TENDER SPECIFICATIONS

Reference: OC/EFSA/SCER/2018/03
Subject: Transformation and further development of the Compendium of botanicals
Procurement procedure: Open call
Project/Process code: SCER-08
Budget Line: 3210

Tender specifications purpose:

1. specify what EFSA is to buy under the contract resulting from this tender procedure
2. announce the criteria which EFSA will apply to determine the successful contractor among the offers received
3. guide tenderers to establish and dispatch their offer in the required form and time

These tender specifications will form annex 1 of the contract resulting from this tender procedure and will be binding during the contract implementation.

Additional guidance:
The economic operators wishing to submit an offer following this call for tenders are also invited to read the **EFSA Guidance for tenderers** available on the EFSA website. The general guidance aims to assist the potential tenderers in their understanding of EFSA procurement procedures and to complete the specific information contained in this tender specifications.

Submitting your tender on time:
Follow carefully the guidance in annex 2 "e-Submission quick reference guide for economic operators".
Do not wait until the last day to upload your offer. Responsibility rests with you to ensure that your tender is fully, completely and correctly uploaded before the time limit for receipt. Failure to respect the time limit for receipt will result in the rejection of your offer for non-compliance with the deadline for tenders.

Please note that offers sent via e-mail will be rejected.

Provide EFSA with feedback:
If you considered applying to this call for tenders but finally decided not to do so, your feedback and reasoning for such a decision would be very much appreciated. You should address your feedback to **EFSAProcurement@efsa.europa.eu.** Please note that your comments will be kept strictly confidential and will only be used for the purpose of improving future EFSA procurement calls.

INDICATIVE PROCEDURE TIMETABLE

Milestone	Date[1]	Comments
Launch date	15/10/2018	Date of publication being sent to OJ
Deadline for sending a request for clarification to EFSA	**23/01/2019 at 14:30 (CET)**	***Attention:*** *Requests for clarification may only be submitted through the e-Tendering website as described in the Invitation Letter.*
"Receipt Time Limit" - Closing date and time for offers reception	**31/01/2019 at 14:30 (CET)[2]**	See details in the Invitation letter. Please also refer to part 3 of the tender specifications "How to submit your offer – e-Submission application guide" and the e-Submission quick reference guide for economic operators, link provided in annex 2.
Opening session	01/02/2019	14:30hr, EFSA premises, Parma
Notification of the evaluation results	MARCH 2019	Estimated. *Attention: outcome of the present procurement procedure will be communicated to all tenderers to the e-mail address indicated in their offer. Accordingly, the tenderers who have submitted offers under the present call are strongly invited to check regularly the inbox in question.*
Contract signature	MARCH 2019	Estimated

[1] All times are in the time zone of the country of the EFSA.

[2] **Do not wait until the last day to upload your offer. Responsibility rests with you to ensure that your tender is fully, completely and correctly uploaded before the time limit for receipt. Failure to respect the time limit for receipt will result in the rejection of your offer for non-compliance with the deadline for tenders.**

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

1.1 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 stakeholders, EFSA provides independent scientific advice and clear communication on existing and emerging risks.

The EFSA Strategy 2020[3] includes the strategic objective to "Widen EFSA's evidence base and optimise access to its data". Under this Objective, EFSA plans to "migrate towards structured scientific data" as a move towards efficiency, innovation and new methods in risk assessment through structuring of data from monitoring schemes, regulated product applications and EFSA outputs, in agreed formats and based, where possible, on existing international standards, enabling their re-use. As a consequence the EFSA "Information Management Programme" has a number of projects designed to increase the use of standardised data structures for both receipt and publication of information used in food and feed risk assessments.

The Scientific Committee and Emerging risk (SCER) unit supports the development and implementation of approaches of a horizontal cross-cutting nature for scientific evaluations through the organisation of the work of EFSA's Scientific Committee and its working groups. The Unit is responsible for coordinating the preparedness for responding to urgent issues and the development of hazard databases as cross-cutting tools for assisting EFSA's scientific activities as well as in developing and implementing approaches for the identification of emerging risks in the areas within EFSA's mandate. The SCER unit is also responsible for the overarching programme to increase transparency and engagement throughout its risk assessment processes (TERA) and for the Risk Assessment Methodology Programme (RAM-Pro) to co-ordinate projects to achieve EFSA's strategic objectives in relation to development of new RA methodologies and their harmonised use, as laid down in Strategy 2020 in Objective 4.

