



FRAMEWORK SERVICE CONTRACT

TITLE – Methodological support for the performance of literature reviews within evidence-based scientific assessments

FRAMEWORK CONTRACT NUMBER – OC/EFSA/MESE/2022/03 – CT01

The European Food Safety Authority, hereinafter referred to as "the Contracting Authority", established by [Regulation \(EC\) No 178/2002](#)⁵ of the European Parliament and of the Council 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 last amended, with offices on Via Carlo Magno 1/a 43126 Parma (Italy), represented by Mr Bernhard Url, Executive Director

on the one part,

and

Leading Partner: Asociación Colaboración Cochrane Iberoamericana

Statutory registration number: 164740

Osep Esquirol 4 1r B 08207 Sabadell (SPAIN)

VAT registration number: ESG61808457

appointed as the leader of the group by the members of the group that submitted the joint tender

and

PARTNER 2: Escuela Andaluza de Salud Pública, S.A.

Statutory registration number: A-18049635

Campus Universitario de Cartuja, Cuesta del Observatorio, 4. 18011 Granada (SPAIN)

VAT registration number: A-18049635

and

⁵ OJ L 31 of 01.02.2002

PARTNER 3: Fundació Institut d'Investigació Sanitària Illes Balears

Statutory registration number: G5732632

Crta. Valldemossa, 79 (Hospital Universitari Son Espases), Edifici S, 1^a planta. 07120 Palma de Mallorca (SPAIN)

VAT registration number: ESG5732632

collectively 'the contractor', represented for the purposes of the signature of this framework contract by Xavier Bonfill Cosp, President of Asociación Colaboración Cochrane Iberoamericana based on the Power of Attorney attached to this contract,

on the other part

HAVE AGREED

to the special conditions, the general conditions for service framework contracts and the following annexes:

- Annex I** – Tender specifications
- Annex II** – Contractor's tender
- Annex III** – Model Specific Contract
- Annex IV** – Declaration on pre-existing⁶ rights
- Annex V** – Power of attorney

which form an integral part of this framework contract (hereinafter referred to as "the FWC").

This FWC sets out:

1. the procedure by which the contracting authority may order services from the contractor;
2. the provisions that apply to any *Order form* or *Specific contract* which the contracting authority and the contractor may conclude under this FWC; and
3. the obligations of the parties during and after the duration of this FWC.

All documents issued by the contractor (end-user agreements, general terms and conditions, etc.) except its tender are held inapplicable, unless explicitly mentioned in the special conditions of this FWC. In all circumstances, in the event of contradiction between this FWC and documents issued by the contractor, this FWC prevails, regardless of any provision to the contrary in the contractor's documents.

⁶ It is important that the awarded contractor fully understands the implications of signing this declaration and it is therefore advisable that the contractor consults with their legal advisors and/or seeks further clarification from EFSA in case of doubt.

I – SPECIAL CONDITIONS FOR SERVICE FRAMEWORK CONTRACT

I.1 ORDER OF PRIORITY OF PROVISIONS

If there is any conflict between different provisions in this FWC, the following rules must be applied:

- (a) The provisions set out in the special conditions take precedence over those in the other parts of the FWC.
- (b) The provisions set out in the general conditions take precedence over those in the specific contract (Annex III).
- (c) The provisions set out in the specific contract (Annex III) take precedence over those in the other annexes.
- (d) The provisions set out in the tender specifications (Annex I) take precedence over those in the tender (Annex II).
- (e) The provisions set out in the FWC take precedence over those in the specific contracts.

I.2 SUBJECT MATTER

The subject matter of the FWC is the provision of methodological support for the performance of literature reviews within evidence-based scientific assessments.

I.3 ENTRY INTO FORCE AND DURATION OF THE FWC

I.3.1 The FWC enters into force on the date on which the last party signs it.

I.3.2 The *Implementation of the FWC* cannot start before its entry into force.

I.3.3 The FWC is concluded for a period of 12 months with effect from the date of its entry into force.

I.3.4 The parties must sign any specific contract before the FWC expires.

The FWC continues to apply to such specific contracts after its expiry. The services relating to such specific contracts must be performed no later than six months after the expiry of the FWC.

I.3.5 FWC renewal

The FWC is renewed automatically three times for twelve months each time, unless one of the parties receives formal Notification to the contrary at least three months before the end of the ongoing duration. Renewal does not change or postpone any existing obligations.

I.4 APPOINTMENT OF THE CONTRACTOR AND IMPLEMENTATION OF THE FWC

I.4.1 Appointment of the contractor

The contracting authority appoints the contractor for a multiple FWC in cascade in first position.

I.4.2 Period of provision of the services

The period for the provision of the services starts to run from the date on which it is signed by the last party.

I.4.3 Implementation of multiple FWC in cascade

The FWC is implemented as follows: the contracting authority orders services by sending a specific contract by e-mail to the contractor who is ranked first in the cascade.

Within 10 working days, the contractor must either:

- (a) send the specific contract back to the contracting authority signed and dated; or
- (b) send an explanation of why it cannot accept the order.

If the contractor does not accept the order or fails to observe the deadline or if it is in a situation of conflicting interests that may negatively affect *the performance of the specific contract* (see Article II.7), the contracting authority may place the order with the next contractor on the cascade.

If the contractor repeatedly refuses to sign order forms or specific contracts or repeatedly fails to send them back on time, the contractor may be considered in breach of its obligations under this FWC as set out in Article II.18.1 (c).

I.5 PRICES

I.5.1 Maximum amount of the FWC and maximum prices

The maximum amount covering all purchases under this FWC, including all renewals is EUR 4,000,000.00 (four million).

However, this does not bind the contracting authority to purchase for the maximum amount.

The maximum prices of the services shall be as listed in Annex II.

I.5.2 Price revision index

Price revision is determined by the formula set out in Article II.20 and using the trend in the harmonised indices of consumer prices (HICP) *MUICP*⁷ published at <http://ec.europa.eu/eurostat/web/hicp/data/database> under HICP (2015 = 100) - monthly data (index) (prc_hicp_midx).

I.5.3 Reimbursement of expenses

Reimbursement of expenses is not applicable to this FWC.

I.6 PAYMENT ARRANGEMENTS

I.6.1 Pre-financing

Pre-financing is not applicable to this FWC.

I.6.2 Interim payment

Interim payment is admissible if both the overall value of the order form or specific contract is \geq EUR 60.000 and the duration is \geq 6 months. The percentage of the interim payment(s) shall be agreed between EFSA and the contractor based on the deliverable(s) as defined in the order form/specific contract

⁷ 'Monetary union index of consumer prices' (MUICP); (euro area) for contracts expressed in euro.

The contractor (or leader in the case of a joint tender) must send an invoice via *e-PRIOR* for payment of the balance due under a specific contract, as provided for in the tender specifications and accompanied by the following:

- a list of all *pre-existing rights* incorporated into the *results* or parts of the results for all deliverables or a declaration stating that there are no such pre-existing rights, as provided for in Article II.13.4; Contractors must submit a declaration stating clearly if any materials incorporated into the deliverables are subject to pre-existing rights. The contractor must explicitly declare which pre-existing rights are contained within the deliverables and must warrant that those materials are free of rights or claims from creators or from any third parties for any use the Contracting Authority has foreseen in art.I.10 of the contract. Absence of such declaration when the deliverable and invoice is received will be understood by the Contracting Authority as confirmation that there are no pre-existing rights within the deliverables and the Contracting Authority will proceed with the payment.

The template declaration is provided in Annex IV of this contract.

- the relevant deliverable as described in the order form/specific contract.

2. The contracting authority must approve the submitted documents or deliverables and pay within 60 days from receipt of the invoice.

3. The contracting authority may suspend the time limit for payment specified in point (2.) in accordance with Article II.21.7.

Once the suspension is lifted, the contracting authority shall give its approval and pay within the remainder of the time-limit indicated in point (2.) unless it rejects partially or fully the submitted documents or deliverables.

I.6.3 Payment of the balance

1. The contractor (or leader in the case of a joint tender) may claim the payment of the balance in accordance with Article II.21.6.

The contractor (or leader in the case of a joint tender) must send an invoice via *e-PRIOR* for payment of the balance due under a specific contract, as provided for in the tender specifications and accompanied by the following:

- a list of all *pre-existing rights* incorporated into the *results* or parts of the results for all deliverables or a declaration stating that there are no such pre-existing rights, as provided for in Article II.13.4; Contractors must submit a declaration stating clearly if any materials incorporated into the deliverables are subject to pre-existing rights. The contractor must explicitly declare which pre-existing rights are contained within the deliverables and must warrant that those materials are free of rights or claims from creators or from any third parties for any use the Contracting Authority has foreseen in art.I.10 of the contract. Absence of such declaration when the deliverable and invoice is received will be understood by the Contracting Authority as confirmation that there are no pre-existing rights within the deliverables and the Contracting Authority will proceed with the payment.

The template declaration is provided in Annex IV of this contract.

- the relevant deliverable as described in the specific contract.

2. The contracting authority must approve the submitted documents or deliverables and pay within 60 days from receipt of the invoice.

3. The contracting authority may suspend the time limit for payment specified in point (2.) in accordance with Article II.21.7.

Once the suspension is lifted, the contracting authority shall give its approval and pay within the remainder of the time-limit indicated in point (2.) unless it rejects partially or fully the submitted documents or deliverables.

In order to ensure swift final report approving and payment process, and in particular to ensure respect of EFSA’s time limit of 60 days, both parties to this Contract agree and commit to respect the following timelines:

Action number	Who	Action	Action deadline (in calendar days)
1	Contractor	Submit final report & invoice	According to tender specifications
2	EFSA	Approve final report or make comments/clarification requests	max 30 days since action 1
3	Contractor	Provide clarifications on final report if requested by EFSA	max 20 days since action 2 – <u>this period is outside the 60 days for EFSA to approve and pay</u>
4	EFSA	Approve final report after clarifications	Max 20 days since action 3
5	EFSA	Pay final payment	max 10 days since action 4

I.6.4 Performance guarantee

Performance guarantee is not applicable to this FWC.

I.6.5 Retention money guarantee

Retention money guarantee is not applicable to this FWC.

I.7 BANK ACCOUNT

Payments must be made to the contractor’s (or leader’s in the case of a joint tender) bank account denominated in euro, identified as follows:

Name of bank: Banco Bilbao Vizcaya Argentaria S.A. (BBVA)

Full address of branch: Avinguda Dr. Moragas, 220 – 08210 Barberà Del Vallés (Barcelona)

Exact designation of account holder: Asociación colaboración Cochrane Iberoamericana

IBAN⁸ code: ES64 0182 3578 1602 0011 1543

I.8 COMMUNICATION DETAILS

For the purpose of this FWC, communications must be sent to the following addresses:

⁸ BIC or SWIFT code for countries with no IBAN code.

Contracting authority:

European Food Safety Authority

Finance Unit – Procurement Team

Via Carlo Magno 1/A

43126 Parma - Italy

Email: EFSAProcurement@efsa.europa.eu

Contractor: (or leader in the case of a joint tender):

Gerard Villar

Asociación Colaboración Cochrane Iberoamericana

Josep Esquirol 4 1r B Sabadell (SPAIN)

E-mail: gerard-villar@economistes.com

By derogation from this Article, different contact details for the contracting authority or the contractor may be provided in specific contracts.

I.9 PROCESSING OF PERSONAL DATA

I.9.1 Processing of personal data by the contracting authority

For the purpose of Article II.9.1, the data controller will be the entity/person representing the contracting authority signing the specific contract;

The data protection notice regarding the procurement process and contract management, is available on EFSA's website: <http://www.efsa.europa.eu/sites/default/files/assets/procurementprivacystatement.pdf>.

I.9.2 Processing of personal data by the contractor

For the purpose of Article II.9.2,

(a) the subject matter and purpose of the processing of personal data by the contractor are related to receiving questions on systematic review findings from member states and/or the public through web-forms or functional mailboxes. For this purpose, personal data such as the name of individual enquirers and their email addresses may be processed.

(b) The localisation of and access to the personal data processed by the contractor shall comply with the following:

i. the personal data shall only be processed within the territory of the European Union and the European Economic Area (EU 27 + Norway, Iceland, Liechtenstein) and Switzerland and will not leave that territory;

ii. the data shall only be held in data centres located with the territory of the European Union and the European Economic Area (EU 27 + Norway, Iceland, Liechtenstein) and Switzerland;

- iii. access to data may be given on a need-to-know basis only to authorised persons established in a country which has been recognised by the European Commission as providing adequate protection to personal data;
- iv. the contractor may not change the location of data processing without the prior written authorisation of the contracting authority;
- v. any transfer of personal data under the FWC to third countries or international organisations shall fully comply with the requirements laid down in Chapter V of Regulation (EU) 2018/1725⁹.

I.10 EXPLOITATION OF THE RESULTS OF THE FWC

I.10.1 Detailed list of modes of exploitation of the results

In accordance with Article II.13.1 whereby the Contracting Authority acquires ownership of the *Results* as defined in this FWC, including the tender specifications, these *Results* may be used for any of the following modes of exploitation:

- (a) use for its own purposes:
 - making available to the staff of the contracting authority;
 - making available to the persons and entities working for the contracting authority or cooperating with it, including contractors, subcontractors whether legal or natural persons, Union institutions, agencies and bodies, Member States' institutions;
 - installing, uploading, processing;
 - arranging, compiling, combining, retrieving;
 - copying, reproducing in whole or in part and in unlimited number of copies.
- (b) distribution to the public in hard copies, in electronic or digital format, on the internet including social networks as a downloadable or non-downloadable file;
- (c) communication through press information services;
- (d) inclusion in widely accessible databases or indexes, such as via 'open access' or 'open data' portals, or similar repositories, whether freely accessible or accessible only upon subscription; in particular any part of the output resulting from this contract will be published on the Knowledge Junction¹⁰ with attribution to the contractor"
- (e) modifications by the contracting authority or by a third party in the name of the contracting authority, including:
 - shortening;
 - summarising;
 - modifying the content, the dimensions;
 - making technical changes to the content (necessary correction of technical errors), adding new parts or functionalities, changing functionalities, providing third parties with additional information concerning the *result* (e.g. source code) with a view to making modifications;
 - addition of new elements, paragraphs, titles, leads, bolds, legend, table of content, summary, graphics, subtitles, sound;

⁹ Regulation (EU) 2018/1725 of 23 October 2018 on the protection of natural persons 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/legalcontent/EN/TXT/PDF/?uri=CELEX:32018R1725&from=EN>

¹⁰ Learn more at <http://www.efsa.europa.eu/en/press/news/190117>

- addition of metadata, for text and data-mining purposes; addition of right-management information; addition of technological protection measures;
- preparation in audio form, preparation as a presentation, animation, pictograms story, slide-show, public presentation;
- extracting a part or dividing into parts;
- incorporating, including by cropping and cutting, the results or parts thereof in other works, such as on websites and webpages;
- translating, inserting subtitles, dubbing in different language versions:
 - English, French, German;
 - all official languages of EU;
 - languages used within EU;
 - languages of candidate countries;

(f) rights to authorise or license the modes of exploitation set out in any of the points (a) to (e) to third parties, provided however that this does not apply to pre-existing rights and pre-existing materials, if they are only licensed to the Contracting Authority, except as foreseen by Article II.13.2.;

(g) other adaptations which the parties may later agree; in such case, the following rules apply: the contracting authority must consult the contractor. If necessary, the contractor must in turn seek the agreement of any *creator* or other right holder and must reply to the contracting authority within one month by providing its agreement, including any suggestions of modifications, free of charge. The contractor may refuse the intended modification only if a *creator* can demonstrate that the intended modification may harm his/her honour or reputation, thereby violating his/her moral rights.

The modes of exploitation may be defined in more details in the specific contract.

The list above is in addition to whatever rights already accrue to the Contracting Authority on the basis of existing exceptions in the applicable legislation, such as the copyright exception to ensure the proper performance or reporting of administrative proceedings, in cases where such exceptions apply.

I.10.2 Licence or transfer of pre-existing rights

All *pre-existing rights* incorporated in the *results*, if any, are licensed to the Contracting Authority as set out in Article II.13.2.

I.10.3 Provision of list of pre-existing rights and documentary evidence

The contractor must provide the contracting authority with a list of *pre-existing rights* as set out in Article II.13.4 together with the invoice for payment of the balance at the latest.

In addition, the contractor must provide the contracting authority with relevant and exhaustive evidence of the acquisition of all the necessary pre-existing rights together with a presentation of relevant result. To this effect, the contractor must provide a statement in accordance with Annex IV, the relevant evidence listed in Article II.13.5 as appropriate or, failing that, third parties' statements in accordance with Annex IV.

I.11 TERMINATION BY EITHER PARTY

Either party may terminate the FWC and/or the FWC and specific contracts by sending *formal notification* to the other party with three months written notice.

If the FWC or specific contract is terminated:

- (a) neither party is entitled to compensation;
- (b) the contractor is entitled to payment only for the services provided before termination takes effect.

The second, third and fourth paragraphs of Article II.18.4 apply.

I.12 APPLICABLE LAW AND SETTLEMENT OF DISPUTES

I.12.1 The FWC is governed by Union law, complemented, where necessary, by the law of Italy.

I.12.2 The General Court of the European Union has exclusive jurisdiction over any dispute regarding the interpretation, application or validity of the FWC.

I.13 INTER-INSTITUTIONAL FRAMEWORK CONTRACT

Not applicable to this FWC

I.14 ELECTRONIC DOCUMENT EXCHANGE AND INSTRUCTIONS FOR INVOICING

It is intended that the document exchange (e.g. invoices, deliverables, specific contracts, etc.) between the Contracting Authority and the Contractor will have to be carried out via electronic means. At the request of the Contracting Authority, the use of such electronic applications will become mandatory during the performance of the contract.

By derogation to article II.19.2, invoices must be submitted electronically via e-Prior following configuration.

Invoices must contain the following information:

- 1) Your contact at EFSA (name, title, telephone, number, email address);
- 2) The reference number of the contract, with the requested amount in euro;
- 3) The mention "the payment should be made into the following bank account" and the following information: beneficiary, bank name and address, bank account number;
- 4) Detailed billing information;
- 5) Each PDF file should only contain one invoice. Any other supporting documents should be scanned and saved separately to the PDF invoice.

I.15 OTHER SPECIAL CONDITIONS

I.15.1 Signature of amendments

Without prejudice to the art II.11 of the GENERAL CONDITIONS, contract amendments will be electronically signed by the delegated EFSA Finance Unit responsible in the following cases:

- Price revision;
- Change of bank account;
- Change of legal entity, and also in case of new name, or where the change of legal entity results from a merge or universal succession. This excludes change of legal entity involving:
 - * assignment of contract to a new entity, total or partial, including the payments or;
 - * change of legal entity where a new institutional DoI has to be assessed

I.15.2 Obligation to notify EFSA of changes

In accordance with article II.18.i the contractor is obliged to notify EFSA of any change to their legal, financial, technical, organisational or ownership situation which is likely to substantially affect the *Implementation of the contract* or substantially modify the conditions under which the contract was initially awarded. This includes but is not limited to notifying EFSA of changes which may have affected the original declaration on honour on exclusion criteria; declaration on honour on selection criteria or the status of the contractor in the Early Detection and Exclusion System (EDES).

I.15.3 Liability for alleged breach of intellectual property rights

By derogation to article II.6.3, in the event that a third party brings an action against EFSA in connection with alleged breach of intellectual property rights, the contractor will be liable for the whole amount of consequential loss or damages caused to EFSA as a consequence of an absent or incorrect declaration on pre-existing rights.

I.15.4 Declarations of interest

Only for specific contracts issued by EFSA, with reference to Article II.7 the contractor shall provide individual declarations of interest for new members in the project team or updated individual declarations for those team members whose interests declared on the occasion of signature of the contract have substantially changed during the implementation of the contract.

An updated institutional declaration of interest must also be provided to EFSA when the interests declared on the occasion of signature of the contract have substantially changed during the implementation of the contract. The declarations will be screen in accordance with the [EFSA's Independence policy](#) and the [Decision of the Executive Director on Competing Interest Management](#) which can be found on the EFSA website.

