Please note that, in case of inconsistency between the text of the call and the contract, the call text prevails.

EXPERT CONTRACT

CONTRACT NUMBER — EOI/EFSA/NUTRI/2019/01 – CT01

This Contract ('the Contract') is between the following parties:

on the one part,

The European Food Safety Authority, hereinafter referred to as "the Contracting Authority", established by Regulation (EC) No 178/20021 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

and on the other part,

Family name

First name

Expert candidature number:

Full official address

Email address

The parties referred to above have agreed to enter into this Contract under the terms and conditions below.

By signing this contract, the expert confirms that s/he has read, understood and accepted the contract and all its obligations and conditions, including the Terms of Reference set out in Annex 1, the Code of Conduct set out in Annex 2 and the Declaration of confidentiality set out in Annex 3.

The contract is composed of:

Terms and conditions
Annex 1 Terms of Reference
Annex 2 Code of Conduct
Annex 3 Declaration of confidentiality
Annex 4 EFSA template summary report

[1] OJ L 31 of 01.02.2002

GENERAL

ARTICLE 1 - SUBJECT OF THE CONTRACT

1. The subject of the contract is an assistance to EFSA with the tasks in the areas of Novel Foods and Nutrient Sources as specified in the Notice of call for expressions of interest. The exact tasks to be performed under this contract are detailed in Annex 1.

2. The tasks should be performed for the dossier of TYPE XXXXX.

ARTICLE 2 - WORKING ARRANGEMENTS

1. The expert's work starts upon receipt of the dossier by the expert and cannot exceed the number of working days stipulated in Annex 1 for the assigned type of the dossier. The expert may not under any circumstances start work before the date on which this Contract enters into force.

CHAPTER 2 - FEES, ALLOWANCES AND REIMBURSEMENT OF EXPENSES

ARTICLE 3 - FEES

1. The expert is entitled to a fee of EUR 350 for each full day actually worked in accordance with Article 2.

   The maximum amount due to the expert shall not exceed the amount specified in the Annex I for the assigned dossier, an amount corresponding to the daily fee multiplied by the maximum number of days of performance of this contract stipulated in Annex 1.

2. The total amount of the fees is calculated to the nearest half day.

ARTICLE 4 - ALLOWANCES AND REIMBURSEMENT OF EXPENSES

1. Where applicable, the travel and subsistence expenses directly connected with execution of the tasks will be reimbursed under the conditions set out in the Annex 1 of the Notice of call for expressions of interest.
2. The amounts indicated in Annex 1 of the Notice of call for expressions of interest refer to return travels.

CHAPTER 3 - RIGHTS AND OBLIGATIONS OF THE PARTIES

ARTICLE 5 - PERFORMANCE OF THE CONTRACT

1. The expert must perform the contract in compliance with its provisions and all legal obligations under applicable EU, international and national law.

   The expert must do so fully, within the set deadlines and to the highest professional standards.

   The expert must, in particular, ensure compliance with:

   - the Code of Conduct (Annex 2); and
   - national legislation, including taxation, social security and labour law regarding any payment received from EFSA

   The terms and conditions of this Contract do not constitute an employment agreement with EFSA.

2. If the expert cannot fulfil its obligations, s/he must immediately inform EFSA.

ARTICLE 6 - KEEPING RECORDS — SUPPORTING DOCUMENTATION

The expert must keep records and other supporting documentation (original supporting documents) as evidence that the Contract is performed correctly, and the expenses were actually incurred. These must be available for review upon EFSA's request.

The expert must keep all records and supporting documentation for five years starting from the date of the last payment. If there are on-going checks, audits, investigations, appeals, litigation or pursuit of claims, the expert must keep the records and supporting documents until these procedures end.

ARTICLE 7 - REQUEST FOR PAYMENT

1. To obtain its fees, travel costs and daily subsistence allowances, the expert must submit a request for payment or invoice in writing via email to EFSAProcurement@efsa.europa.eu.
2. The request(s) for payment must be submitted within 30 days of the date(s) for submitting the report(s) or deliverable(s) specified in Article 2.

