

AMENDMENT No 2
to **CONTRACT with ref.: OC/EFSA/SCER/2014/05**

'Transformation and further development of the Compendium of botanicals reported to contain naturally occurring substances of possible concern for human health when used in food and food supplements'

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 for the purposes of the signature of this amendment by Mr. Bernhard Url, Executive Director

on the one part, and

Institute of Chemical Technology Prague
Public Entity
Technická 5
166 28 Prague 6
CZECH REPUBLIC
VAT registration number: CZ60461373

appointed as the leader by the members of the group that submitted the joint tender, following a power of attorney and represented for the purposes of the signature of this amendment by prof. Ing. Karel Melzoch, C.Sc Rector, legal representative,

and
PARTNER 1:
TECHEM CZ, s.r.o.
Private Company
Ondříčkova 48
130 05 Prague 3
CZECH REPUBLIC
VAT registration number: CZ61852121

represented for the purposes of the signature of this amendment by prof. Ing. Karel Melzoch, C.Sc Rector, based on the Power of attorney attached to this contract.

The parties identified in the main Contract 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 amendment.

Having regard to the Contract concluded between the Authority and the Contractor on 05/12/2014 and to amendment nr 1 concluded on 19/10/2015,

Whereas the Authority has informed the Contractor of its intention to amend the above-mentioned contract as additional services are needed to complete the tasks as detailed in Annex 1 (Amended tender specifications).

¹ OJ L 31 of 01.02.2002

HAVE AGREED AS FOLLOWS:

I. Amended Provisions

Article 1.2.3 – Duration

Article 1.2.3 of the Special Conditions is hereby amended as follows:
The duration of the execution of the tasks shall not exceed 41 months from the signature of the contract on 05/12/2014.

Article 1.3 – Price

The maximum total amount to be paid by the Contracting Authority under this amendment shall be EUR 130.000,00 (one hundred thirty thousand euros) covering all tasks related to deliverables 7, 8 and 9.

Article 1.4 – Payment arrangements

I.4.2 Interim payment

The contractor shall submit an invoice for an interim payment of EUR 78.000 (seventy-eight thousand euros) equal to 60% of the total amount referred to in Article I.3.

Invoices for interim payment shall be accompanied by deliverable 7.
The Contracting Authority shall make the payment within 60 days from receipt of the invoice. The contractor shall have 20 days in which to submit additional information or corrections, or new deliverable if required by the Contracting Authority.

I.4.3 Payment of the balance

The contractor shall submit an invoice for payment of the balance.

The invoice shall be accompanied by deliverables 8 and 9. The Contracting Authority shall make the payment within 60 days from receipt of the invoice. The contractor shall have 20 days in which to submit additional information or corrections, or new deliverables if it is required by the Contracting Authority.

II. Amended Annexes

Section 1.4 (Tasks, deliverables, timeline and payments) of Annex I of the Contract is hereby replaced by Annex I of this Amendment (Amended Tender Specifications).

III. General Provisions

For all matters not expressly covered under this Amendment, the main Contract and its Annexes (including the sections of the original Tender Specifications not covered by this amendment) shall continue to apply.

The present Amendment with Annex I shall form an integral part of the Contract and it shall enter into force after signature by the contracting parties.

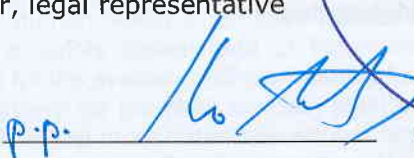
SIGNATURES

For the Contractor,
Institute of Chemical Technology Prague

For the Authority,

prof. Ing. Karel Melzoch,
C.Sc Rector, legal representative

Hans Verhagen
Head of Department

signature: 

signature: 

Done at Prague,

Done at Parma,

Date: 2./12./2016

Date: 5 dec/16

In duplicate in English

Annexes:

- Annex I – Amended tender specifications
- Annex II – Contractor's financial offer



AMENDED TENDER SPECIFICATIONS

Extract of amended articles of the original tender specifications OC/EFSA/SCER/2014/05 –
amended text is highlighted