II – GENERAL CONDITIONS FOR SERVICE FRAMEWORK CONTRACTS

II.1. DEFINITIONS

For the purpose of this FWC, the following definitions (indicated in *italics* in the text) apply:

'Back office': the internal system(s) used by the parties to process electronic invoices;

'Breach of obligations': failure by the contractor to fulfil one or more of its contractual obligations.

'Confidential information or document': any information or document received by either party from the other or accessed by either party in the context of the *Implementation of the FWC*, that any of the parties has identified in writing as confidential. It may not include information that is publicly available;

'Conflict of interest': a situation where the impartial and objective *Implementation of the FWC* by the contractor is compromised for reasons involving family, emotional life, political or national affinity, economic interest, any other direct or indirect personal interest, or any other shared interest with the contracting authority or any third party related to the subject matter of the FWC;

'Creator': means any natural person who contributes to the production of the *Result*;

'EDI message' (electronic data interchange): a message created and exchanged through the electronic transfer, from computer to computer, of commercial and administrative data using an agreed standard;

'e-PRIOR': the service-oriented communication platform that provides a series of web services and allows the exchange of standardised electronic messages and documents between the parties. This is done either through web services, with a machine-to-machine connection between the parties' *back office* systems (*EDI messages*), or through a web application (the *supplier portal*). The Platform may be used to exchange electronic documents (e-documents) such as electronic requests for services, electronic specific contracts, and electronic acceptance of services or electronic invoices between the parties.

'Force majeure': any unforeseeable, exceptional situation or event beyond the control of the parties that prevents either of them from fulfilling any of their obligations under the FWC. The situation or event must not be attributable to error or negligence on the part of the parties or on the part of the subcontractors and must prove to be inevitable despite their exercising due diligence. Defaults of service, defects in equipment or material or delays in making them available, labour disputes, strikes and financial difficulties may not be invoked as *Force majeure*, unless they stem directly from a relevant case of *Force majeure*;

'Formal notification' (or 'formally notify'): form of communication between the parties made in writing by mail or email, which provides the sender with compelling evidence that the message was delivered to the specified recipient;

'Fraud': an act or omission committed in order to make an unlawful gain for the perpetrator or another by causing a loss to the Union's financial interests, and relating to: i) the use or presentation of false, incorrect or incomplete statements or documents, which has as its effect the misappropriation or wrongful retention of funds or assets from the Union budget, ii) the non-disclosure of information in violation of a specific obligation, with the same effect or iii) the misapplication of such funds or assets for purposes other than those for which they were originally granted, which damages the Union's financial interests;

'Grave professional misconduct': a violation of applicable laws or regulations or ethical standards of the profession to which a contractor or a related person belongs, including any conduct leading to sexual or other exploitation or abuse, or any wrongful conduct of the contractor or a related person which has an impact on its professional credibility where such conduct denotes wrongful intent or gross negligence

'Implementation of the FWC': the purchase of services envisaged in the FWC through the signature and *performance of Specific contracts*;

'Interface control document': the guideline document which lays down the technical specifications, message standards, security standards, checks of syntax and semantics, etc. to facilitate machine-to-machine connection. This document is updated on a regular basis;

'Irregularity': any infringement of a provision of Union law resulting from an act or omission by an economic operator, which has, or would have, the effect of prejudicing the contracting authority's budget.

'Notification' (or 'notify'): form of communication between the parties made in writing including by electronic means;

'Order form': a simplified form of specific contract by which the contracting authority orders services under this FWC;

'Performance of a Specific contract': the execution of tasks and delivery of the purchased services by the contractor to the contracting authority;

'Personnel': persons employed directly or indirectly or contracted by the contractor to implement the FWC;

'Personal Data': any information relating to an identified or identifiable natural person ('data subject'); an identifiable natural person is one who can be identified, directly or indirectly, in particular by reference to an identifier such as a name, an identification number, location data, an online identifier or to one or more factors specific to the physical, physiological, genetic, mental, economic, cultural or social identity of that natural person.

'Personal Data processing': any operation or set of operations which is performed on personal data or on sets of personal data, whether or not by automated means, such as collection, recording, organisation, structuring, storage, adaptation or alteration, retrieval, consultation, use, disclosure by transmission, dissemination or otherwise making available, alignment or combination, restriction, erasure or destruction;

'Pre-existing material': any material, document, technology or know-how which exists prior to the contractor using it for the production of a *Result* in the *Implementation of the FWC*;

'Pre-existing right': any industrial and intellectual property right on *Pre-existing material*; it may consist in a right of ownership, a licence right and/or right of use belonging to the contractor, the *creator*, the contracting authority as well as to any other third parties;

'Professional conflicting interest': a situation in which the contractor's previous or ongoing professional activities affect its capacity to implement the FWC or to perform a specific contract to an appropriate quality standard.

'Related person': any natural or legal person who is a member of the administrative, management or supervisory body of the contractor, or who has powers of representation, decision or control with regard to the contractor;

'Request for services': a document from the contracting authority requesting that the contractors in a multiple FWC with re-opening of competition provide a specific tender for services whose terms are not entirely defined under the FWC;

'Result': any intended outcome of the *Implementation of the FWC*, whatever its form or nature. A *Result* may be further defined in this FWC as a deliverable. A *Result* may, in addition to newly created materials produced specifically for the contracting authority by the contractor or at its request, also include *Pre-existing materials*;

'Specific contract': a contract implementing the FWC and specifying details of a service to be provided;

'Supplier portal': the *e-PRIOR* portal, which allows the contractor to exchange electronic business documents, such as invoices, through a graphical user interface; its main features can be found in the [supplier portal overview document available on: http://ec.europa.eu/dgs/informatics/supplier_portal/doc/um_supplier_portal_overview.pdf](http://ec.europa.eu/dgs/informatics/supplier_portal/doc/um_supplier_portal_overview.pdf)

II.2 ROLES AND RESPONSIBILITIES IN THE EVENT OF A JOINT TENDER

In the event of a joint tender submitted by a group of economic operators and where the group does not have legal personality or legal capacity, one member of the group is appointed as leader of the group.

II.3 SEVERABILITY

Each provision of this FWC is severable and distinct from the others. If a provision is or becomes illegal, invalid or unenforceable to any extent, it must be severed from the remainder of the FWC. This does not affect the legality, validity or enforceability of any other provisions of the FWC, which continue in full force and effect. The illegal, invalid or unenforceable provision must be replaced by a legal, valid and enforceable substitute provision which corresponds as closely as possible with the actual intent of the parties under the illegal, invalid or unenforceable provision. The replacement of such a provision must be made in accordance with Article II.11. The FWC must be interpreted as if it had contained the substitute provision as from its entry into force.

II.4 PROVISION OF SERVICES

II.4.1 Signature of the FWC does not guarantee any actual purchase. The contracting authority is bound only by specific contracts implementing the FWC.

II.4.2 The contractor must provide services of high-quality standards, in accordance with the state of the art in the industry and the provisions of this FWC, in particular the tender specifications and the terms of its tender. Where the Contracting Authority has the right to make modifications to the results, they must be delivered in a format and with the necessary information which effectively allow such modifications to be made in a convenient manner.

II.4.3 The contractor must comply with the minimum requirements provided for in the tender specifications. This includes compliance 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/EU¹¹, compliance with data protection obligations resulting from Regulation (EU) 2016/679¹² and Regulation (EU) 2018/1725.¹³

II.4.4 The contractor must obtain any permit or licence required in the State where the services are to be provided.

II.4.5 All periods specified in the FWC are calculated in calendar days, unless otherwise specified.

II.4.6 The contractor must not present itself as a representative of the contracting authority and must inform third parties that it is not part of the European public service.

II.4.7 The contractor is responsible for the *Personnel* who carry out the services and exercises its authority over its *Personnel* without interference by the contracting authority. The contractor must inform its *Personnel* that:

- (a) they may not accept any direct instructions from the contracting authority; and
- (b) their participation in providing the services does not result in any employment or contractual relationship with the contracting authority.

II.4.8 The contractor must ensure that the *Personnel* implementing the FWC and any future replacement personnel possess the professional qualifications and experience required to provide the services, as the case may be on the basis of the selection criteria set out in the tender specifications.

II.4.9 At the contracting authority's reasoned request, the contractor must replace any member of *Personnel* who:

- (a) does not have the expertise required to provide the services; or
- (b) has caused disruption at the premises of the contracting authority.

The contractor bears the cost of replacing its *Personnel* and is responsible for any delay in providing the services resulting from the replacement of *Personnel*.

II.4.10 The contractor must record and report to the contracting authority any problem that affects its ability to provide the services. The report must describe the problem, state when it started and what action the contractor is taking to resolve it.

II.5 COMMUNICATION BETWEEN THE PARTIES

II.5.1 Form and means of communication

Any communication of information, notices or documents under the FWC must:

- (a) be made in writing in paper or electronic format in the language of the contract;
- (b) bear the FWC number and, if applicable, the specific contract number;
- (c) be made using the relevant communication details set out in Article I.8; and

¹¹ OJ L 94 of 28.03.2014, p. 65

¹² Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation), OJ L 119, 4.5.2016, <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32016R0679&from=EN>

¹³ Regulation (EU) 2018/1725 of 23 October 2018 on the protection of natural persons 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/legalcontent/EN/TXT/PDF/?uri=CELEX:32018R1725&from=EN>

(d) be sent by mail, email or, for the documents specified in the special conditions, via *e-PRIOR*.

If a party requests written confirmation of an e-mail within a reasonable time, the other party must provide an original signed paper version of the communication as soon as possible.

The parties agree that any communication made by email has full legal effect and is admissible as evidence in judicial proceedings.

II.5.2 Date of communications by mail and email

Any communication is deemed to have been made when the receiving party receives it, unless this FWC contract refers to the date when the communication was sent.

E-mail is deemed to have been received by the receiving party on the day of dispatch of that e-mail, provided that it is sent to the e-mail address indicated in Article I.8. The sending party must be able to prove the date of dispatch. In the event that the sending party receives a non-delivery report, it must make every effort to ensure that the other party actually receives the communication by email or mail. In such a case, the sending party is not held in breach of its obligation to send such communication within a specified deadline.

Mail sent to the contracting authority is deemed to have been received by the contracting authority on the date on which the department responsible referred to in Article I.8 registers it.

Formal notifications are considered to have been received by the receiving party on the date of receipt indicated in the proof received by the sending party that the message was delivered to the specified recipient.

II.5.3. Submission of e-documents via e-PRIOR

1. If provided for in the special conditions, the exchange of electronic documents (e-documents) such as requests for services, specific contracts and invoices between the parties is automated through the use of the *e-PRIOR* platform. This platform provides two possibilities for such exchanges: either through web services (machine-to-machine connection) or through a web application (the *Supplier portal*).
2. The contracting authority takes the necessary measures to implement and maintain electronic systems that enable the supplier portal to be used effectively.
3. In the case of machine-to-machine connection, a direct connection is established between the parties' *back offices*. In this case, the parties take the measures necessary on their side to implement and maintain electronic systems that enable the machine-to-machine connection to be used effectively. The electronic systems are specified in the *Interface control document*. The contractor (or leader in the case of a joint tender) must take the necessary technical measures to set up a machine-to-machine connection and at its own cost.
4. If communication via the supplier portal or via the web services (machine-to-machine connection) is hindered by factors beyond the control of one party, it must notify the other immediately and the parties must take the necessary measures to restore this communication.
5. If it is impossible to restore the communication within two working days, one party must notify the other that alternative means of communication specified in Article II.5.1 will be used until the supplier portal or the machine-to-machine connection is restored.
6. When a change in the *Interface control document* requires adaptations, the contractor (or leader in the case of a joint tender) has up to six months from receipt of the *Notification* to implement this change. This period can be shortened by mutual agreement of the parties. This period does not apply to urgent measures required by the security policy of the contracting authority to ensure integrity, confidentiality and non-repudiation of information and the availability of *e-PRIOR*, which must be applied immediately.

II.5.4. Validity and date of e-documents

1. The parties agree that any e-document, including related attachments exchanged via *e-PRIOR*:
 - (a) is considered as equivalent to a paper document;
 - (b) is deemed to be the original of the document;
 - (c) is legally binding on the parties once an *e-PRIOR* authorised person has performed the 'sign' action in *e-PRIOR* and has full legal effect; and
 - (d) constitutes evidence of the information contained in it and is admissible as evidence in judicial proceedings.
2. The parties expressly waive any rights to contest the validity of such a document solely on the grounds that communications between the parties occurred through *e-PRIOR* or that the document has been signed through *e-PRIOR*. If a direct connection is established between the parties' *back offices* to allow electronic transfer of documents, the parties agree that an e-document, sent as mentioned in the *Interface control document*, qualifies as an *EDI message*.
3. If the e-document is dispatched through the supplier portal, it is deemed to have been legally issued or sent when the contractor (or leader in the case of a joint tender) is able to successfully submit the e-document without any error messages. The generated PDF and XML document for the e-document are considered as a proof of receipt by the contracting authority.
4. In the event that an e-document is dispatched using a direct connection established between the parties' *back offices*, the e-document is deemed to have been legally issued or sent when its status is 'received' as defined in the *Interface control document*.
5. When using the supplier portal, the contractor (or leader in the case of a joint tender) can download the PDF or XML message for each e-document for one year after submission. After this period, copies of the e-documents are no longer available for automatic download from the supplier portal.

II.5.5. Authorised persons in e-PRIOR

The contractor submits a request for each person who needs to be assigned the role of 'user' in *e-PRIOR*. These persons are identified by means of the European Communication Authentication Service (ECAS) and authorised to access and perform actions in *e-PRIOR* within the permissions of the user roles that the contracting authority has assigned to them.

User roles enabling these *e-PRIOR* authorised persons to sign legally binding documents such as specific tenders or specific contracts are granted only upon submission of supporting documents proving that the authorised person is empowered to act as a legal representative of the contractor.

II.6. LIABILITY

II.6.1 The contracting authority is not liable for any damage or loss caused by the contractor, including any damage or loss to third parties during or as a consequence of *Implementation of the FWC*.

II.6.2 If required by the relevant applicable legislation, the contractor must take out an insurance policy against risks and damage or loss relating to the *Implementation of the FWC*. It must also take out supplementary insurance as reasonably required by standard practice in the industry. Upon request, the contractor must provide evidence of insurance coverage to the contracting authority.

II.6.3 The contractor is liable for any loss or damage caused to the contracting authority during or as a consequence of *Implementation of the FWC*, including in the event of subcontracting, but only up to an amount not exceeding three times the total amount of the relevant specific contract. However, if the damage or loss is caused by the gross negligence or wilful

misconduct of the contractor or of its *Personnel* or subcontractors, as well as in the case of an action brought against the contracting authority by a third party for breach of its intellectual property rights, the contractor is liable for the whole amount of the damage or loss.

II.6.4 If a third party brings any action against the contracting authority in connection with the *Implementation of the FWC*, including any action for alleged breach of intellectual property rights, the contractor must assist the contracting authority in the legal proceedings, including by intervening in support of the contracting authority upon request. If the contracting authority's liability towards the third party is established and that such liability is caused by the contractor during or as a consequence of the *Implementation of the FWC*, Article II.6.3 applies.

II.6.5 If the contractor is composed of two or more economic operators (i.e. who submitted a joint tender), they are all jointly and severally liable to the contracting authority for the *Implementation of the FWC*.

II.6.6 The contracting authority is not liable for any loss or damage caused to the contractor during or as a consequence of *Implementation of the FWC*, unless the loss or damage was caused by wilful misconduct or gross negligence of the contracting authority.

II.7 CONFLICT OF INTEREST AND PROFESSIONAL CONFLICTING INTERESTS

II.7.1 The contractor must take all the necessary measures to prevent any situation of *conflict of interest* or *Professional conflicting interest*.

II.7.2 The contractor must *notify* the contracting authority in writing as soon as possible of any situation that could constitute a *conflict of interest* or a *Professional conflicting interest* during the *Implementation of the FWC*. The contractor must immediately take action to rectify the situation.

The contracting authority may do any of the following:

- (a) verify that the contractor's action is appropriate;
- (b) require the contractor to take further action within a specified deadline;
- (c) decide not to award a specific contract to the contractor.

II.7.3 The contractor must pass on all the relevant obligations in writing to:

- (a) its *Personnel*;
- (b) any natural person with the power to represent it or take decisions on its behalf;
- (c) third parties involved in the *Implementation of the FWC*, including subcontractors.

The contractor must also ensure that the persons referred to above are not placed in a situation which could give rise to conflicts of interest.

II.8 CONFIDENTIALITY

II.8.1 The contracting authority and the contractor must treat with confidentiality any information or documents, in any format, disclosed in writing or orally, relating to the *Implementation of the FWC* and identified in writing as confidential.

II.8.2 Each party must:

- (a) not use *confidential information or documents* for any purpose other than to perform its obligations under the FWC or a specific contract without the prior written agreement of the other party;
- (b) ensure the protection of such *confidential information or documents* with the same level of protection as its own *confidential information or documents* and in any case with due diligence;
- (c) not disclose, directly or indirectly, *confidential information or documents* to third parties without the prior written agreement of the other party.

II.8.3 The confidentiality obligations set out in this Article are binding on the contracting authority and the contractor during the *Implementation of the FWC* and for as long as the information or documents remain confidential unless:

- (a) the disclosing party agrees to release the receiving party from the confidentiality obligation earlier;
- (b) the *confidential information or documents* become public through other means than a breach of the confidentiality obligation;
- (c) the applicable law requires the disclosure of the *confidential information or documents*.

II.8.4 The contractor must obtain from any natural person with the power to represent it or take decisions on its behalf, as well as from third parties involved in the *Implementation of the FWC* a commitment that they will comply with this Article. At the request of the contracting authority, the contractor must provide a document providing evidence of this commitment.

II.9 PROCESSING OF PERSONAL DATA

II.9.1 Processing of personal data by the contracting authority

Any personal data included in or relating to the FWC, including its implementation, shall be processed in accordance with Regulation (EU) 2018/1725. Such data shall be processed solely for the purposes of the implementation, management and monitoring of the FWC by the data controller.

The contractor or any other person whose personal data is processed by the data controller in relation to this FWC has specific rights as a data subject under Chapter III (Articles 14-25) of Regulation (EU) 2018/1725, in particular the right to access, rectify or erase their personal data and the right to restrict or, where applicable, the right to object to processing or the right to data portability.

Should the contractor or any other person whose personal data is processed in relation to this FWC have any queries concerning the processing of its personal data, it shall address itself to the data controller. They may also address themselves to the Data Protection Officer of the data controller. They have the right to lodge a complaint at any time to the European Data Protection Supervisor.

Details concerning the processing of personal data are available in the data protection notice referred to in Article I.9.

II.9.2 Processing of personal data by the contractor

The processing of personal data by the contractor shall meet the requirements of Regulation (EU) 2018/1725 and be processed solely for the purposes set out by the controller.

The contractor shall assist the controller for the fulfilment of the controller's obligation to respond to requests for exercising rights of person whose personal data is processed in relation to this FWC as laid down in Chapter III (Articles 14-25) of Regulation (EU) 2018/1725. The contractor shall inform without delay the controller about such requests.

The contractor may act only on documented written instructions and under the supervision of the controller, in particular with regard to the purposes of the processing, the categories of data that may be processed, the recipients of the data and the means by which the data subject may exercise its rights.

The contractor shall grant personnel access to the data to the extent strictly necessary for the implementation, management and monitoring of the FWC. The contractor must ensure that personnel authorised to process personal data has committed itself to confidentiality or is under appropriate statutory obligation of confidentiality in accordance with the provisions of Article II.8.

The contractor shall adopt appropriate technical and organisational security measures, giving due regard to the risks inherent in the processing and to the nature, scope, context and purposes of processing, in order to ensure, in particular, as appropriate:

- (a) the pseudonymisation and encryption of personal data;
- (b) the ability to ensure the ongoing confidentiality, integrity, availability and resilience of processing systems and services;
- (c) the ability to restore the availability and access to personal data in a timely manner in the event of a physical or technical incident;
- (d) a process for regularly testing, assessing and evaluating the effectiveness of technical and organisational measures for ensuring the security of the processing;
- (e) measures to protect personal data from accidental or unlawful destruction, loss, alteration, unauthorised disclosure of or access to personal data transmitted, stored or otherwise processed.