In this context, the SCER unit has been developing EFSA's Compendium of botanicals reported to contain naturally occurring substances of possible concern for human health. The compendium provides composition and toxicity information for around 2600 plants. Around 2500 substances have been included in the database, on the basis that they contain chemical groups considered as of concern "by default" (e.g. alkaloids), or because they are known to be toxic (Working Group Expert knowledge); the actual toxicity of these substances is still to be characterised.

The SCER unit has also developed EFSA's chemical hazard database "OpenFoodTox" that provides summary toxicological data of food and feed chemicals in humans, animals and the environment. The design of OpenFoodTox takes into account structure templates namely the OECD harmonised templates[4] (OHTs) for the coherent and harmonised reporting of toxicological data. Both the compendium of botanicals and OpenFoodTox collate information on risk assessment endpoints used in chemical safety assessments.

The present Call is based on EFSA's 2018 Work Programme for grants and operational procurements as presented in Annex IX of the EFSA Programming Document 2018 – 2020, available on the EFSA's website[5].

[3] https://www.efsa.europa.eu/sites/default/files/corporate_publications/files/strategy2020.pdf
[4] https://www.oecd.org/ehs/templates/
[5] http://www.efsa.europa.eu/en/corporate/pub/amp1820

1.2 OBJECTIVES

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

The overall objective of this procurement is to update and further develop EFSA's Compendium of Botanicals as an open source tool for EFSA, stakeholders and the risk assessment community as a whole. This requires data on chemical composition and toxicity for around 900 plants to be collated, and to characterise the toxicity of 2500 chemical substances. For the 2500 chemical substances there is a requirement to collate information on toxicity and genotoxicity reference points. In both cases this information should be extracted from literature (including Grey literature) or published datasets. This will require the use of a standardised and reproducible procedure to find and appraise the available evidence. Open datasets for both Compendium of botanicals and OpenFoodTox can be accessed at the links below. The format for the information to be submitted to EFSA will be similar to the format used in these previous projects.

European Food Safety Authority. (2016). EFSA's compendium of botanicals [Data set]. Zenodo. http://doi.org/10.5281/zenodo.1212388

Bassan, Arianna et al. (2018). OpenFoodTox: EFSA's chemical hazards database (Version 2) [Data set]. Zenodo. http://doi.org/10.5281/zenodo.1252752

Specific objectives

The objectives of the contract resulting from the present procurement procedure are as follows:

Objective 1: Extraction of composition and toxicity data for 900 plants

A systematic literature review has been performed for 900 plant species. For each plant, up to 100 bibliographical references will be provided, organised by decreasing order of relevance for EFSA's Compendium needs. The contractor is requested to extract relevant plant composition information. The information provided should include the type of plant material/extract tested, the substance/s detected, details of the analytical method and the concentration measured. A list of substances of concern and a list of chemical groups considered as of concern by default will be provided at the kick-off meeting of the project. The source of the data must be recorded. In cases where a new substance from a group of concern is found in a composition study the new substance should be fully characterised (CAS number, EC number, SMILES, IUPAC name, molecular formula and INCHI where applicable).

The table SUBSTANCE in Annex 9 describes the variables to be extracted. The table COMPOSITION in Annex 9 describes the variables to be extracted.

In case reports of adverse effects/toxicity have been identified following oral intake of the plants / plant parts, this information will be recorded. The table ENDPOINT_STUDY in Annex 9 describes the variables to be extracted.

Objective 2: Characterisation of the toxicity and genotoxicity for 2500 chemical substances:

EFSA will provide a list of 2500 substances of possible concern for human health. These substances will be provided in batches, as they are currently being identified in another ongoing project, or may result from the outcome of Objective 1.

To collect the information on toxicity /genotoxicity, a search of the peer-review literature will need to be done. The literature search should be performed considering the document Application of systematic review methodology to food and feed safety assessments to support decision making. Prior to starting the literature screening, the search mechanism and appraisal process should be agreed with EFSA.