Reference: NP/EFSA/SCER/2016/01
Subject: Transformation and further development of the Compendium of botanicals reported to contain naturally occurring substances of possible concern for human health when used in food and food supplements
Procurement procedure: Art 134 (1)b
Project/Process code: SCER-03
Activity Code: A3.3

1.2 BACKGROUND

The European Food Safety Authority (EFSA) is the keystone of European Union (EU) risk assessment regarding food and feed safety. In close collaboration with national authorities and in open consultation with its stakeholders, EFSA provides independent scientific advice and clear communication on existing and emerging risks.

EFSA was set up in January 2002, following a series of food crises in the late 1990s, as an independent source of scientific advice and communication on risks associated with the food chain.

EFSA was created as part of a comprehensive programme to improve EU food safety, ensure a high level of consumer protection and restore and maintain confidence in the EU food supply.

In the European food safety system, risk assessment is done independently from risk management. As the risk assessor, EFSA produces scientific opinions and advice to provide a sound foundation for European policies and legislation and to support the European Commission, European Parliament and EU Member States in taking effective and timely risk management decisions.

EFSA's remit covers food and feed safety, nutrition, animal health and welfare, plant protection and plant health. In carrying out its work, EFSA also considers the possible impact of the food chain on the biodiversity of plant and animal habitats. The Authority performs environmental risk assessments of genetically modified crops, pesticides, feed additives, and plant pests. In all these fields, EFSA's most critical commitment is to provide objective and independent science-based advice and clear communication grounded in the most up-to-date scientific information and knowledge.

The Scientific Committee of EFSA supports the work of EFSA's scientific Panels on scientific matters of a horizontal nature and providing strategic advice to EFSA's Executive Director. It is also responsible for general co-ordination to ensure consistency in the scientific opinions prepared by the Scientific Panels. The Scientific Committee focuses on developing harmonised risk assessment methodologies in fields where EU-wide approaches are not already defined. The Scientific Committee carries out its work either in response to requests for scientific advice from risk managers or on its own

initiative, e.g. to address the need expressed by Member States' Competent Authorities for further guidance on how to assess the safety of botanicals and botanical preparations used in food. Further information on EFSA's present organisational structure, including information on the work of the various EFSA Units, the EFSA Scientific Panels, as well as the EFSA Scientific Committee is available on the EFSA website^{1,2}.

The EFSA Compendium of botanicals reported to contain naturally occurring substances of possible concern for human health when used in food and food supplements is part of the above-mentioned work on the safety assessment of botanicals. It was created in 2009 to assist risk assessors responsible for the evaluation of plant-based food supplements. It helps identifying the compound(s) of possible concern for the plant species, plant part or plant preparation considered. The Compendium lists in alphabetical order botanicals without any judgment on whether they are suitable or not for food applications in Europe. The Compendium has no legal or regulatory force pertaining to the legal classification of products or substances. Since then, the Compendium has been regularly updated by the Scientific Committee: version 2 was published on the EFSA website in May 2012 and the third version is currently under preparation. For further information on the Compendium, see: <http://www.efsa.europa.eu/en/data/compendium-botanicals>

1.3 OBJECTIVES

The aim of this procurement procedure is to conclude a direct contract for the execution of specific tasks over a clearly defined period as defined in these tender specifications.

The EFSA Scientific Committee and Emerging Risks (SCER) Unit launched the present open call for tender to transform and further develop the EFSA Compendium of botanicals reported to contain naturally occurring substances of possible concern for human health and increase its usefulness for Competent Authorities in EU Member States and other interested parties. For the latter purpose, the existing EFSA Compendium of botanicals reported to contain naturally occurring substances of possible concern for human health (currently in MS Excel format) will be transformed into a set of relational tables according to EFSA data models and controlled terminologies suitable for import into the EFSA data warehouse. Once the transformation is complete database should be updated and expanded with information describing the occurrence of substances of concern in botanical extracts and reported toxicity of substances of concern.