ARTICLE 8 - BANK ACCOUNT

Payments shall be made to the expert's bank account denominated in euro, identified as follows:

Name of bank:

Full address of branch

Exact designation of account holder:

IBAN code:

ARTICLE 9 - PAYMENTS

1. EFSA will make payments within 30 calendar days of receiving the completed payment request(s) unless Article 13 applies.
2. Payments are subject to EFSA's approval of deliverable(s) or report(s), and of the payment request(s). Approval does not mean recognition of compliance, authenticity, completeness or correctness of content.
3. Payments will be made in euros.
4. Payments will be made to the bank account specified by the expert in the payment request referred in Article 8.
5. EFSA's payments are deemed to be carried out on the date on which its account is debited.
6. On expiry of the payment period specified in paragraph 1 and without prejudice to Article 13, the contractor 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 3.5 points. The reference rate is the rate in force on the first day of the month in which the payment period ends, as published in the C series of the Official Journal of the European Union.

   The suspension of the payment periods in accordance with Article 13 may not be considered as a 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 actual payment as defined in paragraph 5.

   However, when the calculated interest is lower than or equal to EUR 200, it must be paid to the contractor only upon request submitted within two months of receiving late payment.

   Conversions between the euro and other currencies will be made at the daily euro exchange rate published in the Official Journal of the European Union or failing that, at the monthly accounting exchange rate established by the European Commission and published on the website http://ec.europa.eu/budget/contracts_grants/info_contracts/inforeuro/inforeuro_en.cfm applicable on the day on which EFSA issues the payment order.

ARTICLE 10 - OWNERSHIP AND USE OF THE RESULTS (INCLUDING INTELLECTUAL PROPERTY RIGHTS)

1. EFSA must fully and irrevocably acquire the ownership of the results under this contract including any rights in any of the results listed in this contract, including copyright and other intellectual or industrial property rights, as well as all technological solutions and information contained within these technological solutions, produced in performance of the contract. EFSA may exploit them as stipulated in this contract. The EFSA must acquire all the rights from the moment the results are delivered by the expert and accepted by EFSA. Such delivery and

acceptance are deemed to constitute an effective assignment of rights from the expert to the Union.

2. EFSA must acquire ownership of each of the results produced as an outcome of this contract which may be used, for the following purposes of:

   (a) giving access upon individual requests without the right to reproduce or exploit, as provided for by Regulation 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents;

   (b) storage of the original and copies made in accordance with this contract;

   (c) archiving in line with the document management rules applicable to EFSA.

3. The EFSA may use, publish, assign or transfer these results as it sees fit, without any limitations (geographical or other), unless intellectual property rights already exist.

ARTICLE 11 - PROCESSING OF PERSONAL DATA

1. Processing of personal data by EFSA

EFSA will process all personal data included in the contract according to Regulation (EU) 2018/1725.

Such data will be processed by Valeriu Curtui ('data controller') only to perform, manage and monitor the contract.

The data may also be sent to persons or bodies responsible for monitoring or inspections in application of EU law.

The expert has the right to access its personal data and to correct it. Any questions about corrections to the expert's personal data must be sent to the data controller.

The expert has the right of recourse to the European Data Protection Supervisor.

2. Processing of personal data by the expert

If the contract requires the expert to process personal data, the expert may only act under the supervision of the data controller identified above. This is the case in particular for determining why personal data should be processed, what categories of data may be processed, who will have the right to access the data, and how the data subject may exercise its rights.

The expert must put in place appropriate technical and organisational security measures to address the risks inherent to data processing and:

(a) prevent unauthorised people from accessing computer systems that process personal data, and especially the:

   (i) unauthorised reading, copying, alteration or removal of storage media;

   (ii) unauthorised data input, disclosure, alteration or deletion of stored personal data;

(iii) unauthorised use of data-processing systems by means of data transmission facilities;

(b) ensure that a data-processing system's authorised users can access only the personal data to which its access right refer;

(c) record which personal data have been communicated by the expert, when and to whom;

(d) ensure that personal data being processed on behalf of third parties can be processed only in the manner prescribed by EFSA;

(e) ensure that, during communication of personal data and transport of storage media, the data cannot be read, copied or deleted without authorisation;

(f) design its organisational structure in a way that meets data protection requirements.

