TENDER SPECIFICATIONS

Reference: D01.01-ENV21-DATA-Y2
Subject: Implementation of a multi-OMICs and inter-species workflow to derive human reference points and health-based guidance values (HBGVs) from quantitative in vitro data.
Procurement procedure: Open call (Article 164(1) (a) of the Financial Regulation)
Project/Process code: EPA13.02-IDATA-01
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[1]	Comments
Launch date	21/03/2022	Date Contract Notice is sent to Official Journal
Deadline for sending request for clarification to EFSA	07/06/2022 at 14:30 (CET/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	09/06/2022	
"Receipt Time Limit" - Closing date and time for receipt of offers	**15/06/2022 at 14:30 (CET/CEST)**	Refer to the Invitation letter and part 3 of these tender specifications regarding how to submit your offer.
Opening session	16/06/2022 at 14:30 (CET/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 September 2022	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 October 2022	

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

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

1.1 BACKGROUND

Assays used in food and feed safety are still largely based on legacy endpoints and in vivo studies. Such approaches not only contribute to the unnecessary use of animals and compromise animal welfare, but also provide limited mechanistic understanding of the molecular mechanisms underlying toxicity or positive health claims. This limits our potential in providing high quality scientific data, scientific advice and preparedness to face future risk assessments (RA) challenges.

As outlined in the EU Farm to Fork strategy[2] and in the EU's chemicals strategy for sustainability (CSS)[3], innovative technologies such as OMICs are critical to transition to sustainable food systems. In line, EFSA is setting to increase its risk assessment capabilities, including methodologies and data, as outlined in the strategic objective 2 of the 2027 strategy. EFSA is also developing a roadmap for action on OMICs and bioinformatics, and this project is meant to complement the roadmap. Building from the conclusions of the 2018 EFSA colloquium on OMICs, such technologies offer opportunities to produce new evidence for the next generation food and feed RA- and contribute to EFSA's preparedness to provide future fit for purpose scientific advice while avoiding the risk of scientific divergences.

OMICs and Organ-on-chip (OoC) technologies emerged in the last decade as a highly promising alternative to animal studies in toxicology.

In OMICs assays, the complete response of a biological system to the exposure of a substance is measured in a single experiment. The amount of omics datasets has increased exponentially over the last two decades, reaching the stunning number of 66 billions in 2019. To facilitate the access to this enormous amount of data, international scientific consortia steered their efforts into the creation of public, curated and structured omics repositories. EFSA has, so far, made little use of these public omics datasets, the main reasons being the relatively novel nature of these data (as compared to legacy endpoints) and its inherent complexity. However, EFSA is aiming to make a more extensive use of such resources. One of the largest public omics databases is the comparative toxicogenomics database (CTD). To date, this resource contains almost 50 million of manually curated chemical–gene/protein, chemical–disease and gene–disease relationships in addition to a vast collection of structured data from exposure studies.

Techniques such as transcriptomics, epigenomics, proteomics or metabolomics proved to be extremely useful to inform on the molecular mechanisms of toxicity, especially when measured altogether in a multi-approach.

In addition, epigenetics is starting to be considered as a relevant aspect in the safety of products, due to its ability to affect multiple generations of individuals.

OoC are in-vitro systems, based on microfluidics technology, capable to recreate a microenvironment of multiple, interconnected, organs which was shown to faithfully recapitulate human physiology and pathology. OoC are one of the most promising NAM (new approach methodologies) models and their use was partially explored in the concluded EU TOxRisk project.

[2] https://ec.europa.eu/food/horizontal-topics/farm-fork-strategy_it
[3] https://ec.europa.eu/environment/strategy/chemicals-strategy_en

The in-vitro techniques proposed in this procurement call (epigenomics and Organs-on-a-chip) have seen to date very limited applications in risk assessment, despite being acknowledged as highly promising. For this reason, they constitute a great opportunity for EFSA to become a leader in the applications of novel methodologies.

This call is based on EFSA's 2022 Work Programme for grants and operational procurements as presented in Annex XII of the Draft Programming Document 2022 – 2024, available on the EFSA's website[4].