More specifically, the contractor will be requested to:

Objective 1:

- Transform the data in the existing MS Excel spreadsheet (see version 2 of the Compendium currently published in the EFSA Journal³) according to the data model presented in Annex 7 of these tender specifications.

| Version 2 of the Compendium currently published in the EFSA Journal | BOTANICAL Name | Family Name | Plant part | Extract | Adverse effect | Composition group | Substance concern | Toxicological study | Reference |
|---|----------------|-------------|------------|---------|----------------|-------------------|-------------------|---------------------|-----------|
| FACT BOTANICAL / BOTANIC | X | | | | | | | | |
| OPINION | | | | | | | | | X |
| COMPOSITION / sampMatCode | | X | X | X | | | | | |
| COMPOSITION /paramCode | | | | | | X | X | | |
| ENDPOINT_STUDY | | | | | X | | | X | |
| ENDPOINT_STUDY id PlantMat | | X | X | X | | | | | |

¹ <http://www.efsa.europa.eu/en/efsawho/efsasstructure.htm?wtrl=01>

² <http://www.efsa.europa.eu/en/panels.htm>

³ <http://www.efsa.europa.eu/en/efsajournal/pub/2663.htm>

| | | | | | | | | | |
|--------------------------|--|--|--|--|--|--|---|--|--|
| ENDPOINT_STUDY paramCode | | | | | | | X | | |
|--------------------------|--|--|--|--|--|--|---|--|--|

The data model is based on existing EFSA data collections⁴. The successful tenderer will be provided with the latest version of the Compendium at the signature of the contract. This will require transformation of the data from the MS Excel spreadsheet to the relational tables as specified in Annex 7 of these tender specifications, including the assignment and management of unique identifiers and foreign keys, coding of variables and categories (for example species and substances) according to EFSA controlled terminology and completing missing information in the tables. The transformation and data management can be performed using the software of choice of the contractor. EFSA will require the resulting tables to be exported in XML format and submitted via the EFSA Data Collection Framework⁵. The submitted data will be subjected to automated validation and only transmissions where all tables have the status "Valid" will be accepted.

- Develop a Standard Operating Procedure (SOP) for extracting the information from literature and completing the Compendium records for botanical species.
- Give a presentation on the Compendium for EFSA experts and staff at EFSA premises.

Objective 2:

- Perform an extensive literature search for the plant species and plant preparations already present in the Compendium (around 2200 plants are currently listed), but for which the Scientific Committee Working Group on Compendium has identified data gaps, or on new plant species / plant preparations identified by the Scientific Committee Working Group on Compendium. The literature search should be performed considering the document Application of systematic review methodology to food and feed safety assessments to support decision making.
- Using the SOP developed in Objective 1 extract data from the literature to expand and update the Compendium. The updated Compendium should be resubmitted via the EFSA Data Collection Framework on a routine basis. The submissions will be subject to automated validation and validation of scientific content by the Scientific Committee Working Group on Compendium. Revision of the Compendium maybe required based on the outcome of the scientific content validation.

Activities related to both objectives will run in parallel, according to the timeline detailed in section 1.4.

⁴ Standard Sample Description doi:10.2903/j.efsa.2013.3424, Chemical Hazards Database <http://www.efsa.europa.eu/en/supporting/pub/458e.htm>