ARTICLE 12 - CHECKS, AUDITS AND INVESTIGATIONS

1. EFSA may carry out checks and audits to ascertain compliance with the proper implementation of the tasks (including assessment of deliverables and reports) under this contract and whether the expert is meeting its obligations.

   It may do so throughout the contract's validity and up to five years after the last payment is made. The expert must provide — within the deadline requested — any information and data in addition to deliverables and reports already submitted. The expert must allow access to sites and premises on which the tasks specified in this contract are performed.

2. Under Regulation No 2185/96[2] and Regulation No 883/2013[3] (and in accordance with its provisions and procedures), the European Anti-Fraud Office (OLAF) may — at any moment during implementation of the contract or afterwards — 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 EU.

3. Under Article 287 of the Treaty on the Functioning of the EU (TFEU) and Article 161 of the Financial Regulation No 966/2012[4], the European Court of Auditors (ECA) may — at any moment during implementation of the Contract or afterwards —carry out audits.

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[2] 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 (OJ L 292, 15.11.1996).

[3] Regulation (EU, Euratom) No 883/2013 of the European Parliament and of the Council of 11 September 2013 concerning investigations conducted by the European Anti-Fraud Office (OLAF) and repealing Regulation (EC) No 1073/1999 of the European Parliament and of the Council and Council Regulation (Euratom) No 1074/1999 (OJ L 248).

[4] Regulation (EU, Euratom) No 966/2012 of the European Parliament and of the Council of 25 October 2012 on the financial rules applicable to the general budget of the Union and repealing Council Regulation (EC, Euratom) No 1605/2002 (OJ L218, 26.10.2012).

The ECA has the right of access for the purpose of checks and audits.

4. Findings in checks, audits or investigations may lead to the reduction or rejection of fees, rejection of claims for allowances and expenses in accordance with Articles 14 and 15, or recovery of undue amounts in accordance with Article 16.

   Moreover, findings arising from an OLAF investigation may lead to criminal prosecution under national law.

CHAPTER 4 - EFFECTS OF BREACHING CONTRACTUAL OBLIGATIONS

ARTICLE 13 - SUSPENSION OF THE PAYMENT TIME LIMIT

1. EFSA may at any point suspend the payment time limit if a request for payment cannot be processed because it does not comply with the contract's provisions.
2. EFSA must notify the expert of the suspension and the reasons for it.
3. The suspension takes effect on the day notification is sent by EFSA.
4. If the condition for suspending the payment time limit as referred to in paragraph 1 is no longer met, the suspension will be lifted — and the remaining period will resume.

   If the suspension exceeds two months, the expert may ask EFSA if the suspension will continue.
5. If the payment time limit has been suspended due to the non-compliance of the reports or deliverables in accordance with Article 2 and the revised report or deliverables or payment request is not submitted or was submitted but is also rejected, EFSA may also terminate the contract as referred to in Article 17.

ARTICLE 14 - REDUCTION OF FEES OR REJECTION OF FEES, CLAIMS FOR ALLOWANCES AND EXPENSES

1. EFSA may reject:

   (a) (parts of) the fees if the expert does not fulfil the tasks set out in Article 2;

   (b) claims for allowances or expenses if they do not fulfil the conditions set out in Article 4.
2. EFSA may reduce the fee if the expert is in breach of any of its other obligations under the Contract (including the obligations set out in the Code of Conduct).
3. EFSA must formally notify the expert of its intention, include the reasons why, and invite him/her to submit any observations within 30 calendar days of receiving notification.

   If EFSA does not accept these observations, it will formally notify confirmation of the rejection or reduction.

ARTICLE 15 - RECOVERY OF UNDUE AMOUNTS

1. EFSA may recover any amount that was paid but was not due under the Contract.
2. EFSA must formally notify the expert of its intention, include the reasons why and invite him/her to submit any observations within 30 calendar days of receiving notification.

   If EFSA does not accept these observations, it will confirm recovery by formally notifying a 'debit note' that specifies the payment terms and date.