Relevant studies would include:

- studies where the test substance is sufficiently characterised to be matched to the lists of substances and chemical groups of concern;
- studies relevant for human or animal health;
- studies where the method description is sufficient to identify the route of exposure, the test organism and the duration of the study;
- toxicity studies reporting one of more of NOAEL, NOEL, BMDL, dose level, LOAEL, LD50 and the nature of the adverse effect;

  or
- genotoxicity studies reporting positive or negative for gene mutation or genome mutation or chromosome aberration or DNA damage/repair

The source of the data must be recorded. The tables ENDPOINT_STUDY and GENOTOX in Annex 9 describes the variables to be extracted.

Objective 3: Hazard characterisation of substance of concern

For substances of concern which are not include in EFSA OpenFoodTox, information on safety assessment outcomes will be looked for; the aim is to retrieve possibly existing health-based guidance values (e.g. TTC, TDI, ADI, ARfD, UL) already derived for these substances. EFSA Partners' websites (e.g. EMA, ECHA, JECFA, NIEHS NTP, Member States Competent Authorities) will need to be looked at to retrieve this type of information. A list of these sources of information will be provided at the kick-off meeting.

The source of the data must be recorded. The tables HAZARD in Annex 9 describes the variables to be extracted

Objectives 1, 2 and 3 will be run in parallel.
A tool will be created by the contractor to allow for EFSA to check the validity of the data collected before they have actually transferred via the EFSA Data Collection Framework. In order to allow for this validation step, data shall be provided 2 months prior the anticipated date of the transfer.

Objective 4: Transfer to EFSA of datasets via the EFSA Data Collection Framework

The final data models for the transfer of data to EFSA will be agreed at the kick-off meeting. The current data models are included in Annex 9.
The data should be then submitted in XML format to the Data Collection Framework (DCF) of EFSA in order to ensure that the dataset is compliant with EFSA IT standards. Technical assistance with regards to IT aspects to optimise the data transfer will be provided by EFSA. During the transfer process, the dataset will be validated for data type, presence of mandatory fields and compliance with controlled terminologies and business rules. EFSA expects to receive a dataset, which passes all validation phases.

EFSA controlled terminologies can be downloaded from the link below European Food Safety Authority. (2018). Harmonized terminology for scientific research [Data set]. Zenodo. http://doi.org/10.5281/zenodo.1163629

The data management can be performed using the software of choice of the contractor. The submitted data will be subjected to automated validation and only transmissions where all tables have the status "Valid" will be accepted.

1.3 TASKS, DELIVERABLES, TIMELINE AND PAYMENTS

No	Tasks	Can be subcontracted?	Deadline for finalisation
1	Agreement of final data models and business rules to be applied.	Yes	1 month from kick off meeting
2	Valid test submission of the FACT_BOTANICAL, ENDPOINT_STUDY, OPINION, COMPOSITION, GENOTOX, HAZARD, COMPONENT data in XML format via the DCF	Yes	2 months from kick off meeting
3	Preparation of data retrieval, appraisal and extraction protocols for composition toxicity and genotoxicity	Yes	2 months from kick off meeting
4	Submission of data - Objective 1: Extraction of composition and toxicity data for 900 plants	Yes	2 years from kick off meeting
5	Submission of data for 2500 chemical substances: - Objective 2: Characterisation of the toxicity and genotoxicity - Objective 3: Hazard characterisation of substance of concern	Yes	4 years after the entry into force of the contract
No	**Meetings**		**Deadline for finalisation**
1	Kick off meeting (physical meeting in Parma - one day) During this meeting, in addition to project operational implementation it can be considered as an opportunity to discuss administrative and financial matters related to contract implementation.		1 month after the entry into force of the contract
2	Mid-term project review (physical meeting, 1.5 day) - Report on progress of project's objectives During this meeting, in addition to project operational implementation it can be considered as an opportunity to discuss administrative and financial matters related to contract implementation.		Month 12, 24 and 36 after entry into force of the contract
3	Final meeting (physical meeting in Parma - one day) with presentation of the final project report.		47 months after the entry into force of the contract
4	Intermediate teleconferences A total of 12 Web-conferences will be planned to address possible difficulties encountered during the project implementation.		1 web-conference every three months after kick-off meeting
No	**Deliverables**		**Deadline for submission to EFSA**
1	Valid submission of data resulting from objective 1 to the DCF		30 months from kick off meeting
2	Valid submission of data resulting from objectives 2 and 3 to the DCF		a) 300 substances at month 9 b) 400 substances at month 16 c) 400 substances at month 23 d) 400 substances at month 30 e) 500 substances at month 37 f) 500 substances at month 45