⁵ <http://www.efsa.europa.eu/en/datexsubmitdata/datexdatacollframework.htm>

1.4 TASKS, DELIVERABLES, TIMELINE AND PAYMENTS

| No | Tasks | Can be subcontracted? | Deadline for finalisation |
|----|---|-----------------------|--|
| 1 | Submission of the Compendium according to the data model presented in Annex 7 of these tender specifications via the EFSA Data Collection Framework (DCF) (900 plant species, referred as "plants of the white list"). | Yes | 3 months from the entry into force of the contract |
| 2 | Drafting part 1 of the (Interim report 1) External Scientific Report synthesising, analysing and summarising the reorganisation activities of the data from the current Compendium. The SOP for data extraction from literature and data entry in the Compendium should be included in the report. | No | 4 months from the entry into force of the contract |
| 3 | Presentation of version 3 of the Compendium (half a day duration at EFSA premises in Parma, Italy) for EFSA experts and staff (approximately 12 persons). | Yes | 4 months from the entry into force of the contract |
| 4 | Perform an extensive literature search for the plant species and plant preparations already present in the Compendium, but for which the Scientific Committee Working Group on Compendium has identified data gaps, or on new plant species / plant preparations identified by the Scientific Committee Working Group. (1000 plant species, referred as " plants of the yellow list ") Submission of the new data via the DCF, by batches of plant species, to the Scientific Committee Working Group on compendium for validation. | Yes | Bi-monthly from agreement of the SOP and methodology for the extensive literature search Bi-monthly submission of batches of updated plant species via the DCF |
| 5 | In case the submitted data could not be validated by Scientific Committee Working Group on Compendium or are still insufficient for inserting the considered plant species in the EFSA data warehouse, the contractor will go back to the extensive literature search and resubmit via the DCF the corrected / missing data to the Scientific Committee Working Group on compendium. | Yes | Two weeks after the notification by EFSA that the plant species could not be validated by the Scientific Committee Working Group on Compendium |
| 6 | 2 nd Interim External Scientific Report synthesising, analysing and summarising the outcome of the extensive literature search and extraction activities (i.e. Tasks 4-5), as well as to review part 1 of the same report. | No | 24 months from the entry into force of the contract |
| 7 | Control of the taxonomy for all the plant species transferred to / to be transferred to | Yes | 25 months from the entry into force of the contract |

⁶ If a subcontractor provides the whole or a very large part of the financial capacity OR executes the whole or a very large part of the tasks, EFSA may demand that that the subcontractor signs the contract.

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| | EFSA. The source of information for the taxonomy checking will be provided by EFSA | | |
| 8 | Perform an extensive literature search for the plants of the "white list" that were transferred directly to EFSA as part of task 1. The new data will be submitted to the Scientific Committee (SC) Working Group on Compendium for validation before they are transferred to EFSA via the DCF. | Yes | Bi-monthly submission of batches of updated plant species via the DCF |
| 9 | Proceed with tasks 4 and 5 for an additional 600 plant species added to the "yellow list" by the SC Working Group on Compendium and not yet addressed with tasks 4 and 5. | Yes | Bi-monthly submission of batches of updated plant species via the DCF |
| No | Meetings/Teleconferences | | Deadline for finalisation |
| 1 | <p>Kick-off meeting (as a physical meeting at EFSA premises in Parma, Italy - one working day⁷)</p> <p>To be attended by the Project Leader and at least two other experts from the team.</p> <p>The purpose of the kick-off meeting is to verify:</p> <ul style="list-style-type: none"> the contractor's specific understanding of the assignments under the contract; the proposed approach and methodology to carry out the services requested by EFSA (incl. the fine-tuning of the methodology, with particular reference to the current data model of EFSA's Compendium of botanicals for the submission of the data on the DCF, timelines and structure of the various deliverables, etc.) that will be documented in the minutes of the kick-off meeting; the species to be included in the extensive literature search and mechanism for feedback from the Scientific Committee Working Group on Compendium; fine-tuning the composition of the contractor's team proposed for the assignment; the proximate dates of the subsequent physical meetings and teleconference calls. <p>The minutes of the kick-off meeting shall be taken and provided to EFSA by the contractor at the latest 2 weeks after the kick-off meeting.</p> | | within 1 month after the entry into force of the contract |
| 2 | <p>1st Interim meeting (as a physical meeting at EFSA premises in Parma, Italy - one working day) together with members of the Scientific Committee Working Group on Compendium.</p> <p>To be attended by the Project Leader and at least two other experts from the team.</p> <p>The purpose of this meeting is to:</p> <ul style="list-style-type: none"> discuss part 1 of the draft External Scientific | | 4 months from the entry into force of the contract |

⁷ A working day consists of 8 working hours; likewise a half day is 4 working hours.