3. The expert must repay the amount specified in the debit note to EFSA.
4. If the expert does not repay the requested amount by the date specified in the debit note, late-payment interest will be added to the amount to be recovered.

   The interest rate used will be the same as the rate applied by the European Central Bank (ECB) for its main refinancing operations in euros ('reference rate'), plus three and a half points. The reference rate is the rate in force on the first day of the month in which the payment deadline specified in the debit note expires, as published in the C series of the *Official Journal of the European Union*.
5. If the expert does not repay the requested amount by the date specified in the debit note, EFSA may recover the amounts due by offsetting them against any amounts owed to the expert by the EU institutions or an executive agency (from the EU or Euratom) budget without the expert's consent.

ARTICLE 16 - TERMINATION OF THE CONTRACT

1. EFSA may at any moment terminate the contract if the expert:

   (a) is not performing its tasks or is performing them poorly; or

   (b) has committed substantial errors, irregularities or fraud, or is in serious breach of its obligations under the selection procedure or under the contract, including false declarations and obligations relating to the Code of Conduct.
2. EFSA must formally notify the expert of its intention, include the reasons why and invite him/her to submit any observations within 30 calendar days of receiving notification.

   If EFSA does not accept these observations, it will formally notify confirmation of the termination.
3. The termination will take effect on the date the notification is sent by EFSA.
4. The expert may at any moment terminate the contract if s/he is not able to fulfil its obligations in carrying out the work required as referred to in Article 5.
5. The expert must formally notify EFSA and include the reasons why by giving 15 days' notice.
6. The termination will take effect on the date EFSA will formally notify confirmation of the termination.
7. Only fees for accomplishing the tasks and expenses for travel actually carried out before termination may be paid subject to Article 14. The expert must submit the payment request for the tasks already executed on the date of termination within 30 calendar days from the date of termination.
8. On termination of the contract, EFSA may hire another expert to carry out or finish the work. It may claim from the expert all extra costs incurred while doing this, without prejudice to any other rights or guarantees it may have under the contract.

ARTICLE 17 - LIABILITY FOR DAMAGES

EFSA cannot be held liable for any damage caused or sustained by the expert or a third party during or as a consequence of performing the contract, except in the event of EFSA's wilful misconduct or gross negligence.

ARTICLE 18 - FORCE MAJEURE

1. 'Force majeure' means any situation or event that:
   - prevents either party from fulfilling its obligations under the contract;
   - was unforeseeable, exceptional and beyond the parties' control;
   - was not due to error or negligence on its part and
   - proves to be inevitable in spite of exercising due diligence.
2. A force majeure must be immediately and formally notified to the other party.

   Notification must include details of the situation's nature, likely duration and expected effects.
3. The party faced with a force majeure will not be held in breach of its contractual obligations if the force majeure has prevented it from fulfilling them.

CHAPTER 5 - FINAL PROVISIONS

ARTICLE 19 - COMMUNICATION BETWEEN THE PARTIES

1. Communication under the contract must:
   - be made in writing and
   - bear the contract's number;

   Formal notifications must be made by e-mail with return receipt or equivalent, or by equivalent electronic means.
2. Communications to EFSA on administrative issues must be sent to the following address: EFSAProcurement@efsa.europa.eu

   Communications to EFSA on the operational implementation of the contract must be sent to the following address, or to other addresses provided by EFSA, if needed: nda_admin@efsa.europa.eu

   Electronic communication is considered to have been received by the parties on the day of dispatch of that communication provided it is sent to the e-mail addresses as stated on the beginning of the contract for the expert and in paragraph 2 of this Article for EFSA.

   Dispatch must be deemed unsuccessful if the sending party receives a message of non-delivery. In this case, the sending party must immediately send again such communication to the e-mail address provided in this contract. In case of unsuccessful

dispatch, the sending party is not held in breach of its obligation to send such communication within a specified deadline.

The sender must send the original signed paper version without unjustified delay if requested by any of the parties.

3. Formal notifications are considered to have been received by the receiving party on the date of receipt indicated on the return receipt or equivalent.