The contractor shall notify relevant personal data breaches to the controller without undue delay and at the latest within 48 hours after the contractor becomes aware of the breach. In such cases, the contractor shall provide the controller with at least the following information:

- (a) nature of the personal data breach including where possible, the categories and approximate number of data subjects concerned and the categories and approximate number of personal data records concerned;
- (b) likely consequences of the breach;
- (c) measures taken or proposed to be taken to address the breach, including, where appropriate, measures to mitigate its possible adverse effects.

The contractor shall immediately inform the data controller if, in its opinion, an instruction infringes Regulation (EU) 2018/1725, Regulation (EU) 2016/679, or other Union or Member State data protection provisions as referred to in the tender specifications.

The contractor shall assist the controller for the fulfilment of its obligations pursuant to Article 33 to 41 under Regulation (EU) 2018/1725 to:

- (a) ensure compliance with its data protection obligations regarding the security of the processing, and the confidentiality of electronic communications and directories of users;
- (b) notify a personal data breach to the European Data Protection Supervisor;
- (c) communicate a personal data breach without undue delay to the data subject, where applicable;
- (d) carry out data protection impact assessments and prior consultations as necessary.

The contractor shall maintain a record of all data processing operations carried on behalf of the controller, transfers of personal data, security breaches, responses to requests for exercising rights

of people whose personal data is processed and requests for access to personal data by third parties.

The contracting authority is subject to Protocol 7 of the Treaty on the Functioning of the European Union on the privileges and immunities of the European Union, particularly as regards the inviolability of archives (including the physical location of data and services as set out in Article I.9.2) and data security, which includes personal data held on behalf of the contracting authority in the premises of the contractor or subcontractor.

The contractor shall notify the contracting authority without delay of any legally binding request for disclosure of the personal data processed on behalf of the contracting authority made by any national public authority, including an authority from a third country. The contractor may not give such access without the prior written authorisation of the contracting authority.

The duration of processing of personal data by the contractor will not exceed the period referred to in Article II.24.2. Upon expiry of this period, the contractor shall, at the choice of the controller, return, without any undue delay in a commonly agreed format, all personal data processed on behalf of the controller and the copies thereof or shall effectively delete all personal data unless Union or national law requires a longer storage of personal data.

For the purpose of Article II.10, if part or all of the processing of personal data is subcontracted to a third party, the contractor shall pass on the obligations referred to in Articles I.9.2 and II.9.2 in writing to those parties, including subcontractors. At the request of the contracting authority, the contractor shall provide a document providing evidence of this commitment.

II.10 SUBCONTRACTING

II.10.1 The contractor must not subcontract and have the FWC implemented by third parties beyond the third parties already mentioned in its tender without prior written authorisation from the contracting authority.

II.10.2 Even if the contracting authority authorises subcontracting, the contractor remains bound by its contractual obligations and is solely responsible for the *Implementation of the FWC*.

II.10.3 The contractor must ensure that the subcontract does not affect the rights of the contracting authority under this FWC, particularly those under Articles II.8, II.13 and II.24.

II.10.4 The contracting authority may request the contractor to replace a subcontractor found to be in a situation provided for in points (d) and (e) of Article II.18.1.

II.11 AMENDMENTS

II.11.1 Any amendment to the FWC or a specific contract must be made in writing before all contractual obligations have been fulfilled. A specific contract does not constitute an amendment to the FWC.

II.11.2 Any amendment must not make changes to the FWC or a specific contract that might alter the initial conditions of the procurement procedure or result in unequal treatment of tenderers or contractors.

II.12 ASSIGNMENT

II.12.1 The contractor must not assign any of the rights and obligations arising from the FWC, including claims for payments or factoring, without prior written authorisation from the

contracting authority. In such cases, the contractor must provide the contracting authority with the identity of the intended assignee.

II.12.2 Any right or obligation assigned by the contractor without authorisation is not enforceable against the contracting authority.

II.13 INTELLECTUAL PROPERTY RIGHTS

II.13.1 Ownership of the rights in the results

The Contracting Authority acquires irrevocably worldwide ownership of the *Results* and of all intellectual property rights on the newly created materials produced specifically for the Contracting Authority under the FWC and incorporated in the results, without prejudice however to the rules applying to pre-existing rights on pre-existing materials, as per Article II.13.2.

The intellectual property rights so acquired include any rights, such as copyright and other intellectual or industrial property rights, to any of the *Results* and in all technological solutions and information created or produced by the contractor or by its subcontractor in *Implementation of the FWC*. The contracting authority may exploit and use the acquired rights as stipulated in this FWC. The Contracting Authority acquires all the rights from the moment the contractor has created the results

The payment of the price includes any fees payable to the contractor about the acquisition of ownership of rights by the Contracting Authority including for all forms of exploitation and of use of the *Results*.

II.13.2 Licensing rights on pre-existing materials

Unless provided otherwise in the special conditions, the Contracting Authority does not acquire ownership of *Pre-existing rights* under this FWC.

The contractor licenses the *Pre-existing rights* on a royalty-free, non-exclusive and irrevocable basis to the Contracting Authority, which may use the *Pre-existing materials* for all the modes of exploitation set out in this FWC or in specific contracts. Unless otherwise agreed, the licence is non-transferable and cannot be sub-licensed, except as provided hereafter:

(a) the pre-existing rights can be sub-licensed by the contracting authority to persons and entities working for it or cooperating with it, including contractors and subcontractors, whether legal or natural persons, but only for the purpose of their mission for the contracting authority;

(b) if the result is a "document" such as a report or a study, and it is meant to be published, the existence of pre-existing materials in the result may not prevent the publication of the document, its translation or its "reuse", it being understood however that the "reuse" may only be made of the result as a whole and not of the pre-existing materials taken separately from the result; for the sake of this provision, "reuse" and "document" have the meaning given by the Commission Decision of 12 December 2011 on the reuse of Commission documents (2011/833/EU).

All pre-existing rights are licensed to the Contracting Authority from the moment the results are delivered and approved by the contracting authority.

The licensing of *Pre-existing rights* to the contracting authority under this FWC covers all territories worldwide and is valid for the duration of intellectual property rights protection.

The payment of the price as set out in the specific contracts is deemed to also include any fees payable to the contractor in relation to the licensing of *Pre-existing rights* by the contracting authority, including for all forms of exploitation and of use of the *Results*.

Where *Implementation of the FWC* requires that the contractor uses *Pre-existing materials* belonging to the contracting authority, the contracting authority may request that the contractor signs an adequate licence agreement. Such use by the contractor will not entail any transfer of rights to the contractor and is limited to the needs of this FWC.

II.13.3 Exclusive rights

The contracting authority acquires the following exclusive rights:

- (a) reproduction: the right to authorise or prohibit direct or indirect, temporary or permanent reproduction of the *Results* by any means (mechanical, digital or other) and in any form, in whole or in part;
- (b) communication to the public: the exclusive right to authorise or prohibit any display, performance or communication to the public, by wire or wireless means, including the making available to the public of the *Results* in such a way that members of the public may access them from a place and at a time individually chosen by them; this right also include the communication and broadcasting by cable or by satellite;
- (c) distribution: the exclusive right to authorise or prohibit any form of distribution of *Results* or copies of the *Results* to the public, by sale or otherwise;
- (d) rental: the exclusive right to authorise or prohibit rental or lending of the *Results* or of copies of the *Results*;
- (e) adaptation: the exclusive right to authorise or prohibit any modification of the *Results*;
- (f) translation: the exclusive right to authorise or prohibit any translation, adaptation, arrangement, creation of derivative works based on the *Results*, and any other alteration of the *Results*, subject to the respect of moral rights of authors, where applicable;
- (g) where the *Results* are or include a database: the exclusive right to authorise or prohibit the extraction of all or a substantial part of the contents of the database to another medium by any means or in any form; and the exclusive right to authorise or prohibit the re-utilization of all or a substantial part of the contents of the database by the distribution of copies, by renting, by on-line or other forms of transmission;
- (h) where the *Results* are or include a patentable subject-matter: the right to register them as a patent and to further exploit such patent to the fullest extent;
- (i) where the *Results* are or include logos or subject-matter which could be registered as a trademark: the right to register such logo or subject-matter as a trademark and to further exploit and use it;
- (j) where the *Results* are or include know-how: the right to use such know-how as is necessary to make use of the *Results* to the full extent provided for by this FWC, and the right to make it available to contractors or subcontractors acting on behalf of the contracting authority, subject to their signing of adequate confidentiality undertakings where necessary;
- (k) where the *Results* are documents:
 - (i) the right to authorise the reuse of the documents in conformity with the Commission Decision of 12 December 2011 on the reuse of Commission documents (2011/833/EU), to the extent it is applicable and the documents fall within its scope and are not excluded by any of its provisions; for the sake of this provision, "reuse" and "document" have the meaning given to it by this Decision;
 - (ii) the right to store and archive the *Results* in line with the document management rules applicable to the contracting authority, including digitisation or converting the format for preservation or new use purposes;

- (l) where the *Results* are or incorporate software, concerning source code, object code and, where relevant, documentation, preparatory materials and manuals, in addition to the other rights mentioned in this Article:
 - (i) end-user rights, for all uses both by the contracting authority or by subcontractors which result from this FWC and from the intention of the parties
 - (ii) the rights to receive both the source code and the object code;
- (m) the right to license to third parties any of the exclusive rights or of the modes of exploitation set out in this FWC; however, for *pre-existing materials* which are only licensed to the contracting authority, the right to sub-license does not apply, except in the two cases foreseen by Article II.13.2.;
- (n) to the extent that the contractor may invoke moral rights, the right for the contracting authority, except where otherwise provided in this FWC, to publish the *Results* with or without mentioning the *creator(s)*' name(s), and the right to decide when and whether the *Results* may be disclosed and published.

The contractor warrants that the exclusive rights and the modes of exploitation may be exercised by the contracting authority on all parts of the *Results*, be it via a transfer of ownership of the rights, on those parts which were specifically created by the contractor, or via a licence of the pre-existing rights, on those parts consisting of pre-existing materials.

Where *Pre-existing materials* are inserted in the *Results*, the contracting authority may accept reasonable restrictions impacting on the above list, provided that the said materials are easily identifiable and separable from the rest, that they do not correspond to substantial elements of the *Results*, and that, should the need arise, satisfactory replacement solutions exist, at no additional costs to the contracting authority. In such case, the contractor will have to clearly inform the contracting authority before making such choice and the contracting authority has the right to refuse it.

II.13.4 Identification of pre-existing rights

When delivering the *Results*, the contractor must warrant that, for any use that the contracting authority may envisage within the limits set in this FWC, the newly created parts and the *Pre-existing material* incorporated in the *Results* are free of claims from *creators* or from any third parties and all the necessary *Pre-existing rights* have been obtained or licensed.

To that effect, the contractor must establish a list of all *Pre-existing rights* to the *Results* of this FWC or parts thereof, including identification of the rights' owners. If there are no *Pre-existing rights* to the *Results*, the contractor must provide a declaration to that effect. The contractor must provide this list or declaration to the contracting authority together with the invoice for payment of the balance at the latest.

II.13.5 Evidence of granting of pre-existing rights

Upon request by the contracting authority, the contractor must, in addition to the list mentioned under Article II.13.4, provide evidence that it has the ownership or the right to use all the listed *Pre-existing rights*, except for the rights owned or licensed by the contracting authority. The contracting authority may request this evidence even after the end of this FWC.

This provision also applies to image rights and sound recordings.

This evidence may refer, for example, to rights to: parts of other documents, images, graphs, tables, data, software, technical inventions, know-how, IT development tools, routines, subroutines or other programs ('background technology'), concepts, designs, installations or pieces of art, data,

source or background materials or any other parts of external origin. This evidence must include, as appropriate:

- (a) the name and version number of a software product;
- (b) the full identification of the work and its author, developer, *creator*, translator, data entry person, graphic designer, publisher, editor, photographer, producer;
- (c) a copy of the licence to use the product or of the agreement granting the relevant rights to the contractor or a reference to this licence;
- (d) a copy of the agreement or extract from the employment contract granting the relevant rights to the contractor where parts of the *Results* were created by its *Personnel*;
- (e) the text of the disclaimer notice if any.

Provision of evidence does not release the contractor from its responsibilities if it is found that it does not hold the necessary rights, regardless of when and by whom this fact is revealed.

The contractor also warrants that it possesses the relevant rights or powers to execute the transfer and that it has paid or has verified payment of all due fees including fees due to collecting societies, related to the final *Results*.

II.13.6 Quotation of works in the result

In the *Result*, the contractor must clearly point out all quotations of existing works. The complete reference should include as appropriate, the following: name of the author, title of the work, date and place of publication, date of creation, address of publication on the internet, number, volume and other information that allows the origin to be easily identified.

II.13.7 Moral rights of creators

By delivering the *Results*, the contractor warrants that the *creators* will not object to the following on the basis of their moral rights under copyright:

- (a) that their names be mentioned or not mentioned when the *Results* are presented to the public;
- (b) that the *Results* be divulged or not after they have been delivered in their final version to the contracting authority;
- (c) that the *Results* be adapted, provided that this is done in a manner which is not prejudicial to the *creator's* honour or reputation.

If moral rights on parts of the *Results* protected by copyright may exist, the contractor must obtain the consent of *creators* regarding the granting or waiver of the relevant moral rights in accordance with the applicable legal provisions and be ready to provide documentary evidence upon request.

II.13.8 Image rights and sound recordings

If natural persons appear in a *Result* or their voice or any other private element is recorded in a recognisable manner, the contractor must obtain a statement by these persons (or, in the case of minors, by the persons exercising parental authority) giving their permission for the described use of their image, voice or private element and, on request, submit a copy of the permission to the contracting authority. The contractor must take the necessary measures to obtain such consent in accordance with the applicable legal provisions.

II.13.9 Copyright notice for pre-existing rights

When the contractor retains *Pre-existing rights* on parts of the *Results*, reference must be inserted to that effect when the *Result* is used as set out in Article I.10.1, with the following disclaimer: '© —

year — European Union. All rights reserved. Certain parts are licensed under conditions to the EU', or with any other equivalent disclaimer as the contracting authority may consider best appropriate, or as the parties may agree on a case-by-case basis. This does not apply where inserting such reference would be impossible, notably for practical reasons.

II.13.10 Visibility of contracting authority funding and disclaimer

When making use of the *Results*, the contractor must declare that they have been produced under a contract with the contracting authority and that the opinions expressed are those of the contractor only and do not represent the contracting authority's official position. The contracting authority may waive this obligation in writing or provide the text of the disclaimer.

II.14 FORCE MAJEURE

II.14.1 If a party is affected by *Force majeure*, it must immediately *notify* the other party, stating the nature of the circumstances, their likely duration and foreseeable effects.

II.14.2 A party is not liable for any delay or failure to perform its obligations under the FWC if that delay or failure is a *Result of Force majeure*. If the contractor is unable to fulfil its contractual obligations owing to *Force majeure*, it has the right to remuneration only for the services actually provided.

II.14.3 The parties must take all necessary measures to limit any damage due to *Force majeure*.

II.15 LIQUIDATED DAMAGES

II.15.1 Delay in delivery

If the contractor fails to perform its contractual obligations within the applicable time limits set out in this FWC, the contracting authority may claim liquidated damages for each day of delay using the following formula:

$$0.3 \times (V/d)$$

where:

V is the price of the relevant purchase or deliverable or *Result*;

d is the duration specified in the relevant specific contract for delivery of the relevant purchase or deliverable or *Result* or, failing that, the period between the date specified in Article I.4.2 and the date of delivery or performance specified in the relevant specific contract, expressed in days.

Liquidated damages may be imposed together with a reduction in price under the conditions laid down in Article II.16.

II.15.2 Procedure

The contracting authority must *formally notify* the contractor of its intention to apply liquidated damages and the corresponding calculated amount.

The contractor has 30 days following the date of receipt to submit observations. Failing that, the decision becomes enforceable the day after the time limit for submitting observations has elapsed.

If the contractor submits observations, the contracting authority, taking into account the relevant observations, must *notify* the contractor:

- (a) of the withdrawal of its intention to apply liquidated damages; or
- (b) of its final decision to apply liquidated damages and the corresponding amount.

II.15.3 Nature of liquidated damages

The parties expressly acknowledge and agree that any amount payable under this Article is not a penalty and represents a reasonable estimate of fair compensation for the damage incurred due to failure to provide the services within the applicable time limits set out in this FWC.

II.15.4 Claims and liability

Any claim for liquidated damages does not affect the contractor's actual or potential liability or the contracting authority's rights under Article II.18.

II. 16 REDUCTION IN PRICE

II.16.1 Quality standards

If the contractor fails to provide the service in accordance with the FWC or a specific contract ('unperformed obligations') or if it fails to provide the service in accordance with the expected quality levels specified in the tender specifications ('low quality delivery'), the contracting authority may reduce or recover payments proportionally to the seriousness of the unperformed obligations or low quality delivery. This includes in particular cases where the contracting authority cannot approve a *Result*, report or deliverable as defined in Article I.6 after the contractor has submitted the required additional information, correction or new version.

A reduction in price may be imposed together with liquidated damages under the conditions of Article II.15.

II.16.2 Procedure

The contracting authority must *formally notify* the contractor of its intention to reduce payment and the corresponding calculated amount.

The contractor has 30 days following the date of receipt to submit observations. Failing that, the decision becomes enforceable the day after the time limit for submitting observations has elapsed.

If the contractor submits observations, the contracting authority, taking into account the relevant observations, must *notify* the contractor:

- (a) of the withdrawal of its intention to reduce payment; or
- (b) of its final decision to reduce payment and the corresponding amount.

II.16.3 Claims and liability

Any reduction in price does not affect the contractor's actual or potential liability or the contracting authority's rights under Article II.18.

II.17 SUSPENSION OF THE IMPLEMENTATION OF THE FWC

II.17.1 Suspension by the contractor

If the contractor is affected by *Force majeure*, it may suspend the provision of the services under a specific contract.

The contractor must immediately *notify* the contracting authority of the suspension. The *Notification* must include a description of the *Force majeure* and state when the contractor expects to resume the provision of services.

The contractor must *notify* the contracting authority as soon as it is able to resume *performance of the Specific contract*, unless the contracting authority has already terminated the FWC or the specific contract.

II.17.2 Suspension by the contracting authority

The contracting authority may suspend the *Implementation of the FWC or Performance of a Specific contract* or any part of it:

- (a) if the procedure for awarding the FWC or a specific contract or the *Implementation of the FWC* proves to have been subject to *irregularities, fraud or breach of obligations*;
- (b) in order to verify whether the presumed *irregularities, fraud or breach of obligations* have actually occurred.

The contracting authority must *formally notify* the contractor of the suspension and the reasons for it. Suspension takes effect on the date of *Formal notification*, or at a later date if the *Formal Notification* so provides.

The contracting authority must *notify* the contractor as soon as the verification is completed whether:

- (a) it is lifting the suspension; or
- (b) it intends to terminate the FWC or a specific contract under Article II.18.1(f) or (j).

The contractor is not entitled to compensation for suspension of any part of the FWC or a specific contract.

The contracting authority may in addition suspend the time allowed for payments in accordance with Article II.21.7.