1.2 OBJECTIVES AND DIVISION IN LOTS

The overarching goal of the project is to define, validate and apply a standardised workflow (experimental and computational) for deriving reliable human reference points and health-based guidance values (HBGVs) using cutting edge in-vitro approaches, namely organ-on-a-chip (OoC) platforms and multiple OMICs endpoints (transcriptomics, metabolomics, epigenomics). This ambitious objective addresses directly the expected operational results (EOR) 2.1.2 (preparedness and identification of emerging risks), 2.1.3 (quality of methodologies) and 2.1.5 (broader exploitation of data) of the EFSA 2027 strategy[5].

The objectives of the contract/s resulting from this procurement procedure are as follows:

- Objective 1: Implementation of a multi-OMICs and inter-species workflow. In phase one, a set of data-rich substances will be selected (6 to 12 compounds) and used for an extensive toxicological screening based on OoC and multi-OMICs profiling (transcriptomics, epigenomics, metabolomics). Selected substances will include legacy hazards in food/feed and compounds/nutrients with positive health claims (e.g. resveratrol, to be used to verify applicability of OMICs in assessing beneficial dietary effects). The experimental design will be largely based on the procedures established in EU ToxRisk[6]. The newly generated data will be used to develop and train a bioinformatics pipeline suitable to predict mechanistic information such as mode of action, adverse outcomes, key biomarkers, in-vivo reference points (using IVIVE-PBK modelling) and health-based guidance values. The bioinformatics pipeline will be trained to deliver the best predictions, using the numerous evidences and opinions available for these data-rich substances (e.g. previous risk assessment opinions, literature, databases such as OpenFoodTox). Importantly, the pipeline will also be calibrated to minimize the amount of necessary experimental data, to reduce the costs and duration of the assay phase (keeping in mind industrial applications). In phase two, the experimental and bioinformatics workflow defined and tested in phase one will be used to predict reference points and mechanistic information for a new set of around 50 data-poor, emerging hazardous substances or substances with positive health claims related to food and feed. These results will work as highly reliable experimental evidence for the data-poor compounds which is

[4] https://www.efsa.europa.eu/sites/default/files/event/mb-20211216/C05.SPD-2022-2024-4.mb211216-a2.pdf
[5] https://www.efsa.europa.eu/sites/default/files/2021-04/draft-strategy-2027-for-public-consultation_0.pdf
[6] https://www.eu-toxrisk.eu/

completely animal-free (NAM only) and will pave the way to the standardised use of OMICs/bioinformatics and OoC in RA. This deliverable is directly linked with EOR2.1.2 of the EFSA 2027 strategy "the quality and scale of crisis preparedness and the identification of emerging risk is improved".

- Objective 2: Inference of chemical grouping from processed OMICS data in the comparative toxicogenomics database (CTD[7]). In principle, data hosted in CTD is of great value for chemical grouping, as it could allow disclosing the exact molecular mechanisms associated with up to 8000 chemicals. The proposed work package foresees to reanalyse the data of CTD to predict the grouping of chemicals and interpret the results in the light of the cumulative assessment groups (CAGs) recently established for the pesticides with effects on the nervous system, thyroid and foetus. This work package aims to determine if using omics approaches would yield similar/comparable CAGs. In that case, it would provide further insight into the mode of action and adverse outcome pathways underlying the toxicological effects and would also allow the identification of other chemicals (outside the pesticides domain) that could be included in those CAGs.

This tender is divided into the following 2 lots:

- **Lot 1 – Implementation of a multi-OMICs and inter-species workflow (objective 1).**
- **Lot 2 – Inference of chemical grouping from processed OMICS data in CTD (objective 2).**

Importantly, all the codes, scripts and pipeline written as deliverables in Lot1 and Lot2 must be in an open source / license free programming language such as those commonly used in bioinformatics (R, Python, C).

You may submit an offer for one or more lots but your offer should indicate clearly for which lot you are applying. In case you decide to apply for both lots, a technical and financial offer for each lot must be provided.