		Following the kick-off meeting
3	**External scientific report** synthesising, analysing and summarising the extraction activities for the new data.	47 months after the entry into force of the contract

No	Payments	Linked to approval by EFSA of deliverable No
1	Interim payment 1 of 20%	Deliverable 2a
2	Interim payment 2 of 25%	Deliverables 2b and 2c
3	Interim payment 3 of 25%	Deliverables 1 and 2d
4	Payment of the balance (30%)	Deliverables 2e, 2f and 3

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

1.4 INFORMATION ON THE CONTRACT

Type of contract: direct contract

Nature of expense: services

Duration of tasks in direct contracts: 48 months from the kick off meeting.

Budget information:
The maximum budget EFSA has available is 300,000 €. Any offer exceeding this maximum will not be retained for contract award.

Important information for British tenderers:
Please be aware that after the UK's withdrawal from the EU, the rules of access to EU procurement procedures of economic operators established in third countries will apply to tenderers from the UK depending on the outcome of the negotiations. In case such access is not provided by legal provisions in force tenderers from the UK could be rejected from the procurement procedure.

1.5 OWNERSHIP AND INTELLECTUAL PROPERTY RIGHTS

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

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

- To ensure that terms and conditions asserted by any copyright holder of publications or information referred to in the final deliverable for EFSA are fully satisfied;
- To make the necessary arrangements enabling EFSA to reproduce and make non-commercial use of publications and information referred to in the final deliverable it commissioned. As needed, the contractor shall consult with copyright licensing

authorities (i.e. at national level) for guidance on purchasing copyright licenses to reproduce any publications provided to EFSA. The contractor remains solely responsible and liable for obtaining all necessary authorizations and rights to use, reproduce and share the publications provided to EFSA

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

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

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

The draft contract attached in **Annex 3** contains further provisions on ownership of intellectual property rights. All quotations or information the tenderer provides in the technical and financial offer for EFSA which originates from other sources to which third parties may claim rights, have to be clearly marked in the offer in a way allowing easy identification (source publications, including date & place, creator, number, full title etc.). The tenderer shall take account of the above specification on ownership and copyrights in their technical and financial offer.

Use of results

EFSA is committed to the publication of contract deliverables in the Knowledge Junction in order to improve transparency, reproducibility and evidence reuse. The Knowledge Junction[6] 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 with attribution to the contractor.

[6] Learn more at http://www.efsa.europa.eu/en/press/news/161114

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 also refer to the **EFSA Guidance for tenderers**.

2.1 OPENING OF OFFERS

The main aim of the public opening session is to check whether the offer received was dispatched within the closing date for tender receipt[7] 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 on exclusion criteria); Selection criteria (Declaration on Honour on selection criteria).

2.3 GROUNDS FOR EXCLUSION

The offers declared admissible during the opening session will be further verified against the eligibility and the exclusion criteria.

As regards the eligibility of the tenderers to submit an offer following this call please refer to the **EFSA Guidance for tenderers** available at EFSA website. Only offers from tenderers established in eligible countries will be allowed to the next step of the evaluation – exclusion criteria verification.

Tenderers must not be in one of the exclusion situations listed in the **EFSA Guidance for tenderers** available at EFSA website.

Evidence requested in the offer:

- Tenderers must declare that they are not in one of the exclusion situations by providing a signed and dated Declaration on Honour on exclusion criteria, available in **Annex 4**. In case of a joint offer from a group of economic operators, such declaration should be submitted for each member of the group. Evidence may be requested in support of this declaration to the successful tenderer.

For info: EFSA will request further supporting evidence, from the awarded tenderers, prior to the signature of the contract. Such requested evidence will be specified in the award letter and will have to be provided to EFSA before the contract is signed.

[7] **Do not wait until the last day to upload your offer. Responsibility rests with you to ensure that your tender is fully, completely and correctly uploaded before the time limit for receipt. Failure to respect the time limit for receipt will result in the rejection of your offer for non-compliance with the deadline for tenders.**

2.4 SELECTION CRITERIA

The offers from tenderers declared eligible and not in one of the exclusion situations will be further verified against the selection criteria.

A) ECONOMIC AND FINANCIAL CAPACITY:
The tenderer must have the following **economic and financial capacity** to perform the contract, in particular the tenderer must have generated an overall annual turnover of at least 600,000€ in each of the last 2 closed financial years (2016 and 2015).