II.18 TERMINATION OF THE FWC

II.18.1 Grounds for termination by the contracting authority

The contracting authority may terminate the FWC or any on-going specific contract in the following circumstances:

- (a) if provision of the services under an on-going specific contract has not actually started within 15 days of the scheduled date and the contracting authority considers the new date proposed, if any, is unacceptable, taking into account Article II.11.2;
- (b) if the contractor is unable, through its own fault, to obtain any permit or licence required for *Implementation of the FWC*;

- (c) if the contractor does not implement the FWC or perform the specific contract in accordance with the tender specifications or *request for service* or is in breach of another substantial contractual obligation or repeatedly refuses to sign specific contracts. Termination of three or more specific contracts in these circumstances also constitutes grounds for termination of the FWC;
- (d) if the contractor or any person that assumes unlimited liability for the debts of the contractor is in one of the situations provided for in points (a) and (b) of Article 136(1) of the Financial Regulation¹⁴;
- (e) if the contractor or any *Related person* is in one of the situations provided for in points (c) to (h) of Article 136(1) or to Article 136(2) of the Financial Regulation.
- (f) if the procedure for awarding the FWC or the *Implementation of the FWC* prove to have been subject to *irregularities, fraud or breach of obligations*;
- (g) if the contractor does not comply with applicable obligations under environmental, social and labour law established by Union law, national law, collective agreements or by the international environmental, social and labour law provisions listed in Annex X to Directive 2014/24/EU;
- (h) if the contractor is in a situation that could constitute a *conflict of interest* or a *Professional conflicting interest* as referred to in Article II.7;
- (i) if a change to the contractor's legal, financial, technical, organisational or ownership situation is likely to substantially affect the *Implementation of the FWC* or substantially modify the conditions under which the FWC was initially awarded;
- (j) in the event of *Force majeure*, where either resuming implementation is impossible or the necessary ensuing amendments to the FWC or a specific contract would mean that the tender specifications are no longer fulfilled or result in unequal treatment of tenderers or contractors;
- (k) if the needs of the contracting authority change and it no longer requires new services under the FWC; in such cases ongoing specific contracts remain unaffected;
- (l) if the termination of the FWC with one or more of the contractors means that the multiple FWC with reopening of competition no longer has the minimum required level of competition;
- (m) if the contractor is in breach of the data protection obligations resulting from Article II.9.2;
- (n) if the contractor does not comply with the applicable data protection obligations resulting from Regulation (EU) 2016/679.

II.18.2 Grounds for termination by the contractor

The contractor may terminate the FWC or any on-going specific contract if the contracting authority fails to comply with its obligations, in particular the obligation to provide the information needed for the contractor to implement the FWC or to perform a specific contract as provided for in the tender specifications.

II.18.3 Procedure for termination

A party must *formally notify* the other party of its intention to terminate the FWC or a specific contract and the grounds for termination.

The other party has 30 days following the date of receipt to submit observations, including the measures it has taken or will take to continue fulfilling its contractual obligations. Failing that, the decision to terminate becomes enforceable the day after the time limit for submitting observations has elapsed.

¹⁴ Regulation (EU, Euratom) 2018/1046 of the European Parliament and of the Council of 18 July 2018 on the financial rules applicable to the general budget of the Union, amending Regulations (EU) No 1296/2013, (EU) No 1301/2013, (EU) No 1303/2013, (EU) No 1304/2013, (EU) No 1309/2013, (EU) No 1316/2013, (EU) No 223/2014, (EU) No 283/2014, and Decision No 541/2014/EU and repealing Regulation (EU, Euratom) No 966/2012, OJ L 193 of 30.7.2018, p.1 https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2016.119.01.0001.01.ENG

If the other party submits observations, the party intending to terminate must *formally notify* it either of the withdrawal of its intention to terminate or of its final decision to terminate.

In the cases referred to in points (a) to (d), (g) to (i), (k) and (l) of Article II.18.1 and in Article II.18.2, the date on which the termination takes effect must be specified in the *Formal notification*.

In the cases referred to in points (e), (f) and (j) of Article II.18.1, the termination takes effect on the day following the date on which the contractor receives *Notification* of termination.

In addition, at the request of the contracting authority and regardless of the grounds for termination, the contractor must provide all necessary assistance, including information, documents and files, to allow the contracting authority to complete, continue or transfer the services to a new contractor or internally, without interruption or adverse effect on the quality or continuity of the services. The parties may agree to draw up a transition plan detailing the contractor's assistance unless such plan is already detailed in other contractual documents or in the tender specifications. The contractor must provide such assistance at no additional cost, except if it can demonstrate that it requires substantial additional resources or means, in which case it must provide an estimate of the costs involved and the parties will negotiate an arrangement in good faith.

II.18.4 Effects of termination

The contractor is liable for damage incurred by the contracting authority as a result of the termination of the FWC or a specific contract including the cost of appointing and contracting another contractor to provide or complete the services, except if the damage is a result of a termination in accordance with Article II.18.1(j), (k) or (l) or Article II.18.2. The contracting authority may claim compensation for such damage.

The contractor is not entitled to compensation for any loss resulting from the termination of the FWC or a specific contract, including loss of anticipated profits, unless the loss was caused by the situation specified in Article II.18.2.

The contractor must take all appropriate measures to minimise costs, prevent damage and cancel or reduce its commitments.

Within 60 days of the date of termination, the contractor must submit any report, deliverable or *Result* and any invoice required for services that were provided before the date of termination.

In the case of joint tenders, the contracting authority may terminate the FWC or a specific contract with each member of the group separately on the basis of points (d), (e) or (g) of Article II.18.1, under the conditions set out in Article II.11.2

II.19 INVOICES, VALUE ADDED TAX AND E-INVOICING

II.19.1 Invoices and value added tax

Invoices must contain the contractor's (or leader's in the case of a joint tender) identification data, the amount, the currency and the date, as well as the FWC reference and reference to the specific contract.

Invoices must indicate the place of taxation of the contractor (or leader in the case of a joint tender) for value added tax (VAT) purposes and must specify separately amounts not including VAT and amounts including VAT.

The contracting authority is exempt from all taxes and duties, including VAT, in accordance with Articles 3 and 4 of the Protocol 7 of the Treaty on the Functioning of the European Union on the privileges and immunities of the European Union.

The contractor (or leader in the case of a joint tender) must complete the necessary formalities with the relevant authorities to ensure that the supplies and services required for *Implementation of the FWC* are exempt from taxes and duties, including VAT.

II.19.2 E-invoicing

If provided for in the special conditions, the contractor (or leader in the case of a joint tender) submits invoices in electronic format if the conditions regarding electronic signature specified by Directive 2006/112/EC on VAT are fulfilled, i.e. using a qualified electronic signature or through electronic data interchange.

Reception of invoices by standard format (pdf) or email is not accepted.

II.20 PRICE REVISION

If a price revision index is provided in Article I.5.2, this Article applies to it.

Prices are fixed and not subject to revision during the first year of the FWC.

At the beginning of the second and every following year of the FWC, each price may be revised upwards or downwards at the request of one of the parties.

A party may request a price revision in writing no later than three months before the anniversary date of entry into force of the FWC. The other party must acknowledge the request within 14 days of receipt.

At the anniversary date, the contracting authority must communicate the final index for the month in which the request was received, or failing that, the last provisional index available for that month. The contractor establishes the new price on this basis and communicates it as soon as possible to the contracting authority for verification.

The contracting authority purchases on the basis of the prices in force at the date on which the specific contract enters into force.

The price revision is calculated using the following formula:

$$Pr = Po \times \left(\frac{Ir}{Io} \right)$$

where: Pr = revised price;

Po = price in the tender;

Io = index for the month in which the FWC enters into force;

Ir = index for the month in which the request to revise prices is received.

II.21 PAYMENTS AND GUARANTEES

II.21.1 Date of payment

The date of payment is deemed to be the date on which the contracting authority's account is debited.

II.21.2 Currency

Payments are made in euros, unless another currency is provided for in Article I.7.

II.21.3 Conversion

The contracting authority makes any conversion between the euro and another currency at the daily euro exchange rate published in the Official Journal of the European Union, or failing that, at the monthly accounting exchange rate, as established by the European Commission and published on the website indicated below, applicable on the day when it issues the payment order.

The contractor makes any conversion between the euro and another currency at the monthly accounting exchange rate, established by the Commission and published on the website indicated below, applicable on the date of the invoice.

http://ec.europa.eu/budget/contracts_grants/info_contracts/inforeuro/inforeuro_en.cfm

II.21.4 Costs of transfer

The costs of the transfer are borne as follows:

- (a) the contracting authority bears the costs of dispatch charged by its bank;
- (b) the contractor bears the costs of receipt charged by its bank;
- (c) the party causing repetition of the transfer bears the costs for repeated transfer.

II.21.5 Pre-financing, performance and money retention guarantees

If, as provided for in Article I.6, a financial guarantee is required for the payment of pre-financing, as performance guarantee or as retention money guarantee, it must fulfil the following conditions:

- (a) the financial guarantee is provided by a bank, or a financial institution approved by the contracting authority or, at the request of the contractor and with the agreement of the contracting authority, by a third party; and
- (b) the guarantee shall have the effect of making the bank or financial institution or the third party provide irrevocable collateral security, or stand as first-call guarantor of the contractor's obligations without requiring that the contracting authority has recourse against the principal debtor (the contractor).

The contractor bears the cost of providing such guarantee.

Pre-financing guarantees must remain in force until the pre-financing is cleared against interim payments or payment of the balance. Where the payment of the balance takes the form of a debit note, the pre-financing guarantee must remain in force for three months after the debit note is sent to the contractor. The contracting authority must release the guarantee within the following month.

Performance guarantees cover compliance with substantial contractual obligations until the contracting authority has given its final approval for the service. The performance guarantee must

not exceed 10 % of the total price of the specific contract. The contracting authority must release the guarantee fully after final approval of the service, as provided for in the specific contract.

Retention money guarantees cover full delivery of the service in accordance with the specific contract including during the contract liability period and until its final approval by the contracting authority. The retention money guarantee must not exceed 10 % of the total price of the specific contract. The contracting authority must release the guarantee after the expiry of the contract liability period as provided for in the specific contract.

The contracting authority must not request a retention money guarantee for a specific contract where it has requested a performance guarantee.

II.21.6 Interim payments and payment of the balance

The contractor (or leader in the case of a joint tender) must send an invoice for interim payment, as provided for in Article I.6 or in the tender specifications or in the specific contract.

The contractor (or leader in the case of a joint tender) must send an invoice for payment of the balance within 60 days of the end of the period of provision of the services, as provided for in Article I.6, in the tender specifications or in the specific contract.

Payment of the invoice and approval of documents does not imply recognition of the regularity, authenticity, completeness and correctness of the declarations and information they contain.

Payment of the balance may take the form of recovery.

II.21.7 Suspension of the time allowed for payment

The contracting authority may suspend the payment periods specified in Article I.6 at any time by *notifying* the contractor (or leader in the case of a joint tender) that its invoice cannot be processed. The reasons the contracting authority may cite for not being able to process an invoice are:

- (a) because it does not comply with the FWC;
- (b) because the contractor has not produced the appropriate documents or deliverables; or
- (c) because the contracting authority has observations on the documents or deliverables submitted with the invoice.

The contracting authority must *notify* the contractor (or leader in the case of joint tender) as soon as possible of any such suspension, giving the reasons for it. In cases b) and c) referred above, the contracting authority shall notify the contractor (or leader in case of a joint tender) the time limits to submit additional information or corrections or a new version of the documents or deliverables if the contracting authority requires it

Suspension takes effect on the date the contracting authority sends the *notification*. The remaining payment period resumes from the date on which the requested information or revised documents are received or the necessary further verification, including on-the-spot checks, is carried out. Where the suspension period exceeds two months, the contractor (or leader in the case of a joint tender) may request the contracting authority to justify the continued suspension.

Where the payment periods have been suspended following rejection of a document referred to in the first paragraph of this Article and the new document produced is also rejected, the contracting authority reserves the right to terminate the specific contract in accordance with Article II.18.1(c).

II.21.8 Interest on late payment

On expiry of the payment periods specified in Article I.6, the contractor (or leader in the case of a joint tender) is entitled to interest on late payment at the rate applied by the European Central Bank for its main refinancing operations in euros (the reference rate) plus eight points. The reference rate is the rate in force, as published in the C series of the *Official Journal of the European Union*, on the first day of the month in which the payment period ends.

Suspension of the payment period as provided for in Article II.21.7 is not considered as giving rise to late payment.

Interest on late payment covers the period running from the day following the due date for payment up to and including the date of payment as defined in Article II.21.1.

However, when the calculated interest is EUR 200 or less, it must be paid to the contractor (or leader in the case of a joint tender) only if it requests it within two months of receiving late payment.

II.22 REIMBURSEMENTS

II.22.1 If provided for in the special conditions or in the tender specifications, the contracting authority must reimburse expenses directly connected with the provision of the services either when the contractor provides it with supporting documents or on the basis of flat rates.

II.22.2 The contracting authority reimburses travel and subsistence expenses on the basis of the shortest itinerary and the minimum number of nights necessary for overnight stay at the destination.

II.22.3 The contracting authority reimburses travel expenses as follows:

- (a) travel by air: up to the maximum cost of an economy class ticket at the time of the reservation;
- (b) travel by boat or rail: up to the maximum cost of a first-class ticket;
- (c) travel by car: at the rate of one first class rail ticket for the same journey and on the same day;

In addition, the contracting authority reimburses travel outside Union territory if it has given its prior written approval for the expenses.

II.22.4 The contracting authority reimburses subsistence expenses on the basis of a daily subsistence allowance as follows:

- (a) for journeys of less than 200 km for a return trip, no subsistence allowance is payable;
- (b) the daily subsistence allowance is payable only on receipt of supporting documents proving that the person concerned was present at the destination;
- (c) the daily subsistence allowance takes the form of a flat-rate payment to cover all subsistence expenses, including meals, local transport including transport to and from the airport or station, insurance and sundries;

- (d) the daily subsistence allowance is reimbursed at the flat rates specified in Article I.5.3;
- (e) accommodation is reimbursed on receipt of supporting documents proving the necessary overnight stay at the destination, up to the flat-rate ceilings specified in Article I.5.3.

II.22.5 The contracting authority reimburses the cost of shipment of equipment or unaccompanied luggage if it has given its prior written approval for the expense.

II.23 RECOVERY

II.23.1 If an amount is to be recovered under the terms of the FWC, the contractor must repay the contracting authority the amount in question.

II.23.2 Recovery procedure

Before recovery, the contracting authority must *formally notify* the contractor of its intention to recover the amount it claims, specifying the amount due and the reasons for recovery and inviting the contractor to make any observations within 30 days of receipt.

If no observations have been submitted or if, despite the observations submitted, the contracting authority decides to pursue the recovery procedure, it must confirm recovery by *formally notifying* a debit note to the contractor, specifying the date of payment. The contractor must pay in accordance with the provisions specified in the debit note.

If the contractor does not pay by the due date, the contracting authority may, after informing the contractor in writing, recover the amounts due:

- (a) by offsetting them against any amounts owed to the contractor by the Union or by the European Atomic Energy Community or by an executive agency when it implements the Union budget;
- (b) by calling in a financial guarantee if the contractor has submitted one to the contracting authority;
- (c) by taking legal action.

II.23.3 Interest on late payment

If the contractor does not honour the obligation to pay the amount due by the date set by the contracting authority in the debit note, the amount due bears interest at the rate indicated in Article II.21.8. Interest on late payments will cover the period starting on the day after the due date for payment and ending on the date when the contracting authority receives the full amount owed.

Any partial payment is first entered against charges and interest on late payment and then against the principal amount.

II.23.4 Recovery rules in the case of joint tender

If the contract is signed by a group (joint tender), the group is jointly and severally liable under the conditions set out in Article II.6 (liability). The contracting authority shall send the debit note first to the leader of the group.

If the leader does not pay by the due date the whole amount, and if the amount due cannot be offset or can only be offset partially in accordance with Article II.23.2 (a), then the contracting authority may claim the amount still due to any other member or members of the group by

respectively *notifying* them with a debit note in conformity with the provisions laid down in Article II.23.2.

II.24 CHECKS AND AUDITS

II.24.1 The contracting authority and the European Anti-*Fraud* Office may check or require an audit on the *Implementation of the FWC*. This may be carried out either by OLAF's own staff or by any other outside body authorised to do so on its behalf.

Such checks and audits may be initiated at any moment during the provision of the services and up to five years starting from the payment of the balance of the last specific contract issued under this FWC.

The audit procedure is initiated on the date of receipt of the relevant letter sent by the contracting authority. Audits are carried out on a confidential basis.

II.24.2 The contractor must keep all original documents stored on any appropriate medium, including digitised originals if authorised under national law, for a period of five years starting from the payment of the balance of the last specific contract issued under this FWC.

II.24.3 The contractor must grant the contracting authority's staff and outside personnel authorised by the contracting authority the appropriate right of access to sites and premises where the FWC is implemented and to all the information, including information in electronic format, needed to conduct such checks and audits. The contractor must ensure that the information is readily available at the moment of the check or audit and, if so requested, that information is handed over in an appropriate format.

II.24.4 On the basis of the findings made during the audit, a provisional report is drawn up. The contracting authority or its authorised representative must send it to the contractor, who has 30 days following the date of receipt to submit observations. The contractor must receive the final report within 60 days following the expiry of the deadline to submit observations.

On the basis of the final audit findings, the contracting authority may recover all or part of the payments made in accordance with Article II.23 and may take any other measures which it considers necessary.

II.24.5 In accordance with Council Regulation (Euratom, EC) No 2185/96 of 11 November 1996 concerning on-the-spot checks and inspection carried out by the Commission in order to protect the European Communities' financial interests against *Fraud* and other *irregularities* and Regulation No 883/2013 of the European Parliament and of the Council of 11 September 2013 concerning investigations conducted by the European Anti-*Fraud* Office, the European Anti-*Fraud* Office may carry out investigations, including on the spot checks and inspections, to establish whether there has been *Fraud*, corruption or any other illegal activity under the contract affecting the financial interests of the Union. Findings arising from an investigation may lead to criminal prosecution under national law.

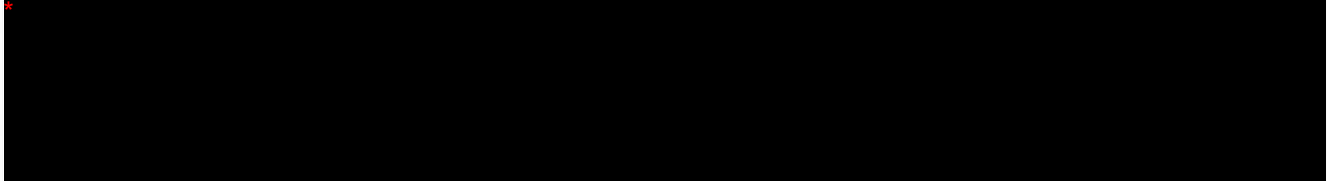
The investigations may be carried out at any moment during the provision of the services and up to five years after the payment of the balance of the last specific contract issued under this FWC.

II.24.6 The Court of Auditors, the European Public Prosecutor's Office established by Council Regulation (EU) 2017/1939¹⁵ ('the EPPO') and, for the processing of personal data, the European Data Protection Supervisor, have the same rights as the contracting authority, particularly right of access, for the purpose of checks, audits and investigations.

SIGNATURES

For the contractor,
Asociación Colaboración Cochrane
Iberoamericana

For the Contracting Authority,
Bernhard URL
Executive Director



Done at Sabadell

Done at Parma

¹⁵ Council Regulation (EU) 2017/1939 of 12 October 2017 implementing enhanced cooperation on the establishment of the European Public Prosecutor's Office

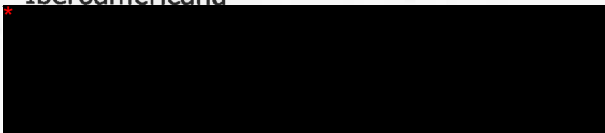
ARTICLE 1341, 2ND PARAGRAPH OF THE ITALIAN CIVIL CODE

In accordance with the provisions of Article 1341, 2nd paragraph, of the Italian Civil Code, the Contractor expressly declares to accept the following provisions:

- 1) Article I.3 Special Conditions (Entry into force and duration);
- 2) Article I.9 Special Conditions (Processing of Personal Data);
- 3) Article I.10 Special Conditions (Exploitation of the results of the contract);
- 4) Article I.11 Special Conditions (Termination by either party);
- 5) Article I.12 Special Conditions (Applicable Law and Settlement of disputes);
- 6) Article I.15 Special Conditions (Liability for alleged breach of intellectual property rights);
- 7) Article II.2 General Conditions (Joint Tenders);
- 8) Article II.3 General Conditions (Severability);
- 9) Article II.6 General Conditions (Liability);
- 10) Article II.10 General Condition (Subcontracting);
- 11) Article II.12 General Condition (Assignment);
- 12) Article II.13 General Conditions (Intellectual property rights);
- 13) Article II.14 General Conditions (Force majeure);
- 14) Article II.15 General Conditions (Liquidated damages);
- 15) Article II.16 General Conditions (Reduction in price);
- 16) Article II.17 General Conditions (Suspension of the Implementation of the FWC);
- 17) Article II.18 General Conditions (Termination of the FWC);
- 18) Article II.24 General Conditions (Checks and audits).