ARTICLE 20 - AMENDMENTS TO THE CONTRACT

1. In justified cases — and provided that the amendment does not entail changes to the contract which would call into question the selection procedure — any party may request an amendment.

   Amendments must be made before new contractual obligations are enforced.

2. The party requesting an amendment must formally notify the other party the requested amendment together with the reasons why.

   The party receiving the request must formally notify its agreement or disagreement, within 30 calendar days of receiving notification.

ARTICLE 21 - APPLICABLE LAW AND DISPUTE SETTLEMENT

1. This Contract is governed by Union law and is supplemented, where necessary, by the law of Italy.
2. Disputes concerning the contract's interpretation, application or validity that cannot be settled amicably must be brought before courts of Parma.

ARTICLE 22 - ENTRY INTO FORCE

This contract enters into force on the day on which the last party signs.

Done in two copies in English.

Expert:	For EFSA:
	Valeriu CURTUI
	Head of Nutrition Unit
Date:	Date:
Signature:	Signature:

ANNEX 1 - TERMS OF REFERENCE (SPECIFICATIONS)

The expert is required to prepare a structured summary report on **critical TOXICOLOGICAL data*** extracted from an application (dossier) for the safety assessment of the Novel Food / Nutrient Source**.**

To this end, the expert should undertake the following **TASKS**, in particular:

(A) Check compliance of the dossier/data requirement with EFSA/applicable guidance.

- Guidance on the preparation and presentation of an application for authorisation of a novel food in the context of Regulation (EU) 2015/2283.
- Guidance on safety evaluation of sources of nutrients and bioavailability of nutrient from the sources.

(B) Critically analyse and review the data (studies) submitted in the dossier.

(C) Extract critical data from the dossier, and from literature search where applicable. The data extracted should be factual, concisely summarising the overall data and key findings/study observations, indicating the relevance of critical data, highlighting uncertainties and inconsistencies identified and missing information. The critical toxicological data extracted should be presented in a structured summary according to the EFSA Template (**Annex 4**).

(D) On some occasions following the evaluation of the initially submitted dossier, there may be requests to applicants for submission of additional data/studies. In these cases, the expert may be requested to carry out within the specified timeline the above-mentioned tasks for the additional data submitted.

***** TOXICOLOGICAL data that are relevant for the safety assessment of the NF/NS are submitted in the dossier or are identified from additional literature search, where applicable. They could relate to:

- Absorption, distribution, metabolism, and excretion (ADME studies)
- Bioavailability studies
- Genotoxicity studies
  - *In vitro* tests
  - *In vivo* tests
- General toxicity studies
  - Preliminary/Dose Range Finding studies
  - Subchronic toxicity - 90-day oral study
  - Chronic toxicity/Carcinogenicity studies
  - Reproductive/Developmental toxicity studies
- Other studies
  - Neurotoxicity
  - Immunotoxicity
  - Allergenicity
  - Other experimental and/or human studies (investigating safety parameters)

The three types of dossiers are:	TYPE I	TYPE II	TYPE III
WORKING DAYS required to perform the tasks specified in the ToR	**5**	**11**	**14**
PRICE *(The price is based on a fixed fee of 350 euros per day worked)*	**1,750€**	**3,850€**	**4,900€**

Deliverables, Timelines and Payments

Steps	Expert / EFSA	Timelines
1	Contract is signed	
2	The Expert will be given access to the application (dossier)	
3	Acknowledgement of receipt of the dossier by the expert via e-mail to nda_admin@efsa.europa.eu. Where EFSA identifies additional relevant publication(s) (not in the dossier), they will be emailed to the Expert as soon as possible	**Within 2 working days from the receipt**
4	Perform TASKS above-mentioned in the Terms of Reference	
5	Submit the **Summary Report** to EFSA by e-mail to nda_admin@efsa.europa.eu	**TYPE I**: **within 15 calendar days** from receipt of the dossier **TYPE II**: **within 20 calendar days** from receipt of the dossier **TYPE III**: **within 25 calendar days** from receipt of the dossier
6	Upon request of EFSA: ▪ Revisions of the Summary Report taking into consideration EFSA comments ▪ Revision of the Summary Report incorporating the additional data (e.g. from the applicant)	**Within 5 calendar days** from the receipt of EFSA request
7	Payment by EFSA:	Upon the approval by EFSA of TOTAL/FINAL Summary Report