Evidence requested:
Tenderers must declare that they fulfil the economic and financial criteria indicated above by providing a signed and dated Declaration on Honour on selection criteria, available in **Annex 5**. In case of a joint offer from a group of economic operators, such declaration should be completed by the leading partner.

EFSA will request further supporting evidence (proof of annual turnover), from the awarded tenderer, prior to the signature of the contract. Such requested evidence will be specified in the award letter and will have to be provided to EFSA before the contract is signed. The evidence will be evaluated on a consolidated basis.

B) TECHNICAL AND PROFESSIONAL CAPACITY:
The tenderer must have the following **minimum technical and professional capacity** to perform the contract:

a) The tenderer must have extensive and demonstrable experience in collecting, analysing and summarising large and complex datasets, with a particular focus on chemical / toxicological / botany / (phyto) pharmacological data;
b) The tenderer must have access to a minimum of 3 relevant bibliographical databases for contract execution;
c) The tenderer must have access to a reference management software compatible with Endnote™;
d) Ability to provide a team compliant with these specific expertise requirements:

Team experts with an academic background (Masters university degree or PhD) in the area of chemistry / toxicology / botany / (phyto) pharmacy and with at least 3 years of professional work experience in:

- managing IT platforms, data management, building databases and/or data model structure; and/or
- handling, reviewing or preparing scientific publications and reports; and/or
- providing training in English; and/or
- full Systematic Reviews step-wise process; and/or
- Information and Documentation science and, more specifically, in performing Extensive Literature Search.

A **Project Leader** with an academic background (Masters university degree or PhD) in the area of chemistry or toxicology or botany or (phyto) pharmacy or applied informatics) and with at least 5 years of professional work experience and a proven record in project management. The Project Leader shall be responsible for the overall contract, management and coordination of the implementation of all services requested by EFSA in this call for tender. The Project Leader will be the interface for all commercial and contractual matters and the overall contact point for the services requested by EFSA. The Project Leader shall be a member of staff from the tenderer or the consortia leader. The Project Leader can also be involved

in the implementation of the project as an expert. In this case the Project Leader shall also meet the requirement set for team experts.

The experts (including the Project Leader) shall be able to organise the tasks requested and to write reports in English. For non-English mother tongues, the knowledge of English shall be proven by: (i) experience in international projects where English is the working language; or (ii) at least 1 year of work/study in an English-speaking environment; or (iii) certificate of English proving at least a C1 level (Effective Operational Proficiency).

Evidence requested:

- For requirement a): A list of major relevant projects and/or publications related to the subject of this assignment carried out in the course of the past 10 years;
- For requirement b): A statement confirming that the tenderer will have access to a minimum of 3 relevant bibliographical databases. (The bibliographical databases shall be named in the submitted technical offer);
- For requirement c): A statement confirming that the tenderer has access and knowledge of a reference management software compatible with EndNote™;
- For requirements d): Detailed CVs of all team members proposed for the assignment, taking into account the specific expertise requirements detailed above; EFSA strongly recommends submitting the CVs in the EU CV format (including list of relevant publications/projects) which can be accessed here.
- Generic evidence: **Declaration on Honour on selection criteria** available in Annex 5. To be completed by the tenderer or by the leading partner in case of a joint offer.
- Generic evidence in case of joint offer and/or subcontracting: **Confirmatory statement of resources:** statement confirming that they will have at their disposal the resources necessary for performance of the contract by producing a commitment on the part of those entities (i.e. each partner in a joint offer and/or each subcontractor).
- Generic evidence in case of joint offer and/or subcontracting: **Allocation of tasks between the partners/subcontractors:** a statement clearly defining the allocation of tasks between the entities.

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

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.
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 tender at this stage. The requirement to submit Institutional and Individual DoIs will be specified in the award letter and will have to be provided and assessed by the EFSA Authorising Officer before and as a condition of contract signature.

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

If you have already submitted any of the above-mentioned evidence to EFSA in response to a previous EFSA call, provided the evidence is exactly the same as requested in these tender specifications, you are not required to submit the evidence again. Please specify the reference of the EFSA call for tenders under which you have already submitted the evidence to EFSA if this is the case.

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.