SIGNATURE

For the Contractor,
Asociación Colaboración Cochrane
Iberoamericana



Date: 05/09/2022

Done at Sabadell

ANNEX I – TENDER SPECIFICATIONS



TENDER SPECIFICATIONS

Reference: OC/EFSA/MESE/2022/03

Subject: Methodological support for the performance of literature reviews within evidence-based scientific assessments

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

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

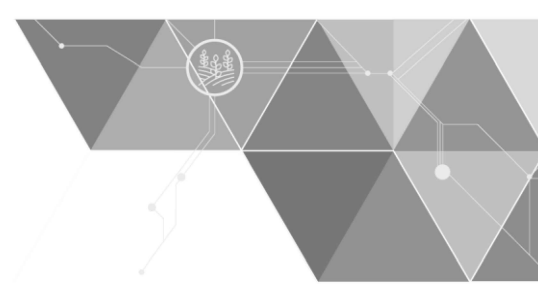
Milestone	Date ¹	Comments
Launch date	23/03/2022	Date Contract Notice is sent to Official Journal
Deadline for sending request for clarification to EFSA	20/05/2022 at 14:30	Requests for clarification may only be submitted through the e-Tendering website as described in the Invitation Letter. EFSA is not obliged to reply to clarifications received less than 6 working days before the deadline for submission of offers.
Deadline for EFSA to reply to clarification questions	24/05/2022	
"Receipt Time Limit" - Closing date and time for receipt of offers	30/05/2022 at 14:30	Refer to the Invitation letter and part 3 of these tender specifications regarding how to submit your offer.
Opening session	31/05/2022 at 14:30	Due to ongoing COVID-19 related restrictions for accessing the EFSA premises, the public opening session will be held online as a virtual meeting. 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 JUNE 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 JULY 2022	

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

This call for tenders is being launched by the European Food Safety Authority and aims at providing to EFSA a framework contract for the provision of scientific services of methodological support for literature reviews for evidence-based scientific assessments. Such support may be requested to perform and/or appraise full or part(s) of systematic reviews (SRs), as well as scoping and narrative literature reviews.

Questions arising from EFSA's mandates could be of different types, including scientific assessments in humans, animals or plants related to chemical, microbiological, pest or other hazards and GMOs, environmental risk assessments, nutritional, efficacy and animal welfare assessments, emerging risks identification, monitoring and/or surveillance activities and assessment of methods.

EFSA analysed the use of systematic reviews (SR) to retrieve, appraise and synthesise publicly available scientific evidence to produce evidence-based risk assessments (EFSA, 2010²) and concluded that due to its methodological rigor and objective and transparent nature, systematic review methodology and its principles could provide additional value for answering well-formulated questions generated by the risk assessment process or other analytical frameworks in food and feed safety. Hence, EFSA supports the use of systematic review methodology (as defined in EFSA, 2010 and referred to in this document as the "EFSA SR Guidance") for food and feed safety assessments.

As systematic review is resource intensive, scientific services are required to support the performance of SR or parts of it. Such services imply the application of standardised and internationally recognised methods for retrieving, appraising and synthesising scientific evidence as well as for appropriately reporting and documenting the processes, to enhance transparency and allow reproducibility of all results.

This call is based on EFSA's 2022 Work Programme for grants and operational procurements as presented in Annex XIa of the Programming Document 2022 – 2024³.

1.2 OBJECTIVES

This procurement procedure aims to select multiple framework contractors to provide methodological support to EFSA in performing and/or appraising full or part(s) of literature reviews to support evidence-based scientific assessments⁴. Such reviews may include systematic reviews (SRs) or parts of them (as listed below), as well as scoping and narrative literature reviews, and will be related to the types of scientific questions described in section 1.1.

² 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. [48 pp.]. doi:10.2903/j.efsa.2010.1637. Available online: <http://www.efsa.europa.eu/en/efsajournal/doc/1637.pdf>

³ https://www.efsa.europa.eu/sites/default/files/corporate_publications/files/amp2224.pdf

⁴ The results and conclusions of the tasks performed by the contractors will be reviewed by EFSA before being considered in the development of an EFSA scientific output.



In the scope of this contract, methodological support refers to the tasks described in this section 1.2. Such methodological support requested will be specified in detail in specific contracts, which will describe, each time the exact details, tasks and conditions of the request. Possible tasks that may be requested each time will include one or more of the following:

1. Systematic Literature Reviews (SRs)

Contractors may be asked to conduct or support EFSA in conducting full or parts of SRs in line with the methodology described in the EFSA SR Guidance. This task may refer to one, more or all of the steps of the SR as described in the EFSA SR Guidance:

- Preparing the review:
 - Developing the review protocol (including defining the review question and developing the eligibility criteria for studies)
 - Setting the logistics for doing the review
- Searching for research studies (including scoping searches and extensive literature searches (ELS))
- Selecting studies for inclusion or exclusion in the review
- Collecting data from the included studies and creating evidence tables
- Assessing methodological quality of included studies
- Synthesising data from included studies – Meta-analysis
- Presenting data and results
- Interpreting results and drawing conclusions

2. Narrative literature reviews

Contractors may be requested to conduct or support EFSA in conducting narrative literature reviews. Such reviews are usually broader in scope, but less systematic and rigorous in the approaches followed for the various steps of the review. Such tasks would not need to necessarily follow the EFSA SR Guidance, but rather requested approaches and criteria that will be each time defined by EFSA in the specific contracts.

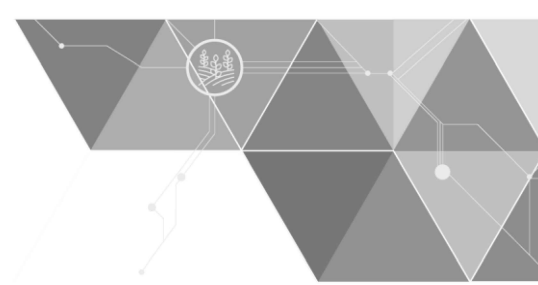
3. Scoping literature reviews

Contractors may be asked to conduct or support EFSA in conducting scoping literature reviews, which, for example may have the objective of identifying and assessing the state of evidence for a review question (e.g., the quantity of research and types of studies). The EFSA SR Guidance does not prescribe in detail the approaches for scoping reviews, therefore more details on the requested requirements will be each time defined by EFSA in the specific contracts.

4. Reviewing, assessing and appraising the quality of already conducted reviews

Contractors may be asked to review protocols, plans or strategies for conducting full or parts of SRs and other reviews mentioned above. They may also be asked to assess and/or appraise the quality of full or parts of already conducted literature reviews of the type mentioned under tasks 1 to 3 above, in line with the EFSA SR Guidance and/or other specific requirements, that will be indicated in each specific contract. In all such cases, the contractor will be expected to provide comments and suggest improvements of the reviewed materials (concerning, for example, methodologies, reporting etc.) and/or review possible proposals for such improvements.

The above description of tasks, under points 1 to 4, is not exhaustive and other similar tasks may also be requested.



All services mentioned above will need to be carried out and supported by Distiller SR⁵, whenever applicable. The contractors do not need to have access to Distiller SR, as EFSA will provide them with the appropriate licenses, as and for as long is required for the execution of the tasks. Previous experience with using Distiller is highly desirable, however, not required, as trainings on the use of Distiller SR at the level necessary to carry out the tasks requested in each specific contract might be provided to the contractors by EFSA.

At the end of each specific contract, a report documenting and reporting the method and results of the SR (or any part(s) of the SR process) and/or any other types of reviews or tasks undertaken could be asked to be produced by the contractor. To develop this Report, the contractor is encouraged to consider the PRISMA statement⁶ whenever relevant. When the statement is not fully applicable, the contractor should document and explain the discrepancies from the PRISMA statement.

An interim Report may also be asked, especially for long-term projects.

The contractor may be asked to attend one or more teleconferences or physical meetings to discuss the content, the objectives and the progress of the requested review and/or task(s). Meetings may also take place physically at the premises of EFSA or in any other major city in the EU. The number and type of such meetings will be detailed in each specific contract. The amount for each specific contract will include the financial provision for these physical meetings, based on the financial offer submitted by the contractor.

The services/activities (including a detailed description of the tasks to be undertaken) will be requested by EFSA in the context of specific contracts setting out all terms and conditions as well as the timelines. The contractor may be asked to carry out several individual assignments in parallel and if accepted, will need to provide the required services within assigned time and according to the quality criteria defined by EFSA in the specific contracts. However, in terms of possible workload for the contractor, it should be noted that the FWC is being set up in cascade, specifically to allow flexibility to the contractors to accept or refuse specific requests from EFSA based on their availability. If the first ranked contractor refuses an assignment as they are unavailable at that time to carry out the work, EFSA will revert to the second ranked contractor and so on. More information on how the cascade will function can be found in section 1.4 of these tender specifications. The contractor will be responsible for maintaining, updating and revising each document linked to the service execution (and duly specified in each specific contract) of the above service groups.

The frequency, size and duration of services under the specific contracts will be based on the future needs of EFSA which cannot be estimated in detail at this stage. It is expected that EFSA will request at least six assignments per year, in any case this estimation does not represent a commitment. The duration of the assignments could last up to several months, also possibly exceeding one year.

Frequent communication with EFSA throughout the implementation of the contract is a requirement. For this purpose, regular coordination web-conferences (indicatively once every month but to be defined per each specific contract) with EFSA will be organized. For

⁵ <https://www.evidencepartners.com/products/distillersr-systematic-review-software/>

⁶ Please note that this statement is specific for reporting systematic reviews of benefits and harms of health care interventions (The PRISMA Statement (<http://www.prisma-statement.org/>) for Reporting Systematic Reviews and Meta-Analyses of Studies That Evaluate Health Care Interventions: Explanation and Elaboration (<http://www.plosmedicine.org/article/info%3Adoi%2F10.1371%2Fjournal.pmed.1000100#s8>)).



any given assignment, the contractor will be expected to collaborate closely with EFSA staff and EFSA experts.

1.3 TASKS, DELIVERABLES, TIMELINE AND PAYMENTS

No	Tasks & deliverables	Can be subcontracted?	Deadline
1-4	<p>Tasks: Carry out or provide methodological assistance in performing or appraising literature reviews (systematic, scoping, narrative) or parts of them. Some of the tasks that may be requested, and related activities are described in section 1.2 (Objectives). This description of tasks is not exhaustive and exact details will be defined in the specific contracts.</p> <p>Deliverables: The number of deliverables will depend on the tasks described by the specific contract. Deliverables should be provided in the English language. A non-exhaustive list of deliverables related to the tasks above are:</p> <ul style="list-style-type: none"> • Preliminary / Interim / Final report(s) • Plan of the work • Protocol for a full SR or parts of an SR • Lists of studies identified in a scoping review. • Input on the appraisal of full or parts of already conducted reviews • Suggested improvements of the reviewed materials • Review of possible proposals for such improvements • Presentation of results (including graphs, tables, and other presentations/visualizations of results) • Participation in one or more meetings (including kick-off meeting) with EFSA and/or WG experts or other contractors in order to discuss the requested tasks, support requests and to provide advice, or answers to related questions. The meetings will predominantly be by web-meeting, but some may take place in Parma or any other location in a major city in the EU • Ad hoc teleconferences during the contract implementation between EFSA and the contractor • Meeting minutes 	Yes (unless stated otherwise in the specific contract)	Defined in the specific contract
No	Payments		Linked to approval of deliverable No.
	The payment modalities applicable to each specific contract are detailed in the draft framework contract.		NA

The working language for contract implementation including execution of all tasks, meetings and deliverables shall be English. Any written deliverables must be to a high standard of English which does not require proof reading. All deliverables shall follow the most updated version of the EFSA templates, which will be provided prior to signature of specific contracts. Teleconferences will use a software approved by EFSA.



1.4 INFORMATION ON THE CONTRACT

<u>Nature of expense</u>	services
<u>Type of contract</u>	framework (FWC)
<u>Type of FWC</u>	multiple FWC in cascade
<u>Maximum number of contractors</u>	10
<u>Place of performance</u>	EFSA premises or contractor's premises

Duration of FWC

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

Budget information

The financial ceiling available for specific contracts under the framework contract is 4,000,000 €. A contingency of 10% and possible price indexations are already included in these ceilings.

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 4,000,000 €.

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 through specific contracts awarded through a cascade mechanism. Every time there is a need for a service to be performed, EFSA will send the specific contract to the first ranked framework contractor, detailing the precise assignment, the number of senior and junior person-days required, timescales for performance of the work and the prices agreed under the framework contract (based on each framework contractor financial offer). The first ranked contractor has a maximum of 10 working days, commencing the day after the date the request was sent, to accept, sign and return the specific contract. If the first ranked framework contractor decides not to accept and sign the specific contract, the next framework contractor in the ranking will be sent the request and the process will continue as described, until a specific contract will be signed.

In the event that the first ranked framework contractor is unavailable to accept the request, due to already high workload and/or competing priorities, they should inform EFSA as soon as possible, preferably before 10 working days from the date of request have passed. In this way, EFSA can proceed quickly to request the services from the second ranked and so on. Tenderers should note that there is no obligation on the contractor to accept an assignment under the framework contract and this flexibility should help the contractors to accommodate peaks of work in the best way possible.



The specific contract will set out the specific conditions for performing the individual assignment. For more details on the administrative implementation modalities of the framework contract please refer to the draft Contract in Annex 2. An example of the details of a specific assignment, which will be included in the specific contract, is reported in table 1.

Table 1 - Example of the details of a specific assignment

Type (or combination of types) of literature review and tasks	<p>Example of possible options:</p> <ul style="list-style-type: none"> • Systematic Review, or parts of it (see section 1.2) • Narrative Review • Scoping Review • Reviewing, assessing and appraising the quality of already conducted reviews
Subject	<p>Example of possible options:</p> <p>scientific assessments in humans, animals or plants related to chemical, microbiological, pest or other hazards and GMOs, environmental risk assessments, nutritional, efficacy and animal welfare assessments, emerging risks identification, monitoring and/or surveillance activities and assessment of methods</p>
Background, description of the activities and methodological support needed	<p>Brief text giving the background and providing a short description of the activities to be carried out within this specific assignment. Description of the methodological support needed, i.e tasks mentioned in section 1.2 .</p>
Number and competencies of the team of experts	<p>Number senior experts⁷ (in person-days) and competencies Number junior experts (in person-days) and competencies</p> <p>The above numbers will include also the experts' time for participation to regular and <i>ad hoc</i> meetings.</p> <p>The description of the possible profiles and competencies of the requested senior experts are described in section 2.4. At least one senior project leader will be requested for each assignment to coordinate the activities and be the contact person with EFSA (corresponding to profile d.1 under section 2.4 B). In addition, for each individual assignment at least one expert in the relevant specific scientific area might be required (see section 2.4 B profile e).</p> <p>Examples of competencies that might be requested for junior experts are detailed below.</p> <ul style="list-style-type: none"> • Junior expert with at least 3 years' proven professional experience⁸ in working with at least two of the bibliographic databases listed in Annex 3 and with reference management software (e.g. EndNote, Citavi, Zotero, Mendeley or similar). • Junior expert with at least 3 years' proven professional experience participating in the full SR stepwise process in a life sciences context

⁷ Senior experts are expected to have at least 5 years' proven professional experience while junior experts at least 3 years' proven professional experience in the respective field

⁸ Whenever proven professional experience is required, this should be evidenced in the CV by indicating scientific publications, description of the relevant projects or other relevant activities and, if possible, a description of the role of the expert in those activities. It should be noted that professional experience is referring to independent scientific work undertaken outside of activities related to acquiring a University or professional degree at any level.



	<ul style="list-style-type: none"> Junior expert with at least 3 years' proven professional experience participating in the full SR stepwise process in a life sciences context and proven professional experience in data management, evidence synthesis and data presentation.
Participation in physical meetings needed	Number and duration of physical meetings.
Expected deliverables	<p>Example of possible options (see section 1.3):</p> <ul style="list-style-type: none"> Plan of the work Preliminary / Interim / Final report(s) Protocol for a full SR or parts of an SR Other
Quality criteria	Quality criteria will be defined for each specific assignement.
Bibliographic databases needed in addition to the large multidisciplinary one(s) requested in the minimum technical capacity (section 1.4)	List of bibliographic databases
CVs of the team working on this order	<p>To be provided in case of acceptance of the assignment by the contractor and to be approved by EFSA.</p> <p>Evidence of the required level of spoken and written standard UK English (see section 2.4 B requirement c) should be provided as well for each member of the team and be approved by EFSA.</p>
DoIs of the team working on this order	To be provided in case of acceptance of the assignment by the contractor and to be approved by EFSA.
Timeframe	Expected start and end of the activities
Amount	Amount of the specific contract (the amount is based on the unit costs of the FWC of each contractor and is a fixed amount)

1.5 OWNERSHIP, INTELLECTUAL PROPERTY RIGHTS, USE OF RESULTS

As regards any product or delivery commissioned by the contracting authority 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 the contracting authority, the intellectual property rights will be owned by the contracting authority 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 the contracting authority in performance of the contract, unless the contractor requests the contracting authority ex-ante authorisation and obtains 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 all deliverables, including but not limited to the final deliverable 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.

PARTS OF RESULTS PRE-EXISTING THE CONTRACT

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

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

The draft contract 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 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 Junction⁹ 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

⁹ <http://www.efsa.europa.eu/en/press/news/190117> and <https://zenodo.org/communities/efsa-kj/?page=1&size=20>



several deliverables can be cross-linked among them and to the published final Report on Wiley Online library.

1.6 PERSONAL DATA PROTECTION

Processing of personal data in the context of this contract shall comply with Regulation (EU) 2018/1725 ('the EDPR')¹⁰. 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

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 contract. In particular, the selected contractor shall ensure:

- 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 assist EFSA as respective controllers in the fulfilment of their obligation to respond to requests of data subjects exercising their rights laid down in Chapter III of the EDPR;
- To assist EFSA as respective controllers with their obligations 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 the contracting authority.

Further information on data protection is provided in the EFSA guidance for tenderers on the EFSA website, page 13.

¹⁰ <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32018R1725>



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 tender, the following will be assessed only for the tenderer proposed for contract award: Selection criteria (Professional Conflict of Interest – Institutional and Individual Declarations of Interest); Exclusion criteria (Declaration on Honour, Section A); Selection criteria (Declaration on Honour, section B).

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

Eligibility – access to EU Market

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

Evidence requested in your offer:

Tenderers must submit the Administrative data forms (including LEF and BAF) available [here](#).

Exclusion

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

Evidence requested in your offer:

Tenderers must declare that they are not in one of the exclusion situations by providing a signed and dated Declaration on Honour (section A), 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

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

A) Economic and financial capacity

The tenderer must have generated an overall annual turnover of at least 500,000 € in each of the last 2 closed financial years (2020 and 2019).

Evidence requested in the offer:

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

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

In the event of partners in a joint offer or subcontractors providing the financial capacity, if during contract implementation, in case of request for the addition of new subcontracting or assignment of the contract to a new legal entity, the economic and financial capacity will be checked for the last 2 most recent closed financial years and not necessarily the financial years published with the call.

B) Technical and professional capacity

The contractor shall provide a multidisciplinary team of experts which should include the types of expertise detailed below in this section under 'minimum professional capacity'. Depending on the needs of each assignment, the minimum requirements for the assignment under each specific contract may be refined and/or modified. It is once again reminded that the FWC is being set up in cascade, specifically to allow flexibility to the contractors to accept or refuse specific requests from EFSA based on their availability. Therefore, for every specific contract during the framework contract implementation that a contractor accepts, they will have to make sure that the specific methodological and subject matter expertise relevant and necessary for the specific assignment is provided and, if necessary, subcontracted (for more information on subcontracting, please refer to the draft framework contract). All such expertise will be clearly described in the specific contract.

The tenderer must have the following **minimum professional capacity** to perform the contract:

- a) The tenderer overall must have extensive and demonstrable experience in performing full systematic literature reviews and in project management.



