and/or control over the scientific outputs.

<u>Institutional and Individual DoIs do not need to be provided with your offer</u>. 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 <u>EFSA's policy on independence</u> and the <u>Decision of the Executive Director on Competing Interest Management</u> 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;
propose contractual terms or conditions which deviate from what is provided in the
draft contract (Annex 2),
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 <sup>42</sup> and compliance with data protection obligations resulting
from Regulation (EU) 2016/679 and Regulation (EU) 2018/1725 <sup>43</sup> .

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<sup>&</sup>lt;sup>42</sup> OJ L 94 of 28.03.2014, p. 65

<sup>&</sup>lt;sup>43</sup> 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, <a href="https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32018R1725&from=EN">https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32018R1725&from=EN</a>



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 award criteria. The award criteria serve to identify the **most economically advantageous offer**.

### **A) QUALITY AWARD CRITERIA**

Criteria:
METHODOLOGY PROPOSED FOR IMPLEMENTATION (60 points - minimum threshold 60%)
<ul> <li>a) Convincing justification of the choice of proposed methodology under objectives 1, 2 and 3; advantages and disadvantages; 30 points</li> <li>b) Logical and structured step by step explanation of the methodology under objectives 1, 2 and 3; the offer should include a proposal for the criteria for the selection of the zoonoses under work packages 1, 4 and 5 and for the criteria for the selection of at least three countries under work package 1; 30 points</li> </ul>
PROJECT ORGANISATION (20 points – minimum threshold 60%)
<ul> <li>a) Clear and detailed information on distribution of the tasks among the project team; in case of joint offer &amp; subcontractors, clarity on who does what, when and why (justify why the partner/subcontractor is proposed to do the particular task/work-package); 15 points</li> <li>b) The communication with EFSA (who, how, when) and the internal team communication; in case of joint offers &amp; subcontractors also the communication between joint offers partners and subcontractors; 5 points</li> </ul>
RISK MANAGEMENT, MEASURES TO GUARANTEE QUALITY OF DELIVERABLES AND DEADLINES (20 points - minimum threshold 60%)
This is to assess the risk management awareness of the tenderer, in particular the ability to identify any potential risks to the achievement of the project objectives, assess risk impact & likelihood, and ability to foresee effective mitigating actions:  a) risk identification and proposed risk mitigation actions and their likely effectiveness; in particular measures to ensure availability of proposed team members and mitigation strategies to cover absences; 10 points



 b) measures proposed to ensure the meeting of the deadlines; and special measures for quality assurance proposed for the project and for the quality of deliverables; 10 points

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

Tenderers must provide a detailed technical offer 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 60% of criteria 1, 2 and 3, and at least 70% of maximum possible total points against the quality award criteria.

Tenders that do not reach these minimum quality thresholds will be eliminated from 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.

No more than one tender and, in case of lots, no more than one tender per lot, can be considered per tenderer. If the same tenderer submits more than one tender, neither of which has been withdrawn as described below, only the latest tender will be considered. The tenderer may not refer to earlier submitted tenders to complement, clarify or correct its latest tender.

A natural or legal person cannot participate at the same time and for the same lot (if applicable) within the same procedure either as member of two or more groups of economic operators or as a sole tenderer and member of another group of economic operators. In such case, all tenders in which that person has participated, either as sole tenderer or as member of a group of economic operators, will be rejected.

Economic operators linked by a relationship of control or of association (e.g. belonging to the same economic/corporate group) are allowed to submit different and separate tenders provided that each tenderer is able to demonstrate that its tender was drawn independently and autonomously.

#### **Registration in the Participant Register**

Any economic operator willing to submit a tender must be registered in the <u>Participant Register</u> - 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 <u>EU Grants and Tenders Rules on Legal Entity Validation, LEAR appointment and Financial Capacity assessment.</u>

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 <u>EU Login</u><sup>44</sup>. In case you don't have an <u>EU Login</u>, you can <u>create an account</u> at any moment. For more information see the <u>EU login help</u>. 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 <u>e-Submission guick guide</u> 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 (section A) and Confirmatory statement of resources (section C). All members of a joint tender, including subcontractors – if applicable – must upload the signed and dated declaration on honour using the template available <a href="here">here</a>.
- **Signed declaration on Honour on Selection criteria (section B).** 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 <a href="here">here</a>.
- **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

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<sup>&</sup>lt;sup>44</sup> Previously called European Commission authentication system (ECAS)



Important advices and information on how to get technical support

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

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

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

• **Declaration on honour.** All members of a joint tender, including subcontractors must complete, sign and date the declaration on honour (sections A and C). Only the leader in a joint tender must complete, sign and date the declaration on honour (section B). The declaration on honour 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 <a href="mailto:EFSAProcurement@efsa.europa.eu">EFSAProcurement@efsa.europa.eu</a>.

#### 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.

#### **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.

<u>Please note that you are responsible to ensure that your full tender reaches the destination</u> 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.

#### Contact

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

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

• If you need technical support on e-Submission, you can contact the e-Submission support team, from 08:00 until 20:00 CET at the following address: <a href="mailto:ec-funding-tender-service-desk@ec.europa.eu">ec-funding-tender-service-desk@ec.europa.eu</a>



### **ANNEX 1 - FINANCIAL OFFER TEMPLATE**

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.



# **ANNEX 3 - TABLE SELECTION CRITERIA\_2.4.B**