ANNEX 2 - CODE OF CONDUCT FOR EXPERTS

ARTICLE 1 - PERFORMANCE OF THE CONTRACT

1. The expert works independently, in a personal capacity and not on behalf of any organisation.
2. The expert must:
   (a) carry out its work in a confidential and fair way
   (b) assist EFSA or relevant service to the best of its abilities, professional skills, knowledge and applying the highest ethical and moral standards
   (c) Follow any instructions and time-schedules given by EFSA or relevant service and deliver consistently high quality work.
3. The expert must not delegate another person to carry out the work.

ARTICLE 2 - OBLIGATIONS OF IMPARTIALITY

1. The expert must perform its work **impartially**. To this end, the expert is required to:
   (a) inform EFSA or relevant service of any conflicts of interest arising in the course of its work
   (b) confirm there is no conflict of interest for the work s/he is carrying out by signing a declaration (Annex 3).
2. **Definition of the conflict of interest**: a conflict of interest exists if an expert:
   (a) has any vested interests in relation to the questions upon which s/he is asked to give advice
   (b) or its organisation stands to benefit directly or indirectly, or be disadvantaged, as a direct result of the work carried out
   (c) is in any other situation that compromises its ability to carry out its work impartially.

   EFSA or relevant service will decide whether a conflict of interest exists, taking account of the objective circumstances, available information and related risks when an expert is in any other situation that could cast doubt on its ability to carry out its work, or that could reasonably appear to do so in the eyes of an external third party.
3. **Consequences of a situation of conflict of interest:**
   (a) If a conflict of interest is reported by the expert or established by EFSA or relevant service, the expert must not carry out the work;
   (b) If a conflict becomes apparent in the course of its work, the expert must inform immediately EFSA or relevant service. If a conflict is confirmed, the expert must stop carrying out its work. If necessary, the expert will be replaced.

ARTICLE 3 - OBLIGATIONS OF CONFIDENTIALITY

1. EFSA and the expert must treat confidentially any information and documents, in any form (i.e. paper or electronic), disclosed in writing or orally in relation to the performance of the contract.
2. The expert undertakes to observe strict **confidentiality** in relation to its work.

   To this end, the expert must not use or disclose, directly or indirectly confidential information or documents for any purpose other than fulfilling its obligations under the contract without prior written approval of EFSA.

In particular, the expert:

i. must not discuss its work with others, including other experts or EFSA or relevant service staff not directly involved in its work

ii. must not disclose:

- any detail of its work and its outcomes for any purpose other than fulfilling its obligations under the contract without prior written approval of EFSA
- its advice to EFSA or relevant service on its work to any other person (including colleagues, students, etc.)

3. If material/documents/reports/deliverables are made available either on paper or electronically to the expert who then works from its own or other suitable premises, he/she will be held personally responsible for maintaining the confidentiality of any documents or electronic files sent and for returning, erasing or destroying all confidential documents or files upon completing its work as instructed.
4. If its work takes place in premises controlled by EFSA or relevant service, the expert:

   (a) must not remove from the premises any copies or notes, either on paper or in electronic form

   (b) will be held personally responsible for maintaining the confidentiality of any documents or electronic files sent, and for returning, erasing or destroying all confidential documents or files on completing its work as instructed.
5. If the expert seeks further information (for example through the internet, specialised databases, etc.) to complete its work, he/she:

   (a) must respect the overall rules for confidentiality for obtaining such information

   (b) must not contact third parties without prior written approval of EFSA.
6. These confidentiality obligations are binding on:

   (a) EFSA (see Regulation No 31 (EEC), 11 (EAEC), laying down the Staff Regulations of Officials and the Conditions of Employment of Other Servants of the European Economic Community and the European Atomic Energy Community[5])

[5] OJ 45, 14.6.1962, p. 1385.