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| | <p>Report that will synthesise, analyse and summarise the data reorganisation activities undertaken and the data submitted to the EFSA Data Warehouse via the DCF, as well as to address any possible technical or administrative difficulties encountered in the implementation of the services requested;</p> <ul style="list-style-type: none"> • present version 3 of the Compendium to EFSA experts and staff (approximately 12 persons); • review of the data of the restructured compendium as submitted to the DCF; • agree on the SOP and methodology for the extensive literature search, data extraction and data entry in the Compendium; • Agree on the schedule for the review of botanical species. <p>The minutes of the interim meeting shall be taken and provided to EFSA by the contractor at the latest 2 weeks after the interim meeting.</p> | |
| 3 | <p>Teleconferences⁹ - Expand and update the Compendium</p> <p>The purpose of these teleconferences is to monitor and discuss updates to the Compendium and their transfer to the EFSA Data Warehouse via the DCF, to address any possible technical or administrative difficulties encountered in the implementation of the services requested, and to communicate feedback from Scientific Committee Working Group on Compendium.</p> <p>The minutes of the teleconferences shall be taken and provided to EFSA by the contractor at the latest 2 weeks after each teleconference.</p> | <p>Bi-monthly from agreement of the SOP and methodology for the extensive literature search</p> |
| 4 | <p>2nd Interim Meeting (as a physical meeting at EFSA premises in Parma, Italy - one working day or as teleconference)</p> <p>To be attended by the Project Leader.</p> <p>The purpose of this meeting is:</p> <ul style="list-style-type: none"> • to discuss part 2 of the draft External Scientific Report that will synthesise, analyse and summarise the extensive literature search activities undertaken and the data submitted to EFSA; • to review part 1 of the same report synthesising, analysing and summarising the data reorganisation activities undertaken and the data submitted to the EFSA Data Warehouse via the DCF (already discussed during the interim meeting); • to discuss next steps and possible needs regarding the check of the taxonomy for all the plant species if the database, the extensive literature review / data extraction / data validation / data transfer to EFSA applied to the plant species of the white list, and the continuation of | <p>23 months from the entry into force of the contract</p> |

⁹ The maximum duration of each teleconference shall be 0.5 working days (i.e. 4 working hours).

| | <p>the extensive literature review / data extraction / data validation / data transfer to EFSA of the plants added to the yellow list and not addressed so far.</p> <p>The minutes of the interim meeting/teleconference shall be taken and provided to EFSA by the contractor at the latest 2 weeks after the meeting/teleconference.</p> | |
|----|---|--|
| 5 | <p>3rd Interim meeting (as a physical meeting at EFSA premises in Parma, Italy - one working day or as teleconference) together with members of the Scientific Committee Working Group on Compendium</p> <p>To be attended by the Project Leader and at least two other experts from the team.</p> <p>The purpose of this meeting/teleconference is to review the progress of the extensive literature review / data extraction / data validation / data transfer to EFSA of the plants of the white and yellow lists (tasks 8 and 9).</p> | 34 months from the entry into force of the contract |
| 6 | <p>Final Meeting (as a physical meeting at EFSA premises in Parma, Italy - one working day)</p> <p>To be attended by the Project Leader and at least two other experts from the team.</p> <p>The purpose of this meeting is to discuss the draft final External Scientific Report that will synthesise, analyse and summarise all the activities performed under this contract. The final report will build upon the interim reports submitted as deliverables 3 and 6.</p> <p>The minutes of the final meeting shall be taken and provided to EFSA by the contractor at the latest 2 weeks after the final meeting.</p> | 40 months from the entry into force of the contract |
| No | Deliverables | Deadline for submission to EFSA |
| 1 | <p>Extensive Literature Search protocol</p> <p>The document should describe the method for preparing the protocol; how the eligibility criteria for study selection will be developed; the method for conducting the Extensive Literature Search and study selection, 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; and the method for extracting data from the included studies.</p> | 4 months after the entry into force of the contract |
| 2 | <p>Version 3 of the Compendium of Botanicals submitted via the EFSA Data Collection Framework.</p> | 4 months after the entry into force of the contract |
| 3 | <p>External Scientific Report (part 1) synthesising, analysing and summarising the reorganisation activities of the data from the current Compendium.</p> <p>Protocol for extensive literature review and SOP for data extraction from literature and data entry in the Compendium.</p> | 4 months after the entry into force of the contract |
| 4 | <p>Presentation of version 3 of the Compendium at EFSA.</p> | 4 months after the entry into force of the contract |
| 5 | <p>2nd Interim submission of the Compendium to the EFSA Data Warehouse using the DCF.</p> | 23 months from the entry into force of the contract |