1.3 TASKS, DELIVERABLES, TIMELINE AND PAYMENTS

LOT1: Implementation of a multi-OMICs and inter-species workflow

No.	Tasks & deliverables	Can be subcontracted?[8]	Deadline
1	**Task:** Selection of substances for phase one. Substances will be selected considering different criteria, e.g. legacy, diversity in Mode of Action, relevance in food and feed domains through internal EFSA surveys, interviews or literature. **Deliverable 1:** Interim report 1 containing the list of substances and a comprehensive	Yes	3 months from kick-off meeting

[7] http://ctdbase.org/

[8] If a subcontractor provides the whole or a very large part of the financial capacity OR executes the whole or a very large part of the tasks, EFSA may demand the subcontractor to sign the contract.

	description of the selection criteria.		
2	**Task:** To analyse and test the state-of-the-art tools and approaches (e.g. BMDexpress2) for deriving reference points from OMICs (using public data). The results will inform on the possible methodological gaps and improvements. **Deliverable 2:** Interim report 2 containing a comprehensive description of the benchmarking results and the possible methodological gaps and improvements.	No	8 months from kick-off meeting
3	**Task:** To code a pipeline prototype for deriving reference points from multi-OMICs data, improving upon the gaps found in the previous analysis (Task 2). **Deliverable 3:** Interim report 3 and Alpha version pipeline. The report comprehensively illustrates how the pipeline improves over the state of the art.	No	12 months from kick-off meeting
4	**Task:** To generate experimental OMICs data for the selected data-rich emerging substances of Task1. The multi-omics dataset generated for each substance will feature transcriptomics (RNA-seq), metabolomics (untargeted) and epigenetics (e.g. H3k4me3 or H3k27ac) on approximately 40 different data points (different dosages, different times). **Deliverable 4:** Interim report 4 and raw data. The report summarizes the methodologies used for the generation of the samples, the challenges and solutions. It also contains the list of all generated samples and their metadata.	No	21 months from kick-off meeting
5	**Task:** Selection of substances for phase two. Around 50 substances will be selected similarly as in Task1, but this time focused on new emerging substances relevant for EFSA. **Deliverable 5:** Interim report 5 containing the list of substances and a comprehensive description of the selection criteria.	Yes	21 months from kick-off meeting
6	**Task:** To define the final analysis pipeline and experimental workflow for predicting molecular mechanisms and reference points. **Deliverable 6:** Interim report 6 and beta version pipeline. The report contains the comprehensive description of the final methodologies (in silico and experimental workflow), with particular attention to their	No	24 months from kick-off meeting

	strengths and weaknesses and how they improve over the previous state of the art.		
7	**Task:** To generate experimental OMICs data for substances in Task5. **Deliverable 7:** Interim report 7 and raw data. The report summarizes the methodologies used for the generation of the samples, the challenges and solutions. It also contains the list of all generated samples and their metadata.	No	30 months from kick-off meeting
8	**Task:** To apply the pipeline of Task6 to the data generated in Task7, for the prediction of reference points and molecular mechanisms. **Deliverables 8:** a) OMICs data uploaded to public database (e.g. GEO, ENA or similar). b) Codes, script, pipelines shared with EFSA. c) Draft of the final report containing: (i) description of experimental workflow and bioinformatic methodology, with justification of the chosen methodologies (ii) reference points and molecular mechanisms predicted for data rich and data-poor substances (phase two) (iii) comparative analysis of the NAMs results against the animal-studies for data-rich substances (iiii) considerations about strengths and weaknesses of the chosen approach and future perspectives. d) Final report	No	Deliverables 8 a),b),c) 35 months from kick-off meeting. Deliverable 8 d) 36 months from kick-off meeting.

No.	Meetings	Deadline for finalisation
1	**Kick-off meeting**: physical meeting in Parma – half day[9] teleconference During this meeting, in addition to operational implementation the administrative and financial matters related to contract implementation will be discussed.	Within 1 month after entry into force of contract
2	**Interim meeting 2**: half-day teleconference To discuss / review Interim report 1, to discuss Task 2 and Task3 activities.	4 months from kick off meeting
3	**Interim meeting 3**: half-day teleconference To discuss / review Interim report 2 and discuss Task 3 activities.	9 months from kick off meeting
4	**Interim meeting 4**: half-day teleconference To discuss / review Interim report 3	13 months from kick off meeting
5	**Interim meeting 5**: half-day teleconference	22 months from kick off meeting

[9] One day = 8 hours, half day = 4 hours

	To discuss / review Interim report 4 and report 5.	
6	**Interim meeting 6**: half-day teleconference To discuss / review Interim report 6	25 months from kick off meeting
7	**Interim meeting 7**: half-day teleconference To discuss / review Interim report 7	31 months from kick off meeting
8	**Final meeting**: half-day teleconference To discuss the draft of the final report	35.5 months from kick off meeting
	Bi-monthly meetings will take place to discuss the advancement of the project and the ongoing activities.	