(b) the expert during the performance of the contract and for five years starting from the date of the last payment made to the expert unless:

i. EFSA agrees to release the expert from the confidentiality obligations earlier

ii. the confidential information becomes public through other channels

iii. disclosure of the confidential information is required by law.

ANNEX 3 – DECLARATION OF CONFIDENTIALITY

I. Confidentiality and personal data protection

I confirm that I have read, understood and accepted the code of conduct for experts established in Annex 1 to the contract sent by EFSA.

I also confirm that I will keep all matters entrusted to me confidential and will process the personal data I receive only for the purposes of the performance of the present contract. If unnecessary or excessive personal data are contained in the documents submitted during the implementation of the contract, I will not process them further or take them into account for the implementation of the contract. I will not communicate outside any confidential information that is revealed to me or that I have discovered. I will not make any misuse of information given to me.

I understand that I am responsible for maintaining the confidentiality of any documents or electronic files sent to me and for returning, erasing or destroying all confidential documents or files upon completing the assignment unless otherwise instructed by EFSA.

Expert:

Date:

Signature:

ANNEX 4 – EFSA TEMPLATE SUMMARY REPORT

Summary report

Deliverable under the Contract

Contract EOI/EFSA/NUTRI/2019/01/CT01

European Food Safety Authority (EFSA),

Date: XX/XX/XXX

Question/Application number: EFSA-Q-YYYY-NNNNN

Correspondence: XXX@efsa.europa.eu

The report should contain all critical/relevant data, including confidential data. Confidential data should be highlighted.

Toxicological studies

Study title (Reference)	**Title** (Author et al., XXXX)
Additional administrative info about the study	It has been claimed as confidential and proprietary by the applicant. *Or* Only an abstract has been provided. *Or* Full study report has been provided. *Or (…)*

Tested system *(N°/group if in vivo)*	Wistar rats *Or* S. typhimurium TA98, TA100, TA102, TA1535 and TA1537 *Or* Human lymphocytes *Or* (…) Main groups: 25/sex/group; Recovery groups: 25/sex/group *Or (…)*
Test material *If NF, then justify*	The NF. The applicant provided CoA of batch XX, used also in batch-to-batch analysis. *Or* Component X, indicated by the applicant as a key component of the NF. *Or* Intermediate product of the NF. *Or (…)*
Dose/concentration (route of administration)	Control: 0 (distilled water, 10 ml/kg); low dose 250; mid-dose 500 and high-dose 1,000 mg/kg bw (by gavage). *Or* 0 (deionised water), 0.005, 0.01, 0.03, 0.05, 0.3, 1.0, 3.0 or 5.0 mg/plate in absence and presence of S9 mix (plate incorporation method). *Or (…)*
Method *Short description if not OECD*	OECD 408 *Or (…)*
Author(s)/applicant conclusion(s) *Overall. Indicate applicant conclusions only if different from authors'*	NOAEL = 1,000 mg/kg bw (the highest dose tested). *Or (…)*
Comment(s) *Indicate non-standard uncertainties, deviations from OECD guidelines etc.*[(a)] *Provide critical comments on the study and its relevance for the risk assessment of the NF*	There were deviations from the OECD Guideline: not all parameters were analysed statistically, and no motor activity tests were conducted. One male rat died in the highest dose group (cause of death was not established). *Or (…)* NOAEL proposed by the study authors/applicant could not be accepted since biologically relevant changes in haematological parameters were observed even at lowest dose tested. *Or (…)*

Identification of gaps in the data which require a further clarification from the applicant	Full study report should be provided. *Or* Historical control data should be provided. *Or* Proof (e.g. certificate of analysis) that test material is the NF should be provided. *Or (…)* The applicant is requested to further comment increased ALT values, considering also statistically significant increase in AST. *Or (…)*

Key results[(b)]