- b) The tenderer overall must have extensive and demonstrable experience in preparing scientific publications and/or reports related to the subject matter of the contract.
- c) Each expert individually must have an excellent level of spoken and written standard UK English. For non-native speakers, this should be demonstrated by at least 2 years of professional work in an English-speaking environment; or a University degree (e.g. following attendance of an undergraduate or post-graduate university programme) undertaken in an English-speaking University; or at least 1 year of proven experience in delivering training or teaching in English; or an official certificate of English proving a C1 level for senior experts or a B2 level for junior experts; only in the case of junior experts at least 3 years' experience working in projects in which the working language was English will also be accepted.
- d) Ability to provide a team of experts with a minimum size of **three senior experts** compliant with the below specific expertise requirements (profiles):
 - d.1)** A senior project leader with a PhD and with at least 5 years of proven professional experience in project management and 5 years of proven professional experience in performing the full SR stepwise process addressing at least two of the types of scientific questions discussed in section 1.1. This experience should be evidenced by scientific publications, description of the relevant projects or other relevant activities and a description of the role of the project leader in those publications, projects or activities.
 - d.2)** One senior expert with at least 5 years proven professional experience in performing or supervising the full SR stepwise process in a life sciences context. This experience should be evidenced by scientific publications, description of the relevant projects or other relevant activities and a description of the role of the senior expert in those publications, projects or activities.
 - d.3)** One senior expert librarian or information specialist with at least 5 years of proven professional experience in: a. retrieval of scientific literature for SRs in a life sciences context b. working with at least two of the bibliographic databases listed in Annex 3 and c. working with reference management software (e.g. EndNote, Citavi, Zotero, Mendeley or similar).
- e) For each individual assignment during the framework contract implementation, the contractor will have to make sure that at least one junior or senior expert in the specific scientific area relevant and necessary for the assignment will be included in the project team, if (and as) requested in the specific contract. The specific subject matter expertise will be detailed in the EFSA specific contract and will reflect the types of scientific questions discussed in section 1.1. **The contractor should provide a signed statement confirming that they will provide at least one junior or senior expert with the necessary subject-matter expertise and proven professional experience¹¹**, for the implementation of each individual assignment that they will choose to accept. The CVs and DoIs of the proposed experts for all the cases described under requirement e) will be subject to approval by EFSA before the signature of a specific contract.

¹¹ Senior experts are expected to have at least 5 years' proven professional experience while junior experts at least 3 years' proven professional experience in the respective field



The tenderer must have the following **minimum technical capacity** to perform the contract:

- f) The tenderer must have access to at least two relevant scientific electronic bibliographic databases for the execution of the contract; at least one of them should be a large multidisciplinary database, such as Web of Science Core Collection, Scopus or equivalent. The bibliographic databases should be relevant to cover the types of scientific questions discussed in section 1.1. As an example, the EFSA electronic databases collection is currently composed of the databases shown in Annex 3. It needs to be noted that this is an example, and the tenderer does not need to have access to all these databases, however, access to specific databases (that may or may not be included in the Annex 3 list) may be required for specific assignments under specific contracts.
- g) Access to a reference management software (e.g. Endnote, Citavi, Zotero, Mendeley or similar). EFSA currently uses Endnote X9 and Endnote 20. Also, access to software for the management and presentation of the extracted data and the creation of tables, graphs etc is required (e.g. R or similar).

Evidence requested in the offer:

Requirement a): At least two major projects in which full SRs were performed with evidence of project management responsibility, carried out in the course of the past 5 years;

Requirement b): At least five publications or reports prepared, related to the subject matter of this contract, in the course of the past 5 years;

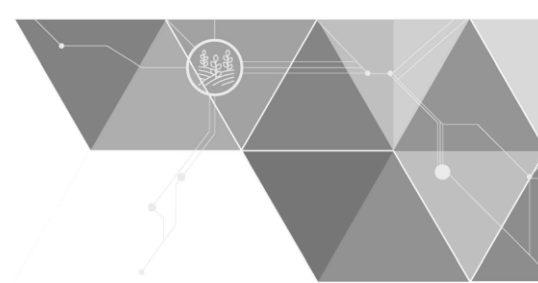
Requirements c) and d): For each member of the team, the minimum expertise requirements should be proven by detailed curriculum vitae, including a list of major and relevant publications and projects undertaken or participated to, in the specified areas. Whenever proven professional experience is required, this should be evidenced in the CV by indicating scientific publications, description of the relevant projects or other relevant activities and, if possible, a description of the role of the expert in those activities. It should be noted that professional experience is referring to independent scientific work undertaken outside of activities related to acquiring a University or professional degree at any level. EFSA strongly recommends submitting the CVs in the EU CV format which can be accessed [here](#); For requirement c): additionally, a copy of the relevant certification, whenever applicable.

Requirement e): Tenderers should provide a signed statement confirming that they will provide at least one junior or senior expert with the necessary subject-matter expertise and proven professional experience for the implementation of each individual assignment that they will choose to accept. It should be noted that professional experience is referring to independent scientific work undertaken outside of activities related to acquiring a University or professional degree at any level.

Requirement f): A statement should be provided that the tenderer has access to at least two relevant scientific electronic bibliographic databases, as described under requirement f) (indicating which ones).

Requirement g): A statement confirming access to the required software.

- **Declaration on Honour (section B)** available [here](#). To be completed by the tenderer (in case of joint offer by the leading partner only);
- **Confirmatory statement of resources** (*only applicable for joint offers or offers with subcontracting*): the signed declaration on honour (section C) available [here](#). Signed by each partner/subcontractor confirming they will provide the necessary resources for the performance of the contract.



C) Professional conflicting interest

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

Evidence requested in the offer:

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 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 framework contract signature. Please refer to EFSA's policy on independence and the Decision of the Executive Director on Competing Interest Management for detailed information.

In the course of the implementation of the FWC, Individual DOIs for the proposed team members will be requested and will be screened and validated before the signature of any Specific contract.

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/EU¹² and compliance with data protection obligations resulting from Regulation (EU) 2016/679 and Regulation (EU) 2018/1725¹³.

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

The technical offers will be evaluated on the basis of the case study defined below. Please read carefully the assignment.

Note

- The case study proposed will only be used for the evaluation of the offers and intends to mimic realistic requirements although it cannot, in any way, be considered exhaustive or representative.
- The case study relates to the quality award criteria ONLY, i.e. it is completely dissociated from the financial offer evaluation, i.e. the financial offer to be proposed using Annex 1 shall not be based on this case study.

Case study

It is hypothetically required (for the purposes of this case study) to conduct a full systematic review on the following subject:

- *'Relationship between the intake of carbohydrate quantity and quality and risk of developing Type 2 diabetes in non-diabetic individuals'*

following the complete process as described in the EFSA SR guidance. Please provide a complete and detailed proposal of how you understand and intend to organise the tasks.

Your proposal should have a clear structure, which shows the understanding of the assignment. It should include a clear and detailed description of the methodology proposed for implementation in line with the SR methodology described in the EFSA SR guidance, e.g.: the method for preparing the protocols; how the eligibility criteria for study selection

¹² OJ L 94 of 28.03.2014, p. 65

¹³ 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>



will be developed; and the method for conducting the SR i.e.: how the preliminary and definitive search strategies will be performed; the range of information sources that will be searched; the method for selecting the studies; the method for extracting data from the included studies; the method for assessing the methodological quality of the included studies; the method for synthesising the data; etc.

Your proposal should also illustrate how the SR will be documented and reported (method and results). The way the various tasks will be organised, and the expertise allocated to each task should be detailed. The proposal should also contain a clear description of the mechanisms to guarantee availability of the contractor for the assignments and the mechanisms to meet the deadlines and to overcome any potential constraints. The back-up plans in case of any constraints should also be detailed. The tenderer should clearly describe the arrangements for communication with EFSA and within the team (which is particularly important in case of a consortium of service providers or in case of subcontracting where more entities are involved in project implementation). The tenderer should detail the functional division of responsibilities and clearly indicate the project leader, back-up project leader and contact person for EFSA. The tenderer should also specify the role and availability of the project leader throughout the duration of the project. In addition, the technical offer should describe the quality assurance and control mechanisms to guarantee high scientific quality of the deliverables.

Ideally your proposal should not exceed **20 pages**.

1. METHODOLOGY PROPOSED FOR IMPLEMENTATION (60 points - minimum threshold 50 %)

- a) Conformity of proposed methodology with the case study question and convincing justification of the choice of proposed methodology; Compliance with the systematic review methodology as illustrated in the EFSA guidance document; advantages and disadvantages; **50 points**
- b) Logical and structured step by step explanation of methodology; **10 points**

2. PROJECT ORGANISATION (30 points – minimum threshold 50%)

- a) Clear and detailed information on organization and distribution of the tasks and responsibilities, as well as of the communication among the project team and with EFSA; in case of joint offer & subcontractors, clarity on who does what, when and why (justify why the partner/subcontractor is proposed to do the particular task/work-package); Role and availability of project leader throughout the duration of the project; **25 points**
- b) Measures proposed to ensure the meeting of the deadlines for deliverables; **5 points**

3. RISK MANAGEMENT (10 points - minimum threshold 50%)

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) Identification of risks associated with the proposed methodology, technical problems, and project management issues which might appear during the implementation of the assignment; Proposed risk mitigation actions; **5 points**
- b) Quality assurance and control mechanisms put in place to guarantee the high quality of deliverables; **5 points**

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



Offers must score at least 50% for each criterion, 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.

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.

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:

<p>TOTAL SCORE OF THE EVALUATED OFFER (C) =</p> <p>30 * Cheapest price offer/price of tender X</p> <p>+</p> <p>70 * Total quality score (out of 100) for all quality award criteria of tender X/100</p>



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](#)¹⁴. In case you don't have an [EU Login](#), you can [create an account](#) at any moment. For more information see the [EU login help](#). After logging in with your EU Login password, the e-Tendering will then display a button 'submit your tender' and you will be able to access the e-Submission.

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

Information to be filled in

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

- **Signed declaration on Honour on Exclusion criteria (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:

¹⁴ 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.

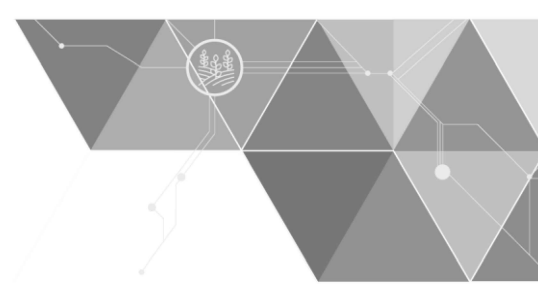
Deadline for receipt of tenders

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

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

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. One financial offer should be submitted with your technical offer.

ANNEX 2 - DRAFT CONTRACT

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

ANNEX 3 – Example of EFSA electronic database collection

The EFSA electronic databases collection is currently composed of:

- Biosis (Web of Science platform)
- CAB Abstracts (Web of Science platform)
- CABI Distribution Maps (Plant Pests and Plant Diseases)
- CABI Crop Protection Compendium
- CABI Forestry Compendium
- Cochrane Library
- Current Content Connects (Web of Science platform)
- Embase
- FSTA, Food Science & Technology Abstracts (Web of Science platform)
- Medline (Web of Science platform and PubMed)
- SciFinder-n
- Scopus
- Web of Science Core collection:
 - Science Citation Index Expanded, SSCI
 - Conference Proceedings Citation Index- Science (CPCI-S)
 - Book Citation Index– Science (BKCI-S)
 - Emerging Sources Citation Index (ESCI)
- Zoological Record (Web of Science platform)

An updated list will be sent to the contractors on an annual basis for information.

Annex II – CONTRACTOR'S TENDER

OC/EFSA/MESE/2022/03

**Methodological support for the performance of literature reviews
within evidence-based scientific assessments**

CASE STUDY

JOINT TENDER:

- **ASOCIACION COLABORACION COCHRANE
IBEROAMERICANA (Group Leader)**
- **FUNDACIO INSTITUT D'INVESTIGACIO SANITARIA ILLES
BALEARS**
- **ESCUELA ANDALUZA DE SALUD PUBLICA**

1. METHODOLOGY PROPOSED FOR IMPLEMENTATION

Proposal for a systematic review on the subject: “Relationship between the intake of carbohydrate quantity and quality and risk of developing Type 2 diabetes in non-diabetic individuals”.

BACKGROUND

The role of carbohydrates (CHD) as a risk factor for T2DM has been extensively studied. The risk profile of total CHD intake and high CHD diets has been studied in relation to T2DM as well as a spectrum of health problems, through systematic reviews and dose-response metaanalysis of observational cohorts (Alhazmi 2012, Greenwood 2013, Hardy 2020, Hosseini 2022, Liu 2021, Neuenschwander 2019, Reynolds 2019). The evidence from systematic reviews links higher levels of total CHD intake to greater incidence of T2DM (Alhazmi 2012, Hardy 2020), with a consistent dose-response effect (Greenwood 2013, Hosseini 2022, Liu 2021, Neuenschwander 2019).

However, the relationship between CHD intake and T2DM should be assessed not only in terms of quantity of CHD intake, but also in terms of quality of CHD. Carbohydrates are classified as monosaccharides, disaccharides and oligosaccharides (including fructooligosaccharides), and polysaccharides (including starch and dietary fibre). Also, based on how they are digested and assimilated, CHD can be classified into simple CHD, which are quickly digested and assimilated by the body, and related to spikes in blood sugar, and complex CHD, which are slowly digested and assimilated. The increased risk of T2DM with CHD intake needs to be explored taking into account the quality of such CHD intake.

A number of reviews have assessed the association between diet quality indexes, such as glycaemic index (GI) or glycaemic load (GL), and incidence of T2DM (Greenwood 2013, Hardy 2020, Neuenschwander 2019, Reynolds 2019). There is low to moderate certainty of evidence, from these systematic reviews, that high GI or GL diets are associated with higher incidence of T2DM (Hardy 2020, Neuenschwander 2019), with a consistent dose-response effect (Greenwood 2013, Reynolds 2019).

The risk profile of different CHD has also been explored in several systematic reviews (Alhazmi 2012, Hardy 2020, Neuenschwander 2019), which have highlighted the different risk profiles of the different sub-types of oligosaccharides (Alhazmi 2012). There is moderate to high certainty of evidence of negative associations between increased intake of whole grains (source of oligosaccharides, starch and dietary fibre), and incidence of T2DM (Hardy 2020, Neuenschwander 2019); that is, higher intakes of dietary fibre or whole grains could confer greater benefit against T2DM.

It's worth noting that the prognostic research conducted so far, linking CHD and T2DM presents several limitations, related to the scope of the aims, the methodology applied for the assessment of the exposures, as well as how the assessment of the validity of the included studies, and the assessment of the quality of the evidence were conducted.

As a consequence of the available evidence on the risk profile of CHD on incidence of T2DM, efforts have been devoted to test the effect of low CHD diets on the incidence of T2DM, particularly for

individuals at risk of T2DM (e.g. overweight and obese). The evidence is still inconclusive, with a recent Cochrane systematic review of randomized clinical trials concluding that low CHD diets show little to no difference in weight and cardiovascular risk factors, up to two years's follow-up, compared to balanced CHD diets, in overweight and obese participants with or without T2DM (Naude 2022).

There are a number of challenges to conduct research on nutrition and diets, particularly due to the complex multicomponent nature of diets, which contain macronutrients with different risk profile (CHD such as sugars, starches, and fibres, but also fats and proteins), and the interrelationship with other factors such as lifestyle (particularly, physical activity and sedentarism), ethnicity, socioeconomic level, etc. A better understanding of these issues is key to define better diet interventions based on control of CHD, which show good efficacy, and to identify the subgroups of the population that will benefit most of such interventions.

For these reasons, we aim to conduct a systematic review that clarifies the association of CHD with incidence of T2DM, taking into account quantity and quality of CHD intake, applying rigorous methods that overcome the limitations of previous research, obtaining estimates of risk for total CHD, indexes of quality of diet (GI and GL) and by type of CHD, and conducting comprehensive subgroup analyses to explore the differential risk of CHD by levels of key prognostic modifiers.

METHODS

This systematic review aims to answer the following healthcare question: ***“What is the relationship between the intake of carbohydrate quantity and quality and risk of developing Type 2 diabetes in non-diabetic individuals?”***

OBJECTIVES

- To assess, in men and women, the relationship between quantity and quality of CHD intake and the risk of developing T2DM (Main objective).
- To assess the differential association in relevant subgroups of interest: Sex, age, baseline T2DM risk, geographical region, ethnicity, baseline level of CHD intake, length of follow-up, method for assessment of exposure, and timeline of exposure (Secondary objective).

DESIGN

The design of this project is a systematic review of risk factors, which is one type of prognostic systematic reviews within the PROGRESS framework (Hemingway 2013). This systematic review will be conducted and reported following established methodological guidelines (EFSA 2010, Higgins 2021, Moola 2020, Riley 2013, Riley 2019). Also, the project will follow current methodological guidance to consider equity and sex/gender in systematic reviews (Antequera 2021, Welch 2021). The protocol for this systematic review will be registered in a public repository, such as PROSPERO.

HEALTHCARE QUESTION (PICO-S FRAMEWORK) AND ELIGIBILITY CRITERIA

We chose the PICO-S framework to specify the healthcare question that defines the systematic review, based on a published previously taxonomy (Munn 2018).

Study designs: we will include prospective cohort studies and randomised and non-randomised clinical trials, which have assessed the relationship between CHD intake (quantity and quality) and incidence of T2DM.

We will consider cohort studies as those studies in which a group of (in general, healthy) people are selected and followed up over time, to ascertain the occurrence of health related events. As the ascertainment of events during the follow-up period is critical, we will only include prospective studies (Vandenbroucke 1991). To ensure that our estimates of association are not biased due to confounding, only cohort studies with at least some control for confounding, either by adjustment in a model or by matching, will be included. A set of minimum key adjustment factors will be defined jointly with the researchers and content experts.

Population: studies should have been conducted in the general population without diabetes.

Exposure: studies should have assessed total CHD intake or CHD quality, either continuously or as a categorical exposure, with more than two categories of exposure. Amount of CHD intake can be presented as grams/day or as percentage energy, or be converted from other measurements. Indicators of CHD quality include content of dietary fibre, whole grains or pulses (starches), and sugars, as well as dietary glycaemic index and glycaemic load (Reynolds 2019).

Comparison: studies should have compared different quantities or quality of CHDs consumed, including isocaloric substitution of CHDs.

Outcomes: the review will assess the following outcomes:

Primary outcomes:

- T2DM incidence (dichotomous or time-to-event data, minimum follow-up: 1 year).

Secondary outcomes:

- Changes in cardiometabolic risk factors (obesity, hypertension, adiposity, dyslipidemia, insulin resistance) (dichotomous or continuous data, minimum follow-up: 1 year)
- All-cause mortality (dichotomous or time-to-event data, minimum follow-up: 5 years).

The proposed list of outcomes was derived from previous literature reviews and expert discussion, since a search of the COMET Database (COMET Initiative <https://www.comet-initiative.org/>) failed to identify any Core Outcome Set (COS) available for this question. The proposed list of outcomes may be modified after discussion and consensus with the research team and content experts.

For a study to be included in the review, it should have reported estimates of the association in the form of:

- 1) relative risk, hazard ratio (HR), rate ratio (RR) or odds ratio (OR), with corresponding 95% confidence intervals (CIs), for a higher versus a lower level of CHD intake (when assessing exposure as categories), or for a continuous change in exposure (when assessing exposure continuously); or
- 2) raw numbers of cases and non-cases or person-years in each category of CHD intake.

Limits: we will only include studies published in English. The search will not be restricted by language of publication, and we will compile the studies which are published in languages other than English and are likely to fulfil inclusion criteria. This list of studies will be shared with the clinical experts, to assess appropriateness of the language restriction.

SEARCH STRATEGY

Sources: We will search the following bibliographic databases, from their inception to the most recent date (MEDLINE (accessed via PubMed), EMBASE (via embase.com), and the Cochrane Central Register of Controlled Trials (via The Cochrane Library)).

We present the search strategy for MEDLINE as an Annex. We will ask (at least) one other information specialist to peer review the search string, according to the PRESS checklist (McGowan 2016). We will adapt the strategy to the requirements and controlled vocabulary of the rest of intended sources.