No.	Payments	Linked to EFSA approval of deliverable No.
1	Interim payment 1 of 10 %	1,2
3	Interim payment 2 of 40 %	3,4,5
3	Interim payment 3 of 20 %	6,7
4	Payment of the balance of 100% - 70% of the interim payment	8 a), b), c), d)

LOT2: Inference of chemical grouping from processed OMICS data in CTD

No.	Tasks & deliverables	Can be subcontracted?[10]	Deadline
1	**Task:** Download of the public, processed omics data in a local environment from CTD. Analysis if other public DBs in addition to CTD can be used, if strictly useful for the purpose of the call. Creation of the scripts to import and parse the data into a working environment. **Deliverable 1:** Interim report 1, describing the main features of downloaded data, and scripts used.	No	1 months from kick-off meeting
2	**Task:** Separation of omics data into relevant experimental groups, i.e. splitting by species, tissue, type of study (acute, chronic) and other relevant experimental variables. Performing preliminary QC of the data (e.g. number of chemicals with enough data, quantification of gene specificity). **Deliverable 2:** Interim report 2, with information on data stratification and QC.	Yes	3 months from kick-off meeting
3	**Task:** Creation and coding of fit-for-purpose algorithm to cluster chemicals based on their inferred mode of action. These codes must be open source and eventually made publicly available. **Deliverable 3:** Interim report 3, with comprehensive description of the analysis and algorithms, and scripts.	No	7 months from kick-off meeting

[10] If a subcontractor provides the whole or a very large part of the financial capacity OR executes the whole or a very large part of the tasks, EFSA may demand the subcontractor to sign the contract.

4	**Task:** Characterization of the clusters from a chemical, biological and industrial perspective, e.g. common chemical structures, common diseases, common market applications. **Deliverable 4:** Interim report 4, with description of clustering results, and scripts.	No	9 months from kick-off meeting
5	**Task:** Analysis and interpretation of the results: comparisons of previously established clusters (Task3) against existing CAGs established for pesticides, definition of the strengths and weaknesses of this approach compared to the state of the art, definition of the reliability of the results for regulatory purposes. **Deliverables 5:** **(a)** Draft of the final report and processed data **(b)** Final report	No	Deliverable 5 a) 11 months from kick-off meeting. Deliverable 5 b) 12 months from kick-off meeting.

No.	Meetings	Deadline for finalisation
1	**Kick-off meeting**: physical meeting in Parma – half day[11] teleconference During this meeting, in addition to operational implementation the administrative and financial matters related to contract implementation will be discussed.	Within 1 month after entry into force of contract
2	**Interim meeting 2**: half-day teleconference To discuss / review Interim report 1 and Task 2 activities	1.5 months from kick off meeting
3	**Interim meeting 3**: half-day teleconference To discuss / review Interim report 2	3.5 months from kick off meeting
4	**Interim meeting 4**: half-day teleconference To discuss / review Interim report 3	7.5 months from kick off meeting
5	**Interim meeting 5**: half-day teleconference To discuss / review Interim report 4	9.5 months from kick off meeting
6	**Final meeting**: half-day teleconference To discuss the draft of the final report	11.5 months from kick off meeting
	Monthly meetings will take place to discuss the advancement of the project and the ongoing activities.	

No.	Payments	Linked to EFSA approval of deliverable No.
1	Interim payment 1 of 30 %	1,2
3	Payment of the balance of 100% - 30% of the interim payment	3,4, 5a) and 5b)

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.

[11] One day = 8 hours, half day = 4 hours

1.4 INFORMATION ON THE CONTRACT

Nature of expense services

Type of contract direct

Place of performance: contractor's premises

Duration of tasks in direct contract
Lot 1: 36 months from kick-off meeting.
Lot 2: 12 months from kick-off meeting.

Budget information
The maximum budget EFSA has available per lot is:
Lot 1: 3,000.000 €
Lot 2: 250,000 €
Any offer exceeding these maximums will be excluded from further assessment during evaluation.