Parameters	**Sex**	**Dose groups (mg/kg bw/day)**					
		0 (control, G1); mean ± SD	**250 (low, G3); mean** ± SD	**500 (intermed., G4); mean** ± SD	**1,000 (high, G5); mean** ± SD	**0 (recovery, G2); mean** ± SD	**1,000 (recovery, G6); mean** ± SD
Clinical chemistry *or* **Urinalysis** *or* **Organ weights** *or* **Histopathological examination** *or (…)*							
Aminotransferase (ALT)	M	26.15 (20.21)	30.23 (25.35)	28.05 (28.15)	27.88 (22.55)	26.60 (20.01)	25.55 (18.05)
	F	25.90 (22.56)	27.56 (25.87)	30.10[(c)] (29.26)	33.10 (30.30)	25.50 (24.53)	26.80 (20.79)
Author(s)/applicant conclusion *Indicate applicant conclusions only if different from authors'*	**Authors:** Although ALT values are showing statistical significance, such findings have no biological significance as the values have a big variance, i.e. the standard deviations are very large compared to the mean ALT values. Also, statistical significance by itself does not necessarily indicate an adverse effect, and no other parameters support that the findings are dose dependent. These observations, taken together, lead to the conclusion that the results are incidental. However, based on the observed decrease in eosinophils in both male and female rats, this parameter may be monitored in future non-clinical and clinical studies with this substance. *Or (…)*						
Specific consideration of these parameters (in regards to biological relevance; comparison with	Statistically significantly higher ALT levels in females of the mid- and high-dose groups compared with the control group were dose-related and returned in normal ranges after the recovery indicating the hepatotoxicity of the test substance. *Or (…)*						

other relevant studies etc.)							
Haematology *or* **Urinalysis** *or* **Organ weights** *or* **Histopathological examination** *or (...)*							
Author(s)/applicant conclusion *Indicate applicant conclusions only if different from authors'*							
Specific consideration of these parameters							

[a] Text written in red needs to be provided by the contractor;
[b] Only to report those results which are or may be biologically relevant.
[c] Results showing statistically significant difference ($p < 0.05$) should be highlighted in different colour.

Human studies

Title of the study (reference)	**Title** (Author et al., XXXX)
Additional administrative info about the study	It has been claimed as confidential and proprietary by the applicant. Full study report provided. *Or (…)*
Study design	Randomised, double-blind, placebo-controlled, parallel study (in accordance with the Guideline for GCP (ICH-6)). *Or* Single-arm study. *Or* Double-blind, placebo-controlled, cross-over study. *Or (…)*
Study population *Indicate key baseline characteristics of participants*	100 participants (aged 30 to 50 years) either healthy or with stable diabetes mellitus and/or hypertension on mono-therapy or low dose combination therapy. *Or* 20 healthy male recreational athletes (30 ± 5.5 years) without history of renal or liver disease. *Or (…)*
Duration of the study	X weeks. *Or (…)*
Test material *If NF, then justify*	The NF. The applicant provided CoA of batch XX, used also in batch-to-batch analysis. *Or* Component X, indicated by the applicant as a key component of the NF. *Or* Intermediate product of the NF. *Or (…)*
Dosage	X mg/day *Or (…)*
Power calculations performed	Yes, based on efficacy parameter of enhancing physical endurance. *Or* Not reported. *Or (…)*
Primary endpoints	Postprandial glycemia and satiety (efficacy parameters). *Or (…)*
Safety-related parameters	Physical examinations (blood pressure…).

	Laboratory parameters (BUSE, creatinine, total bilirubin, AST, ALT, ALP, total protein, albumin and globulin, PSA, glucose, uric acid, lipid profile, full blood count, T:E ratio). Recordings of adverse events. *Or (…)*
Author(s)/applicant conclusion(s) *Overall. Indicate applicant conclusions only if different from authors'*	No significant difference between the NF and placebo groups in safety parameters at baseline, week 6 and at week 12. Two recorded AEs in the NF group could not be attributed to the NF. *Or (…)*
Comment(s) *Indicate non-standard uncertainties.* *Provide critical comments on the study and its relevance for the risk assessment of the NF*	Participants had different health status and were on different medicine regimes, factors not taken into account. *Or (…)* NF has been used in combination with other product. *Or (…)* This study did not investigate safety parameters, thus its' of limited value to the risk assessment. *Or (…)*

Key results[(a)]

[(a)]Reported in a similar manner like for toxicological studies

References:

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