To focus the search results to the type of studies design defined in the inclusion, we will use methodological filters and limitations. In MEDLINE and EMBASE we will use sensitive search filters for identifying randomised trials (Glanville 2019, Lefebvre 2021). To retrieve cohort studies, we will use a specific list of terms related to this study design, according to the inclusion criteria, as there does not exist a validated methodological filter with an optimal performance for prospective cohort studies. We do not plan to place additional restrictions to the search, according to the references' publication date or format.

Furthermore, to identify additional studies or gray literature, we will check the reference list from studies deemed as relevant, and will track forward citations using the Web of Science. We will track ongoing studies during the review process, searching both ClinicalTrials.gov and the ICTRP portal.

Data management: we will use EndNote X20 to create a database for the management of the search results.

STUDY SELECTION, EVIDENCE APPRAISAL AND SYNTHESIS

Study screening and selection: the EndNote X20 database of search results will be uploaded to Covidence, to conduct screening of references. A single reviewer will screen the search results in Covidence, based on the title and abstract, and all references initially selected as potentially eligible will proceed to the full text screen stage.

Two reviewers will independently confirm eligibility based on the full text of the relevant articles. In case of disagreement, they will reach consensus by discussion or involving a third reviewer. We do not plan to quantify agreement (e.g. through kappa statistics) at this stage, but rather to estimate

agreement on key studies to be included in the review. If agreement in key studies is not achieved, we will conduct a revision of the screening criteria and process.

All reviewers will undergo a calibration process with a set of references containing studies verifying the inclusion criteria, definitely ineligible, and doubtful. This test will ensure consistency in the application of the eligibility criteria, and guarantee the validity (reliability and reproducibility) of the screening and selection process. When multiple publications are available from trials or cohort studies, the most complete publication with the longest follow-up will be selected.

Data collection: one reviewer will extract relevant data from eligible studies on their main characteristics, using a pre-tested extraction form. A different researcher will cross-check the data extracted for accuracy. Reviewers will conduct a pilot data extraction test.

Measures of association between CHD and the outcome of interest will be extracted, or derived from the extracted data. Measures of association considered will be RR and OR for dichotomous outcomes, and HR for time-to-event outcomes.

We will extract key information: geographical region of the study, participants' sex/gender, age range or mean age of participants, length of follow-up, numbers of cases and non-cases, method of dietary assessment, and method of outcome assessment, level of dietary exposure (either as mean, median, midpoint, or range for each category or unit of increment for continuous estimates), the standard used to derive GI and GL, estimated RRs with CIs, and characteristics controlled for by modeling, matching, or stratification.

Risk of bias assessment: we will assess risk of bias of cohort studies using the QUIPS tool (Hayden 2013). Bias in randomised and non-randomised controlled trials will be assessed using the Cochrane Risk of Bias 2 tool (Higgins 2021) and the ROBINS-I tool (Sterne 2016). A set of key adjustment factors to be considered in the application of QUIPS will be defined, jointly with the researchers and content experts. Standard tools to assess risk of bias may be further tailored to include assessment of sources of potential bias specific to the review question. Risk of bias assessment will be conducted independently by two reviewers. Reviewers will be specifically trained and will conduct a pilot test of risk of bias assessment, to ensure consistency in assessments and guarantee the validity of the process.

Data synthesis: if a quantitative synthesis of results is feasible for the studies, we will conduct pooled analysis (meta-analysis). We will estimate pooled measures of the association between high vs low levels of CHD quantity and quality and each primary and secondary outcome, combining the measures of association reported in the individual studies with the inverse variance method under a random-effects model. Different measures of association (either HR, RR or OR) will be pooled separately. Pooled measures of association will be presented as point estimates with 95% CI, alongside prediction intervals for a more complete depiction of the variation of treatment effects (Riley 2011). If a quantitative synthesis of results is not feasible, a narrative synthesis will be conducted and we will report our synthesis methods following established guidelines (Campbell 2020).

Additionally, if feasible, we will conduct dose-response meta-analyses (DRMA) to assess the risk of developing T2DM by levels of CHD intake. The advantages of DRMA over standard meta-analysis

methods are that it incorporates all the available evidence from multiples levels of exposure, allows determination of the response curve (including non-linear relationships), and controls the covariance resulting from the comparison of different categories of CHD consumption against a common reference group.

We will arrange the data for the analysis using a common reference level for all studies. The categories of CHD exposure will be defined using the mean level of CHD consumption in the study. When the mean level is not reported, we will use the median or mean values derived from the range of values that define the category. For studies not reporting range values, we will input the data using standard methods (Shim 2019). T2DM risks results reported as ORs or HRs will be converted to RR using previously described equations (Shor 2017).

To conduct the DRMA, we will apply a generalised least-squares (GLS) regression method to estimate the dose-response curves. The GLS regression estimates the dose–response coefficients taking into account the covariance for each exposure category within each study. We will pool the dose–response coefficients from the studies with the DerSimonian–Laird method under a random-effects model.

Our initial dose-response pooling model will assume linearity of the dose-response relationship. To assess if this assumption holds, first we will conduct a visual assessment of the scatterplot of dose and effect size (log relative risk) at study level. Secondly, we will test the null hypothesis of a linear dose-response by applying a Wald test to assess whether there are statistically significant differences between the slopes of the regression lines for each dose level. If the test is significant, we will reject the hypothesis of linear dose-response, and we conduct the dose-response analyses with alternative statistical models that reflect the phenomena more appropriately, such as the quadratic random effects model (Orsini 2011), or the restricted cubic splines model (RCS). We will perform the dose-response analysis using the “dosresmeta” package of R software based on the two-stage method developed by Nicola Orsini.

All statistical analyses and graphical displays will be conducted using appropriate software: STATA (*StataCorp. 2017. Stata Statistical Software: Release 15. College Station, TX: StataCorp LLC*), R (*R Core Team (2020). R: A language and environment for statistical computing. R Foundation for Statistical Computing, Vienna, Austria. URL <https://www.R-project.org/>*) or Review Manager (*Review Manager (RevMan) [Computer program]. Version 5.4, The Cochrane Collaboration, 2020*).

Heterogeneity evaluation: we will explore sources of variation between studies in our quantitative and qualitative synthesis through subgroup and sensitivity analyses, restricted to the primary outcome (T2DM) (Riley 2019, Roqué 2020, Sun 2010).

These subgroups analyses will also provide estimations of relative effect of CHD quantity and quality in subpopulations where evidence was previously uncertain. Separate estimates of association will be obtained by subtype of CHD. Subgroup analyses will be conducted by meta-regression (Thompson 2002) for the main outcome (incidence of T2DM) when feasible, to explore the differential effect of CHD by:

- Sex;
- age groups: <50 vs 50-69 vs >=70;

- baseline T2DM risk: high T2DM risk based on scores of T2DM risk (e.g. FINNRISK) or other T2DM risk factors (e.g. obesity) vs otherwise;
- geographical region: Western vs Asia;
- ethnicity: Chinese vs South Asian vs Hispanic vs Hindi vs other
- baseline level of CHD intake in the study: $\geq 60\%$ vs $<60\%$ of calorie intake from CHD (Hosseini 2022);
- length of follow-up period: <5 years vs ≥ 5 years;
- method for assessment of exposure: food frequency questionnaire assessment vs prospective diet diaries vs retrospective recall of diet;
- timeline of exposure assessment: use of follow-up vs baseline-only.

Estimates of association will be obtained separately by sex, age groups and type and subtype of CHD, in order to explore biological variability. Estimates of association will be obtained for factors identified in the literature as risk factors of T2DM and/or potential modifiers of the association between CHD and T2DM. Our hypotheses are that the association between CHD and T2DM may be stronger in populations with higher baseline risk of T2DM; living in Asia; of Chinese, South Asian or Hispanic ethnicity; and/or with higher baseline CHD intake. Also, we will conduct subgroup analyses to ascertain the impact of methodological characteristics of the studies, such as length of follow-up, method for assessment of exposure, and timeline of exposure.

Finally, we will evaluate the credibility of subgroup or effect modification analyses with the ICEMAN framework (Schandelmaier 2020).

Assessment of certainty of evidence: we will rate the certainty of evidence for a list of selected outcomes of interest, following the GRADE approach (Foroutan 2022, Schünemann 2013). We will rate the quality of evidence across each outcome of interest as high, moderate, low or very low, depending on several factors including; risk of bias, imprecision, inconsistency, indirectness and publication bias.

We will develop a Summary of Findings table (Guyatt 2011), summarising the evidence for the list of key selected outcomes, the relative and absolute effects related to the exposure, and the volume and certainty of evidence. If randomised evidence is included in the review, organisation of randomised and non-randomized evidence on the synthesis will be conducted, following appropriate guidance (Cuello-García 2021). The implications of combining randomised and non-randomized evidence in nutrition research questions will also be considered (Schwingshackl 2020).

DOCUMENT AND REPORT OF THE REVIEW

This systematic review will be reported following the PRISMA reporting guidelines for systematic reviews (Page 2021), adapted to the specificities of a prognostic systematic review.

As a final deliverable, a structured report will be presented for the systematic review, describing the main outputs and results of each review stage. In particular, it will contain:

- The complete literature searches will be reported according to the PRISMA-S statement (Rethlefsen 2021).
- The search and screening processes will be documented by means of a PRISMA 2020 flowchart (Page 2021) and listing the search strategies used in each database. The lists of included and excluded studies will be made available, either as supplementary documents or

as an on-line resource. The main reason for excluding each study in the full text screening will be tabulated.

- The main characteristics of the included studies will be tabulated, listing the outcomes of interest assessed and their main effect estimates.
- A map of evidence will be created, adapting established methodology (White 2020, James 2016), to describe and catalogue the available evidence relating to the question of interest, identifying knowledge gaps, and knowledge clusters. The included studies will be presented graphically, organised by exposure measured (total CHD, and types of CHD), design (cohort, non-randomised clinical trial, randomised clinical trial), and risk of bias for the main outcome T2DM (high, low, unclear).
- The results and interpretation of the evidence synthesis in this review will be presented narratively and summarised in Summary of Findings tables, and graphically (if appropriate)

RAPID REVIEW METHODS

If a rapid review design is deemed necessary (i.e., important time-constraints or need of immediate availability of the review findings), some steps in this protocol could be tailored (Tricco 2016, Tricco 2017, Garrity 2020). The adaptations to be implemented will be all or only a subset of the following:

a) We will limit the focus of the review question, defining the most important populations, interventions, comparators, and outcomes for decision-making.

b) We will restrict searches to MEDLINE/PubMed and limit grey literature and supplemental searching. We will limit the search to the systematic reviews subset in PubMed (systematic[*sb*])

c) We will restrict search terms to title and abstract, and date limits could apply.

d) We will conduct screening of references (title & abstracts and full text stage) by only one previously calibrated reviewer, with a second reviewer cross-checking a representative sample of references.

e) We will report results narratively, and will not systematically consider pooling effect estimates.

An alternative approach that could be taken, if a rapid review design is deemed necessary, and if there is a substantial body of already existing evidence answering the research question, is to conduct an update of an already published systematic review. In this case, we would conduct an exhaustive search of systematic reviews, and select the systematic review that answers the research question, and that combines the highest quality, and the most comprehensive and most recent search. The evidence from the selected systematic review would be updated with the new identified studies.

2. PROJECT ORGANISATION

This section outlines the organisation plan in terms of work organisation (description of the group structure) throughout the Framework Contract (FWC) duration and within each Specific Contract assigned to the Group. For the purposes of this description:

Group is a consortium of economic operators in a joint offer, that will work together during the FWC.

Group Leader (coordinator) is responsible for managing the project, submitting reports and deliverables and acting as intermediary for all contacts with the EU Granting Authority.

Group Members (beneficiaries) are responsible for implementing their part of the project and contribute to the grant administration.

Specific Contract refers to services (tasks) based on the needs of EFSA, e.g.: carry out or provide methodological assistance in performing or appraising literature reviews (systematic, scoping, narrative) or parts of them.

Project Leader is a senior staff member from the Group Leader with at least 5 years of proven professional experience in project management and 5 years of proven professional experience in performing the full systematic reviews. Will oversee all project development and provide resources to ensure that tasks are delivered timely and with highest standards of quality.

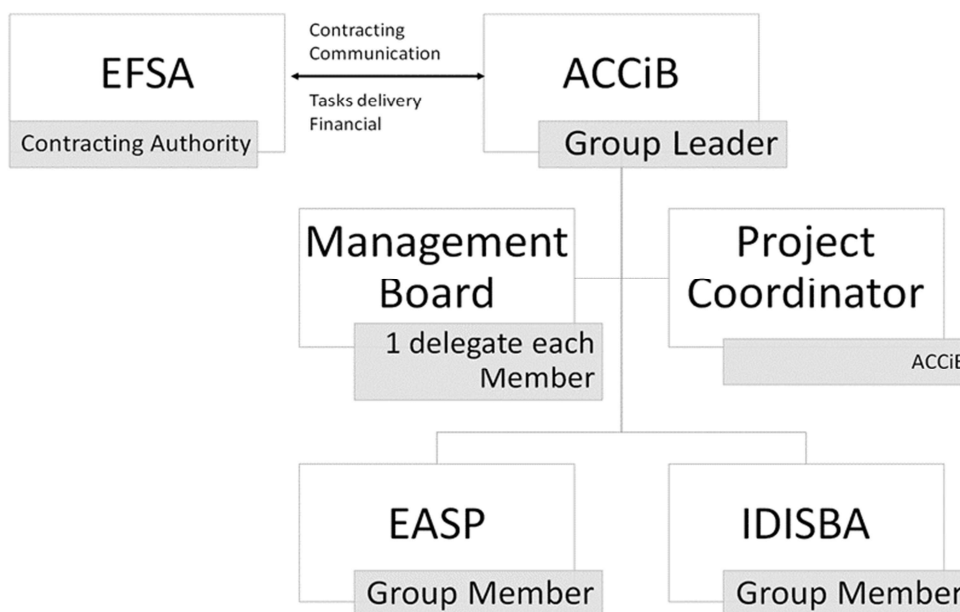
ORGANISATION OF THE WORK - GROUP STRUCTURE

The Group is a consortium of:

Coordinator: Asociación Colaboración Cochrane Iberoamericana (ACCIb)

Beneficiaries: Escuela Andaluza de Salud Pública (EASP), Fundació Institut d'Investigació Sanitària Illes Balears (IDISBA)

ACCIb will act as the contact point for the contracting authority: European Food Safety Authority (EFSA). ACCiB will liaise directly with EFSA for the contract's administrative or financial aspects and operational management. FWC and Specific contracts will be signed between EFSA and ACCiB, authorised by the other Group Members to sign the contract on their behalf via power of attorney.



ACCIb: Asociación Colaboración Cochrane Iberoamericana

EFSA: European Food Safety Authority

IDISBA: Fundació Institut d'Investigació Sanitària Illes Balears

EASP: Escuela Andaluza de Salud Pública

Composition and role of the Management Board

A Management Board will be formed as an organisational body between the Group Leader, Group Members and the contracting authority.

The main objective of the Management Board will be to facilitate the organisation, ensure delivery and achievement of project outputs, therefore it will be formed entirely by staff from the Group Members developing the project.

Each Group Member (including the Group Leader) will nominate a representative with a senior profile. Subcontractors will not be part of the Management Board.

Main tasks of the Management Board will be:

- Providing input to the overall development of the project
- Providing advice on the task distribution
- Help balance conflicting priorities and resources
- Identifying and monitoring potential risks
- Monitoring timelines
- Monitoring the quality of the project as it develops
- Providing advice (and sometimes making decisions) about changes to the project as it develops.
- Translating and ensuring the implementation of management decisions to each Group Member

How often should a Management Board meet?

The Management Board will meet regularly every month through videoconference and at least once during each Specific Contract lifetime.

Before each meeting the Project Leader will share a short agenda, indicating the time planned for the meeting, project progress information, bullet point list of action items and minutes of the last meeting. The minutes should include a list of the actions agreed at the meeting, clearly labelled with the name of the individual responsible for each action and the expected timeline for implementation.

Since regular meetings usually encounter conflicting commitments, each Group Member will be asked to nominate an alternate representative who can attend in place of the first nominee.

COMMUNICATION AND REPORTING

External communication

The Project Leader will be the main contact with EFSA

Centre Cochrane Iberoamericà - Hospital de la Santa Creu i Sant Pau
C/ St. Antoni M. Claret, 167
08025 Barcelona (Espanya)
Tel: (+34) 935537814
Fax: (+34) 935537809

Communication of administrative issues:
Meritxell Girós (Administrative support)

Communication of contracting and financial issues:
Gerard Villar (Financial officer)

Internal functioning and communication

All Group Members' organisation is currently structured around projects and their staff will maintain regular meetings to ensure the work progress within the schedule. These meetings will be held at different levels:

- Scientific meetings: Face-to-face meetings including the senior and junior experts and/or senior expert librarian and/or statistician (depending on project needs). The objective of these meetings is to ensure that the appropriate methodology is applied and to ensure the quality of all deliverables.
- Coordination meetings: Face-to-face meetings including the senior expert and internal representative of the Management Board. Depending on the needs it may also include junior experts, expert librarian and/or statistician. Every month the coordination meeting will be held before the Management Board meeting.

Coordination meeting will mainly cover:

- Data on current achievements
- Significant deviations from plan
- Review the issue log (project document where all the issues are recorded and tracked)
- Action items coming from Management Board

Daily communication within and between Group Members (including Group Leader) will be done preferably through email; when a quick feed-back is needed the team can also use phone calls.

Project Reporting between the Group Leader and contracting authority

The contractor may be asked to attend one or more meetings (including kick-off meeting) with EFSA and/or experts or other contractors to discuss the requested tasks, support requests and to provide advice, or answers to related questions. The meetings will predominantly be by web-meeting, but some may take place physically

At the end of each specific contract, a report documenting and reporting the method and results of the systematic review and/or any other types of reviews or tasks undertaken could be asked to be produced by the contractor.

An interim Report may also be produced (if required) for long-term projects.

PROFILES ASSIGNED TO INDIVIDUAL TASKS

Project leader

Will take the responsibility of :

- Allocating and coordinating tasks internally and among different Group Members

- Organising and attending internal coordination meetings and the Management Board.
- Time planning and identifying project deviations according to project milestones
- Planning, suggesting and implementing solutions to project deviations
- Sending all tasks deliverables (reports and files) to EFSA.

Senior expert (systematic review developer)

Will be the responsible for:

- Supervising the tasks of the junior team
- Ensuring that the appropriate methodology is applied
- Reviewing and editing draft technical materials and reports generated from the systematic review and internally approving them.
- Lead internal scientific meetings, participate in coordination meetings when required.

Junior expert (systematic review developer)

Will be the responsible for:

- Editing the systematic review protocol
- Selecting the relevant literature using specific reference manager software.
- Obtaining the full texts of relevant articles (free access) and asking the librarian full texts when needed (pay per view)
- Performing summaries of identified studies
- Tabulating included studies (characteristics, results, quality).
- Tabulating excluded studies (reasons for exclusions)
- Editing evidence profiles
- Editing Final Technical Reports
- Attending internal scientific meetings
- Reporting to the Senior team

Statistical expert

Will be the responsible for:

- Contributing to specific sections of the systematic review protocols
- Providing feed-back in data-extraction and analysis of the results
- Manage complex statistical packages as required by the methods and type of data.
- Contributing to specific sections Final Technical Reports
- Attending internal scientific meetings

Expert librarian (Information specialist)

Will be the responsible for:

- Contributing to specific sections of the systematic review protocols
- Liaising with the senior team to identify appropriate terms for a new systematic search.
- Designing search strategies to identify appropriate research evidence.
- Running the searches in pre-specified medical literature databases.
- Saving and collating search results, and sharing them with reviewers in appropriate formats compatible with agreed reference manager software.
- Managing high volume search outputs coming from websites or institutions

- Obtaining copies of trial reports for review teams when required (within copyright legislation)
- Checking and formatting the references to included and/or excluded studies.
- Attending internal scientific meetings when required.

Subcontracting

This Technical Offer relies on the personal and technical capacities of a consortium of three large institutions to fully and completely develop all tasks and requirements of the FWC therefore, subcontracting is not expected to be substantial. In some situations, related to problems with the continuity of the service in case of absence of one or more members of the team, subcontracting will be considered as a contingency plan.