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| 6 | 2nd Interim External Scientific Report (part 1 and part 2) synthesising, analysing and summarising the reorganisation activities of the data from the current Compendium, as well as the extensive literature search and extraction activities for the new data. | 24 months after the entry into force of the contract |
| 7 | Minutes of the 3rd interim meeting (point N°5 of the tasks) providing an update in writing on the progress of the extensive literature review / data extraction / data validation / data transfer to EFSA of the plants of the white and yellow lists | 35 months after the entry into force of the contract |
| 8 | Draft final External Scientific Report synthesising, analysing and summarising the reorganisation activities of the data from the current Compendium, as well as the extensive literature search and extraction activities for the new data | 40 months after the entry into force of the contract |
| 9 | Submission of new data resulting from the extensive literature search, organised according to the new data model, as presented in Annex 7 of these tender specifications, for validation by the Scientific Committee Working Group on Compendium. | Performed upon agreement of SOP on a bi-monthly basis and shall be completed at the latest by 41 months from the entry into force of the contract |
| No | Payments | Linked to approval by EFSA of deliverable No |
| | Payments for tasks originally awarded (total value 158.080 euro) | |
| 1 | Pre-financing payment of 30% | N/A |
| 2 | Interim payment of 10% | 1, 2, 3 and 4 |
| 3 | Interim payment of 60 % of initial awarded value | 5 and 6 |
| | Payments for amended tasks (total value of max. 130.000 euro based on the tenderer's financial offer) | |
| 4 | Interim payment of 60 % of amended amount | 7 |
| 5 | Balance payment 40 % of amended amount | 8 and 9 (and upon completion of all tasks) |

The working language for the contract implementation: execution of tasks, meetings and deliverables shall be English.

Annex 1 - FINANCIAL OFFER TEMPLATE

FINANCIAL OFFER

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

- The maximum budget EFSA has available for this assignment is **130.000 €**. Any offer exceeding this maximum will not be retained for contract award.
- 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 is also available on the website of the European Central Bank at the following URL: <http://www.ecb.int/stats/eurofxref/>.
- Pursuant to the provisions of Article 9 of the Italian Law n. 17 dated 10/01/2006 and under Article 151 of Council Directive 2006/112/EC, EFSA is exempt from all duties, taxes and other charges, including VAT. For this reason, all prices given in the financial breakdown should be free of VAT and other taxes or duties.
- The price offered below is understood to be all inclusive. For example any additional costs which can be incurred by the contractor in performing the contract, such as overheads, 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.

| | |
|--|-----------------|
| ALL INCLUSIVE TOTAL PRICE to be used for the evaluation and for the contract in the case of award. | 130.000 € |
|--|-----------------|

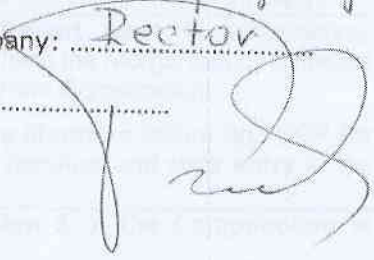
The tenderer, by signing this form, confirms to have the technical and professional capacity to perform the tasks as described in section 1.4 of the tender specifications.

Tenderer name: Vysoka škola chemicko-technologická v Praze

Date: 11.11.2016

Name of person signing the financial offer: prof. Ing. Karel Melzoch, CSc.

His/her position in the company: Rektor

His/her signature: 

 100.