1.5 OWNERSHIP, INTELLECTUAL PROPERTY RIGHTS, USE OF RESULTS

As regards any product or delivery commissioned by EFSA and developed by the contractor in the context of the contract resulting from this call for tenders, as well as source codes of IT applications and models developed for EFSA, the intellectual property rights will be owned by EFSA only in its capacity as financial source of the contract. The contractor cannot file a trademark, patent, copyright or other IPR protection scheme in relation to any of the results or rights obtained by EFSA in performance of the contract, unless the contractor requests EFSA ex-ante authorisation and obtains from EFSA a written consent in this regard.

In addition, the contractor selected as a result of the present procurement procedure shall be solely responsible and liable for the following:

- To ensure that terms and conditions asserted by any copyright holder of publications or information referred to in the final deliverable for EFSA are fully satisfied;
- To make the necessary arrangements enabling EFSA to reproduce and make non-commercial use of publications and information referred to in the final deliverable it commissioned. As needed, the contractor shall consult with copyright licensing authorities (i.e. at national level) for guidance on purchasing copyright licenses to reproduce any publications provided to EFSA. The contractor remains solely responsible and liable for obtaining all necessary authorizations and rights to use, reproduce and share the publications provided to EFSA

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

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

Use of results

EFSA is committed to the publication of contract deliverables - such as supporting evidence in the form of datasets, raw data, protocols etc. in the Knowledge Junction in order to improve transparency, reproducibility and evidence reuse. The Knowledge Junction[12] 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 or equivalent, with attribution to the contractor, and several deliverables can be cross-linked among them and to the published final Report on Wiley Online Library.

1.6 PERSONAL DATA PROTECTION AND CONFIDENTIALITY

Processing of personal data in the context of this contract shall comply with Regulation (EU) 2018/1725 ('the EDPR')[13]. 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.

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

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

Processing of personal data by the selected contractor (processor/sub-processor)
In case tasks and activities under this call relate to the processing of personal data, Article II.9.2 of the draft contract in Annex 2 shall be observed.

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

[12] http://www.efsa.europa.eu/en/press/news/190117 and https://zenodo.org/communities/efsa-kj/?page=1&size=20
[13] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32018R1725

Confidentiality

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

PART 2 EVALUATION - HOW WILL YOUR OFFER BE ASSESSED?

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

2.1 OPENING OFFERS

The aim of the public opening session is to check whether the offer received was dispatched by the deadline for tender receipt and that the tenders are electronically protected until the official opening.

2.2 ORDER OF EVALUATION

Tenderers should note that the content of their offers will be assessed in the following pre-defined order: Exclusion criteria (Access to EU Market); 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).

Evidence under sections 2.3 and 2.4 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 **tenderers** established in eligible countries will be allowed to the next step of the evaluation. Please refer to the **EFSA Guidance for tenderers** for further details.
	Requested evidence:
	Administrative data forms (including LEF and BAF): available here

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 EFSA Guidance for tenderers.
	Requested evidence:
	Declaration on Honour (section A): Tenderers must declare that they are not in one of the exclusion situations by providing for each lot a signed and dated **Declaration on Honour**, available here. In case of a joint offer from a group of economic operators, or in case of subcontracting, such declaration should be submitted for each member of the group and for each identified subcontractor. Further 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. **2.4.A**	Requirements and requested evidence
1	**Minimum economic and financial capacity**
	Requirements:
	LOT1: The tenderer must have generated an overall annual turnover of at least 1,000.000 € in each of the last three closed financial years (2019, 2020 and 2021). **LOT2:** The tenderer must have generated an overall annual turnover of at least 250,000 € in last one closed financial year (2021).
	Requested evidence:
	Declaration on Honour (section B): Tenderers must declare they fulfil the

	economic and financial capacity by providing for each lot a signed and dated **Declaration on Honour**, available here. 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 for the addition of new subcontracting or assignment of the contract to a new legal entity, the economic and financial capacity will be checked for the last (Lot1: three, Lot2: one) most recent closed financial years and not necessarily the financial years published with the call.