3. RISK MANAGEMENT

This section identifies risks associated with the proposed methodology, technical problems, and project management issues which might appear during the implementation of the assignments as well as quality assurance and control mechanisms put in place to guarantee the high quality of deliverables throughout the Framework Contract (FWC).

A complex project involving several experts' consultation and meetings giving important input in the different parts of the project and the validation of reports and deliverables requires a risk management plan. Below are some risks we have anticipated (table).

RISK ANALYSIS AND CONTINGENCY PLANNING

Risk event	Probability	Impact	Contingency Plan
Problems with the continuity of the service in case of absence of one or more members of the team	Low	High	Increasing the time dedication of other researchers from the same member groups. We do not expect a high-volume turnover, but in this scenario, we would subcontract some of the tasks.
Poor performance, delays in reporting or management issues of a particular partner	Low	High	Participating partners have a long tradition of partnership with good experience delivering high-quality outcomes. Competent project coordination will anticipate any issues in advance so they can be resolved.

Lack of synergy between the tasks	Low	High	Special attention is given to the facilitation of communication between the members of the group. Each Member will internally hold regular scientific and coordination meetings. Regular Management Board meetings will overview achievements and outputs across Group Members.
Underestimation in the planning of human resources for specific tasks	Low	Medium	Timely identification of issues by Project Leader will ensure that case of any issues tasks can be reassigned promptly, and consequent reallocation of resources will take place.
Serious underperformance of one of the beneficiaries	Low	Low	The Consortium Agreement caters for this situation, and the corresponding clauses will be applied (warnings, and in case of prolonged underperformance, contract termination with the beneficiary concerned and reallocation of tasks and budget to another or a new beneficiary).

QUALITY CONTROL MEASURES

The quality control to be applied to the services foreseen under the FWC will include activities that verify that project management and project deliverables are of high quality and meet quality standards. Will also be implemented quality improvement cycles to uncover causes of unsatisfactory results and establish lessons learned to avoid similar issues during the execution of the project.

Through the life cycle of the service the project might face problems, gaps, inconsistencies, and conflicts that occur unexpectedly and that require some action, so they do not impact the project performance. The **issue log** will be a project document where all the issues are recorded and tracked. Data on issues may include: issue type, who raised the issue and when, description, priority, who is assigned to the issue, target resolution date, status, final solution. This tool will help the Group Members effectively track and manage issues, ensuring that they are investigated and resolved.

Specific Quality Control targets and control measures

The major quality control activities and processes that the project will include are described in this section. We detail the specific quality control targets and control measures applicable to each of the tasks described in the technical specifications.

Each senior expert will be responsible for overseeing and reviewing this log and flag any issues to the Project Leader.

QUALITY CONTROL TARGET	CONTROL MEASURES
Research protocol	
The protocol will be based on the PICO (population, intervention, comparison, outcome) framework.	For each specific Healthcare Question, a PICO framework is developed.
The protocol should describe: <ul style="list-style-type: none"> § the selection process § methods for measuring agreement § a priori hypotheses to explain heterogeneity § assessment of risk of bias § plans to present results and assess the certainty of evidence 	Yes/no rating
Compliance with the deadlines	Yes/no rating for each deadline
Systematic Search	
Use of databases for each Healthcare Question.	Inclusion of relevant databases in each systematic search: Yes/no rating for each deadline
Compliance with the deadlines	Yes/no rating for each deadline
Synthesise and critically appraise the evidence	
For each Healthcare Question the whole body of evidence identified will be summarised and critically appraised.	Existence of descriptive tables (carrying out meta-analysis when possible)
The standard Cochrane Collaboration methods are followed.	Yes/no rating
PRISMA guidelines for reporting systematic reviews are adhered to.	Yes/no rating
List of included and excluded studies are provided (with reasons for exclusion).	Yes/no rating
Full texts of the studies in a PDF format are provided.	Yes/no rating
Utilisation of GRADE methodology	Yes/no rating
The Evidence Profile (EP), the Summary of Findings (SoF) table using the GRADEPro software are developed.	Yes/no rating
Compliance with the deadlines	Yes/no rating for each deadline

Style quality check

Final version of the reports:

The draft will be proofread thoroughly including:

- Proof-readers will check for linguistic quality: No spelling or grammar mistakes, limited use of abbreviations, acronyms and jargon.
- Proof-readers will check for content quality: coherence in the paper, clarity, and other.
- All reports should have numbered paragraphs, pages and clear identification (contract number, acronym, version, date) for ease of reading and understanding carried out.
- Correct citations and references to the literature.
- A visual check on spacing and alignment will take place.
- Typography rules will be adhered to and implemented.
- Consistency of style will be checked compared against prior scientific background papers.
- Appropriate use of EU terminology.
- A final check on quotations and opinions from experts.
- Outstanding issues will be flagged for rework where necessary one final review of the draft will occur before the presentation of the final draft to contracting authority.

Interactions with contracting authority and meeting participants:

- Use polite, appropriate and professional language in all communications.
- Avoid over-communication; use targeted communications that are brief and to the point.
- Timely communications.
- A Single Point of Contact will be in place to respond to the contracting authority (in this case the Project Leader)
- All written communications will be drafted in a readable style.

Other Quality control measures

Face to face meetings

- A good understanding of the request and methodology of the face-to-face meetings will be checked with the specific EFSA representative.
- Validation of meeting agenda before circulation
- All presentations will be reviewed before acceptance, i.e. formatting

Data Security

- Contact details of experts and any meeting participants will be saved on file along with a date of the last update to ensure ongoing maintenance of valid data.
- Data will be secured across the group members - backed up on servers - to facilitate data retrieval in case of accidental deletion.
- All terminals will be password protected and drive access available only to Consortium staff.
- Immediate reporting of data breaches.

Data confidentiality and privacy actions will include:

- Ensuring that all staff understand and observe their obligations on data security and sign any specific document related to confidentiality when required.

- Mail lists created to ensure appropriate distribution to specific groups.
- In order to take all reasonable efforts a confidentiality disclaimer will be added to those emails containing attachments stating that everything in the email is confidential and that the email should only be read by the intended recipient, and in the case that it was received by someone else that is not the recipient, that they should contact the system manager.

ANNEXES

ANNEX 1. REFERENCES

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ANNEX 2. DRAFTED SEARCH STRING FOR MEDLINE (VIA PUBMED).

```
1 "Dietary Carbohydrates"[Mesh]
2 "Dietary Fiber"[Majr]
3 "Diet, Carbohydrate-Restricted"[Mesh]
4 carbohydrate*[ti]
5 dietary fiber*[tiab]
6 carbohydrate*[tiab] AND (diet*[tiab] OR intake[tiab] OR quality[tiab])
7 #1 OR #2 OR #3 OR #4 OR #5 OR #6
8 "Diabetes Mellitus"[Mesh]
9 diabet*[tiab]
10 T2D[tiab]
11 #8 OR #9 OR #10
12 #7 AND #11
13 "Cohort Studies"[Mesh]
14 prospective*[tiab]
15 cohort[tiab]
16 regression[tiab]
17 multivaria*[tiab]
18 #13 OR #14 OR #15 OR #16 OR #17
19 #12 AND #18
20 #12 NOT #19
21 (randomized controlled trial[pt] OR controlled clinical trial[pt] OR randomized[tiab] OR
placebo[tiab] OR drug therapy[sh] OR randomly[tiab] OR trial[tiab] OR groups[tiab]) NOT (animals
[mh] NOT humans [mh])
22 #20 AND #21
23 #19 OR #22
```

Call ref. OC/EFSA/MESE/2022/03

Title: Methodological support for the performance of literature reviews within evidence-based scientific assessments

ANNEX 1 - FINANCIAL OFFER TEMPLATE

TENDERER NAME: ASOCIACION COLABORACION COCHRANE IBEROAMERICANA

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

1. As referred to in part 1.4, the maximum budget that EFSA has available for the services, for overall maximum 4 years duration of this framework contract is € 4.000.000,00 EUR. **SCENARIO: For the financial evaluation purposes ONLY. Any offer exceeding a maximum of C 25,000 WILL BE EXCLUDED and therefore not retained for contract award.**

2. IMPORTANT NOTE: Please note that WHEN PREPARING THE FINANCIAL OFFER YOU MUST NOT RELY ON THE CASE STUDY.

3. Prices must be quoted in Euro using the conversion rates published in the C series of the Official Journal of the European Union on the day when the invitation to tender was issued. This information can also be found following the instructions on the website of the European Central Bank at the following URL: https://www.ecb.europa.eu/stats/policy_and_exchange_rates/euro_reference_rates/html/index.en.html.

4. 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, EU bodies are exempt from all duties, taxes and other charges, including VAT. For this reason, all prices given in the financial breakdown must be free of VAT and other taxes or duties.

5. The price offered below is understood to be all inclusive. For example any additional costs which can be incurred by the contractor in performing the contract, such as overheads, travelling and subsistence/accommodation expenses, etc. should also be factored in to the all-inclusive price. In addition, if the deliverables incorporate pre-existing rights, the tenderer should factor into their total price the cost of licensing those pre-existing rights to EFSA. This is valid also for the intramuros daily rates that shall include any allowance which the contractor usually pays to its staff in these situations, as EU bodies will not pay any allowance.

6. Should a framework contract be awarded, the unit prices proposed in cells (A) will be binding throughout the contract implementation, subject to possible price indexation/revision foreseen in the framework contract.

7. 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.

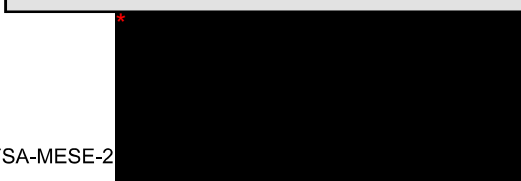
8. INSTRUCTIONS FOR COMPLETION OF FINANCIAL OFFER TEMPLATE: Tenderers should complete their **name in the cell in row 4** (highlighted in yellow). Tenderers should insert their proposed Unit prices into the cells labelled **column A** (highlighted in yellow). The other cells are locked and contain formulas which will automatically calculate the value of the scenario in table column C. Tenderers should **sign and date** the financial offer in the **cell in row 27** (highlighted in yellow).

Item	(A) Unit price TO BE USED for implementation of SPECIFIC CONTRACTS (prices in € all inclusive & without VAT or taxes)	(B) Number of units (days/meetings) — this is only a scenario used for awarding the FWC	(C) Outcome of scenario = unit price offered (A) * number of units foreseen in scenario (B)
(C1) Flat fee per working day* for a Senior expert covering the costs of all related tasks and deliverables described in section 1,2 and 1,3 of the tender specifications, including participation in meetings.	290	10 days	2900
(C2) Flat fee per working day* for a Junior expert covering the costs of all related tasks and deliverables described in section 1,2 and 1,3 of the tender specifications, including participation in meetings.	200	15 days	3000
(C3) Flat fee to cover return travel costs (excluding working time, accommodation and subsistence costs) for one senior or junior expert for participation to a physical (face to face) meeting at EFSA or in any other major city in the EU.	250	1 return travel	250
(C4) Flat fee to cover accommodation and subsistence costs (excluding working time and travel costs) for one senior or junior expert per day for participation to a physical (face to face) meeting at EFSA or in any other major city in the EU.	225	1 night accommodation & subsistence	225
TOTAL – this price will be used for evaluation of the tenders	(C) = C1+C2+C3+C4=		6375

Any offer exceeding a maximum of €25,000 WILL BE EXCLUDED.

*Note: A working day is supposed to consist of 8 working hours; likewise, half a day is 4 working hours.

DATE AND SIGNATURE



ANNEX III – SPECIFIC CONTRACT No [nr]

implementing Framework contract No **OC/EFSA/MESE/2022/03 – CT 01**

The European Food Safety Authority, hereinafter referred to as "the Contracting Authority", established by Regulation (EC) No 178/2002¹⁶ of the European Parliament and of the Council 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 last amended, with offices on Via Carlo Magno 1/a 43126 Parma (Italy), represented by Mr. Bernhard Url, Executive Director

on the one part,

and

[full official name]

[official legal form]

[statutory registration number]

[full official address]

[VAT registration number]

hereinafter referred to as "the contractor", [represented for the purposes of the signature of this specific contract by [forename, surname and function,]]

The parties identified above and hereinafter collectively referred to as 'the contractor' shall be jointly and severally liable vis-à-vis the contracting authority for the performance of this specific contract.

on the other part,

HAVE AGREED

ARTICLE 1 SUBJECT MATTER

1.1 This specific contract implements Framework Contract (FWC) No [complete] signed by the contracting authority and the contractor on [complete date].

1.2 In accordance with the provisions set out in the FWC and in this specific contract and [its][their] annex[es], which form an integral part of it, the contractor must provide the [following services: insert] [services specified in Annex [complete].]

ARTICLE 2 ENTRY INTO FORCE AND DURATION

2.1 This specific contract enters into force [on the date on which the last party signs it] [on [insert date] if both parties have already signed it.].

2.2 The provision of the services starts from [the date of entry into force of this specific contract] [insert date].

¹⁶ OJ L 31 of 01.02.2002

2.3 The provision of the services must not exceed [complete] [days] [months]. The parties may extend the duration by written agreement before it elapses and before expiry of the FWC.

ARTICLE 3 PRICE

3.1 The price payable under this specific contract excluding reimbursement of expenses is EUR [amount in figures and in words].

ARTICLE 4 COMMUNICATION DETAILS

For the purpose of this specific contract, communications must be sent to the following addresses:

Contracting authority:

European Food Safety Authority

[Unit [complete]]

[Full official address]

E-mail: [insert functional mailbox]

Contractor (or leader in the case of a joint tender):

[Full name]

[Function]

[Company name]

[Full official address]

E-mail: [complete]

ARTICLE 5: PERFORMANCE GUARANTEE

Performance guarantee is not applicable to this specific contract.

ARTICLE 6 RETENTION MONEY GUARANTEE

Retention money guarantee is not applicable to this specific contract.

ARTICLE 7 OTHER PROVISIONS

7.1 - Declaration on pre-existing rights

The interim/final deliverables and related invoices must be accompanied by the declaration on pre-existing rights. Absence of such declaration when the deliverable and invoice is received will be understood by the Contracting Authority as confirmation that there are no pre-existing rights within the deliverable and the Contracting Authority will proceed with the payment.

7.2 – Institutional and Individual declarations of interest

With reference to Article II.7 the framework contractor shall provide individual declarations of interest for all members of the proposed project team. During implementation of the specific contract, the contractor shall provide individual declaration of interest for any new members of the project team or updated individual declarations for those team members whose interests declared on the occasion of signature of this specific contract have substantially changed during the implementation of this specific contract. Updated institutional declarations of interest must also be provided when the interests declared on the occasion of signature of this specific contract have substantially changed during the implementation of this specific contract.

ANNEXES

Annex I – Technical specifications

SIGNATURES

For the contractor,
[Company
name/forename/surname/function]

For the Contracting Authority,
[forename/surname/function]

signature: _____

signature: _____

Annex IV - Declaration on pre-existing rights¹⁷

I, *[insert name of the authorised representative of the contractor]* representing *[insert name of the contractor]* ('the contractor'), party to the Framework contract *[insert title and number]*

[option 1: warrant that the results are free of rights or claims from creators or from any third parties for any use the contracting authority may envisage and declare that the results do not contain any pre-existing rights to the results or parts of the results or to pre-existing materials as defined in the above-mentioned contract.]

[option 2: warrant that the results and the pre-existing material incorporated in the results are free of rights or claims from creators or from any third parties for any use the contracting authority may envisage and declare that the results contain the following pre-existing rights:]

[Contractor to complete if option 2 selected] **Please fill in the table – one line per pre-existing right**

Result concerned	Pre-existing material concerned	Rights to pre-existing material	Identification of rights' holder	Creator

In addition, the creators transferred all their relevant rights to the results to *[the contractor]* *[insert name of the rights holder]* through *[an agreement]* *[an employment contract]* *[a relevant extract of]* which is attached to this statement.

The creators *[received all their remuneration on [insert date]]* *[will receive all their remuneration as agreed within [complete] weeks from [delivery of this statement] [receipt of confirmation of acceptance of the work].*

Signature:

Place:

Date:

¹⁷ It is obligatory for the contractor to provide this declaration, appropriately adapted, signed and dated, with the interim/final deliverable and relevant invoice. Please contact EFSA Finance Team well in advance of submission of the interim/final deliverables in the event you have queries about how this declaration should be compiled or the implications of signing such declaration. Absence of such declaration when the deliverable and invoice is received will be understood by the Contracting Authority as confirmation that there are no pre-existing rights within the deliverable and the Contracting Authority will proceed with the payment.

Statement by the creator (or right holder)

Exceptionally, EFSA reserves the right, following submission of the final deliverable with the above-mentioned "Declaration on the list of pre-existing rights" to require the Contractor to provide an additional "Statement by the creator (or right holder)" following the template below.

Concerning [insert name of the relevant result] delivered as part of the Framework contract [insert title and number] concluded between the contracting authority and [name of the contractor]

I the undersigned [insert name of the creator or authorised representative of the right holder] [representing [insert name of the right holder]] declare that I am the right holder of: [identify the relevant parts of the result] [which I created] [for which I received rights from [insert name of other right holder]].

I am aware of the above framework contract, especially Articles [I.10 and II.13] concerning intellectual property rights and exploitation of the results and I confirm that I transferred all the relevant rights to [insert name of contractor or other intermediary right holder].

I declare that [I have received full remuneration] [I agreed to receive remuneration by [insert date]].

[As creator, I also confirm that I do not object to the following:

- (a) that my name be mentioned or not mentioned when the results are presented to the public;
- (b) that the results be divulged or not after they have been delivered in their final version to the contracting authority;
- (c) that the results be adapted, provided that this is done in a manner which is not prejudicial to my honour or reputation.]

Signature:

Place:

Date:

**Annex V – POWER OF ATTORNEY¹⁸ related to the contract
OC/EFSA/MESE/2022/03 – CT01**

we, partner number 1: Asociación Colaboración Cochrane Iberoamericana, statutory registration number: 164740, Osep Esquirol 4 1r B 08207 Sabadell (SPAIN), VAT registration number: ESG61808457, represented for the purposes of the signature of this power of attorney by [REDACTED] President,

and,

we, partner number 2: Escuela Andaluza de Salud Pública, S.A., statutory registration number: A-18049635, Campus Universitario de Cartuja, Cuesta del Observatorio, 4. 18011 Granada (SPAIN), VAT registration number: A-18049635, represented for the purpose of this power of attorney by Blanca Fernández-Capel Baños, Managing Director,

and,

we, partner number 3: Fundació Institut d'Investigació Sanitària Illes Balears, statutory registration number: G5732632, Crta. Valldemossa, 79 (Hospital Universitari Son Espases), Edifici S, 1ª planta. Palma de Mallorca (SPAIN). VAT registration number: ESG5732632, represented for the purpose of this power of attorney by [REDACTED] Manager,

we hereby agree as follows based on the joint tender submitted together:

- to be jointly and severally liable towards the European Food Safety Authority for the performance of the contract and any future amendments;
- to comply with the terms and conditions of the contract and ensure the proper execution of their respective tasks and commitments;
- to designate partner number 1 as leading partner, where the leading partner's legal representative shall sign the contract, any order forms or specific contracts in case of framework contract, and any future amendments to those contracts;
- to allow the leading partner's legal representative to delegate the power of signing any order forms/specific contracts and any potential amendments to order forms/specific contracts;
- any payments by the European Food Safety Authority under the contract shall be made to the leading partner.

For the Leading Partner

[REDACTED]

Done at Sabadell, on 05/07/2022

For Partner number 2

Blanca Fernández-Capel Baños, Managing Director

Signature:

Done at, on.....

For Partner number 3

[REDACTED]

Signature:

Done at, on.....

¹⁸ Any modification to the present power of attorney shall be subject to the European Food Safety Authority's express approval. This power of attorney shall expire when all the contractual obligations of the Members of the Group towards the European Food Safety Authority in connection with the Contract have ceased to exist. The parties cannot terminate it before that date without the European Food Safety Authority's consent.