B) Professional and Technical professional capacity

Criterion No. **2.4.B**	Requirements and requested evidence
1	**Professional capacity: overall at organisational level**
	Requirements:
	LOT1: The tenderer overall must have extensive and demonstrable experience in ○ OMICS data generation and analysis (transcriptomics, metabolomics, epigenomics such as Chip-seq) ○ Bioinformatics ○ Organ-on-chip ○ Toxicology ○ Cheminformatics **LOT2:** The tenderer overall must have extensive and demonstrable experience in ○ Bioinformatics of OMICS data ○ Toxicology
	Requested evidence:
	• A list of five (LOT1) major projects or publications related to the subject matter of each lot, carried out in the course of the past 5 years; • A list of three (LOT2) major projects or publications related to the subject matter of each lot, 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:
	LOT1: One expert can cover more than one of the profiles below, but the minimum number of team experts is 4. a) 1 bioinformatician with expertise in epigenomics and multi-omics data analysis and integration of at least 5 years; b) 1 bioinformatician with expertise in metabolomics and multi-omics data analysis and integration of at least 5 years; c) 1 expert in epigenomics techniques with at least 5 years of experience; d) 1 expert in metabolomics techniques with at least 5 years of experience; e) 1 expert in Organ-on-Chip laboratory techniques with at least 3 years of experience; f) 1 expert in toxicology with at least 3 years of experience; g) 1 expert in cheminformatics with at least 3 years of experience; **LOT2:** The profiles (c) and (d) can be covered by the same expert. a) 1 senior bioinformatician with expertise in epigenomics, transcriptomics and multi-omics data analysis and integration of at least 5 years; b) 1 junior bioinformatician with expertise in epigenomics or transcriptomics or multi-omics data analysis and integration of at least 3 years; c) 1 expert in cheminformatics with at least 3 years of experience; d) 1 expert in toxicology with at least 3 years of experience;
	Requested evidence:
	• Detailed CVs of the Project team members proposed for the assignment for each lot. EFSA strongly recommends submitting the CVs in the EU CV format which can be accessed here. • Tenderers should also provide for each lot a one-page summary of the names of the individual Project team members.
3	**Professional capacity: English language capacity of each team member individually**
	Requirements:
	a) The team of experts of each lot must have individually an excellent

	level of spoken and written standard UK English. For non-native speakers, this should be demonstrated by an Official certificate of C1 level OR at least 2 years of work or studies in an English-speaking environment OR participation in at least two international projects and/or consortia using English as main language OR evidence demonstrating active participation in at least two conferences or publications in English;
	Requested evidence:
	• Detailed CVs of the Project team members proposed for the assignment for each lot. EFSA strongly recommends submitting the CVs in the EU CV format which can be accessed here. • Official certificate of English proving at least a C1 level, where applicable.
5	**Technical capacity: overall at organisational level**
	Requirements:
	LOT: 1 a) Laboratory capacity to perform experimental epigenomics techniques (e.g. libraries preparation, sequencing) and metabolomics techniques; b) Experimental capacity to handle organ-on-chip models; c) Laboratory capacity to perform exposure assays with chemicals or other substances (i.e. perform a dose-response experiment); d) Computational capacity to store and analyse sequencing and metabolomics data (i.e. cluster or equivalent); **LOT 2:** a) Computational capacity to download, store and analyse the data from the relevant databases (i.e. A Linux machine with 64Gb of RAM or equivalent)
	Requested evidence:
	• A signed statement for each lot confirming and describing each requested capacity.
6	**Declaration on Honour on selection criteria (section B)**
	Requirements:
	a) Signed declaration on honour (section B) for each lot.
	Requested evidence:
	• **Declaration on Honour (section B),** available here. To be completed for each lot by the tenderer (in case of joint offer by the leading partner only);

7	**Confirmatory statement of resources(section C)**
	Requirements:
	a) Signed declaration on honour (section C) for each lot
	Requested evidence:
	• **Declaration on Honour (section C),** available here. To be completed by the leading partner, any other partners and/or subcontractors for each lot (**only applicable for joint offers or offers with subcontracting**)

C) Professional conflicting interest

In accordance with article 167(1)(c) of the Financial Regulation and paragraph 104 of the recitals, if EFSA, based on the assessment of the technical and professional capacity evidence, concludes that the tenderer has a professional conflicting interest and therefore does not possess the professional capacity to perform the contract to an appropriate quality standard, the tenderer may be rejected.

Evidence requested:

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

Institutional declaration of interests available here

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

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

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

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

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

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

2.5 COMPLIANCE WITH TENDER SPECIFICATION AND MINIMUM REQUIREMENTS

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

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

- do not comply with minimum requirements laid down in the tender specifications;
- propose a solution different from the one imposed;
- propose a price above the fixed maximum set in the specifications;
- are submitted as variants, when the specifications do not authorise them;
- do not comply with applicable obligations under environmental, social and labour law established by Union law, national law and collective agreements or by the international environmental, social and labour law provisions listed in Annex X to Directive 2014/24/EU[14] and compliance with data protection obligations resulting from Regulation (EU) 2016/679 and Regulation (EU) 2018/1725[15].

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

LOT1

Criterion No. **2.6**	Criteria:
1	**METHODOLOGY PROPOSED FOR IMPLEMENTATION** (maximum 50 points - minimum threshold 60 %)
	a) The tenderer correctly understands the tasks and proposes a clear and step-by-step methodology which addresses each of the requested deliverables; (20 points) b) Convincing justification of the choice of proposed methodology for the generation of the omics data (transcriptomics, metabolomics, epigenomics, Tasks 1,4,5,7); (15 points) c) Convincing justification of the choice of proposed methodology for the

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

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

	computational and experimental workflow development (i.e. Tasks 2,3,6); (15 points)
2	**PROJECT ORGANISATION** (maximum 30 points – minimum threshold 60%)
	a) Convincing description of the overall project planning, division into work packages, project phases, timelines, milestones, deliverables and GANTT chart, with particular focus on the interplay between 'wet' (laboratory) and 'dry' (computational) tasks and deadlines; (20 points) b) Clear and detailed information on distribution of the tasks among the project team; in case of joint offer & subcontractors, clarity on who does what, when and why (justify why the partner/subcontractor is proposed to do the particular task/work-package); (5 points) c) The communication with EFSA (who, how, when); (5 points)
3	**RISK MANAGEMENT** (maximum 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; (10 points) b) Measures proposed to ensure the meeting of the deadlines, especially the deadlines related to the generation of omics data, and quality of the deliverables, especially the quality of omics data; (10 points)

LOT2:

Criterion No. **2.6**	Criteria:
1	**METHODOLOGY PROPOSED FOR IMPLEMENTATION** (maximum 60 points - minimum threshold 60%)
	a) The tenderer correctly understands the tasks and proposes a clear and step-by-step methodology which addresses each of the requested deliverables; (30 points) b) Convincing justification of the choice of proposed methodology for the initial setting up of the data (Tasks 1,2); (15 points) c) Convincing justification of the choice of proposed methodology for the bioinformatic analysis (i.e. Tasks 3,4); (15 points)
2	**PROJECT ORGANISATION** maximum 20 points

	a) Convincing description of the overall project planning, division into project phases, timelines, milestones, deliverables and measures proposed to ensure the meeting of the deadlines (10 points) b) Clear and detailed information on distribution of the tasks among the project team; in case of joint offer & subcontractors, clarity on who does what, when and why (justify why the partner/subcontractor is proposed to do the particular task/work-package); (5 points) c) The communication with EFSA (who, how, when); (5 points)
3	**RISK MANAGEMENT** maximum 20 points
	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; (10 points) b) Measures proposed to ensure the meeting of the deadlines and quality of the deliverables (10 points)

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

Tenderers must provide a detailed technical offer for each lot 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.

For Lot 1, offers must score at least 60% for each criterion, and at least 70% of maximum possible total points against the quality award criteria.

For Lot 2, offers must score at least 60% for criterion 1, 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

For each lot, 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 for each lot based on the following formula:

TOTAL SCORE OF THE EVALUATED OFFER (C) =

30 * Cheapest price offer/price of tender X

+

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

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

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

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

Make sure you submit your tender on time: you are advised to start completing your tender early. To avoid any complications with regard to late receipt/non-receipt of tenders within the deadline, please ensure that you submit your tender several hours before the deadline. It is not possible to submit a tender through eSubmission after the time-limit for receipt of tenders indicated in the contract notice and/or the TED eTendering website.

Registration in the Participant Register

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

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

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

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

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

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

How to Submit your Tender in e-Submission

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

In order to have access to e-Submission, you will need to "Subscribe to call for tenders" on TED e-Tendering first. To subscribe, you will need to login with your an EU Login[16]. In case you don't have an EU Login, you can create an account at any moment. For more information see the EU login help. After logging in with your EU Login password, the e-Tendering will then display a button 'submit your tender' and you will be able to access the e-Submission.

The e-Submission quick guide 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 here.
- **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 here.
- **Exclusion criteria**. If requested in the tender specifications, the tenderer and all members of a joint tender including subcontractors – if applicable – must provide the documentary evidence for exclusion criteria.
- **Selection criteria.** If requested in the tender specifications, the tenderer and all members of a joint tender including subcontractors – if applicable –, must provide the documentary evidence for selection criteria.
- **Technical tender.** It must address all the requirements laid down in the tender specifications.
- **Financial tender** The complete financial tender, including the breakdown of the price as provided in the tender specifications.

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

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

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

Documents to be signed and dated while creating your Tender

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

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

- **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 EFSAProcurement@efsa.europa.eu.

Withdrawal of tenders

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

Alternative tender

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

Deadline for receipt of tenders

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

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

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

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

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

Contact

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

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

ANNEX 1 - FINANCIAL OFFER TEMPLATE FOR LOT 1

Tenderers are requested to use this template for preparing their financial offer. In doing so tenderers confirm they are aware of the following facts:

- As referred to in part 1.4, the maximum budget EFSA has available for this assignment is **3,000.000 €**. Any offer exceeding this maximum will not be retained for contract award.
- Prices must be quoted in Euro. Tenderers from countries outside the euro zone have to quote their prices in euro. The price quoted may not be revised in line with exchange rate movements. It is for the tenderer to bear the risks or the benefits deriving from any variation.
- Pursuant to the provisions of Article 9 of the Italian Law n. 17 dated 10/01/2006 and under Article 151 of Council Directive 2006/112/EC, EFSA is exempt from all duties, taxes and other charges, including VAT. For this reason, all prices given in the financial breakdown should be free of VAT and other taxes or duties.
- The price offered below is understood to be all-inclusive. For example any additional costs which can be incurred by the contractor in performing the contract, such as overheads, travel, subsistence/accommodation expenses, etc. should also be factored in to the all-inclusive price. In addition, if the deliverables incorporate pre-existing rights, the tenderer should factor into their total price the cost of licensing those pre-existing rights to EFSA.
- It is the responsibility of each tenderer to ensure that the total amount of the tender inserted in the relevant field of the e-Submission application corresponds to the amount indicated in the uploaded financial offer. In case of discrepancies, only the amount indicated in the financial offer will be taken into account.

ALL INCLUSIVE TOTAL PRICE **to be used for the evaluation and for contract implementation in the case of award.**	..... €

Tenderer name: .....

Name of person signing the financial offer: .....

His/her position in the company: .....

His/her signature: .....

Date: .....

ANNEX 1 - FINANCIAL OFFER TEMPLATE FOR LOT 2

Tenderers are requested to use this template for preparing their financial offer. In doing so tenderers confirm they are aware of the following facts:

- As referred to in part 1.4, the maximum budget EFSA has available for this assignment is **250,000 €**. Any offer exceeding this maximum will not be retained for contract award.
- Prices must be quoted in Euro. Tenderers from countries outside the euro zone have to quote their prices in euro. The price quoted may not be revised in line with exchange rate movements. It is for the tenderer to bear the risks or the benefits deriving from any variation.
- Pursuant to the provisions of Article 9 of the Italian Law n. 17 dated 10/01/2006 and under Article 151 of Council Directive 2006/112/EC, EFSA is exempt from all duties, taxes and other charges, including VAT. For this reason, all prices given in the financial breakdown should be free of VAT and other taxes or duties.
- The price offered below is understood to be all-inclusive. For example any additional costs which can be incurred by the contractor in performing the contract, such as overheads, travel, subsistence/accommodation expenses, etc. should also be factored in to the all-inclusive price. In addition, if the deliverables incorporate pre-existing rights, the tenderer should factor into their total price the cost of licensing those pre-existing rights to EFSA.
- It is the responsibility of each tenderer to ensure that the total amount of the tender inserted in the relevant field of the e-Submission application corresponds to the amount indicated in the uploaded financial offer. In case of discrepancies, only the amount indicated in the financial offer will be taken into account.

ALL INCLUSIVE TOTAL PRICE **to be used for the evaluation and for contract implementation in the case of award.**	..... €

Tenderer name: .....

Name of person signing the financial offer: .....

His/her position in the company: .....

His/her signature: .....

Date: .....

ANNEX 2 – DRAFT CONTRACT

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