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 are considered not to comply with the tender specifications and are therefore to be rejected if they:

- do not comply with minimum requirements laid down in the tender specifications (non-compliance);
- propose a solution different from the one that is imposed;
- propose a price above the fixed maximum set in the specifications;
- are submitted as variants, when the specifications do not authorise them;
- do not comply with applicable obligations under environmental, social and labour law established by Union law, national law and collective agreements or by the international environmental, social and labour law provisions listed in Annex X to Directive 2014/24/EU[8].

In all these cases, the grounds for rejection is not linked to the award criteria so there is no evaluation as such. The tenderer will be informed of the ground 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 defined award criteria. The award criteria serve to identify the **most economically advantageous offer**.

A) QUALITY AWARD CRITERIA

1. **METHODOLOGY PROPOSED FOR IMPLEMENTATION (70 points - minimum threshold 60%)**

   - **For Objective 1:** Tenderers should provide a logical and structured step-by-step explanation of; how the tenderer intends to extract the relevant information in relation to the 900 plants; the system proposed to retrieve full text, extract data and store information for subsequent validation by EFSA experts; the systems

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

proposed for the transfer of data to EFSA and how they intend to ensure the overall quality of the final deliverables. **(30 points)**

- **For Objective 2:** Tenderers should provide a logical and structured step-by-step explanation of; the strategy for the literature review for the 2500 chemical substances; prioritizing the literature collected, the system proposed to retrieve full text, extract relevant data, and store information for subsequent validation by EFSA, as well as the systems proposed for the transfer of data to EFSA and how they intend to ensure the overall quality of the final deliverables. **(40 points)**

2. **PROJECT ORGANISATION (30 points)**
   - Clear and detailed information on distribution of the tasks among the project team; in case of joint offer & subcontractors, clarity on who does what, when and why (justify why the partner/subcontractor is proposed to do the particular task/work-package); **10 points**
   - The internal team communication and communication with EFSA; in case of joint offers & subcontractors also the communication between joint offers partners and subcontractors should also be described; **10 points**
   - Measures to ensure availability of proposed team members and mitigation strategies to cover absences and ensure deadlines are met; **10 points**

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

Tenderers shall elaborate in the technical offer on all points addressed in the technical specifications, bearing also in mind the above indicated award criteria, in order to score as many points against the quality award criteria as possible. The mere repetition of mandatory requirements set out in the technical specifications, without going into detail or without giving any added value in the technical offer, will only result in a very low score.

Offers must score at least at least 60 % of maximum possible total points against the quality award criteria number 1 and overall must score at least 70 % of the maximum possible total points for all award criteria.

Tenders that do not reach this minimum quality threshold will be eliminated from the subsequent stages of the evaluation process.

B) PRICE AWARD CRITERION:

Tenders which passed the above quality thresholds will be retained for the further assessment of the following:

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:

I. The tenders for which the financial offers were made within the maximum budget for financial offers 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 formula:

TOTAL SCORE OF THE EVALUATED OFFER (C) =

30 * Cheapest price offer/price of tender X

+

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

PART 3 HOW TO SUBMIT YOUR OFFER – e-SUBMISSION APPLICATION GUIDE

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. A tender received after the deadline indicated in the procurement documents will be rejected.

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[9]. 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.

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.** All members of a joint tender, including subcontractors – if applicable – must upload the signed and dated declaration on honour on exclusion criteria using the template available in Annex 4.
- **Signed declaration on Honour on Selection criteria.** 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 in **Annex 5**.
- **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

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

- **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:

- **Declaration on honour(s).** All members of a joint tender, including subcontractors must sign and date the declaration on Exclusion criteria. Only the leader in a joint tender must sign and date the declaration on Selection criteria. The declaration on honour(s) must be converted to PDF format and then signed by the authorised representatives with advanced electronic signature based on qualified certificates or by hand.
- **Tender Report.** This report is generated by e-Submission while you are completing your tender and it contains the list of documents that you submit. The sole tenderer's or leader's authorised representative(s) must sign the report.

You **must send** the signed Tender Report to the email address indicated in the paragraph below (Contact), stating the reference to the call for tenders and the Tender ID.

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

- The original hand signed tender report must be scanned and sent by email immediately after submission, to the following address: EFSAProcurement@efsa.europa.eu.

- 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.

- For technical support on e-Submission, please contact support as described in the help page:

  https://webgate.ec.europa.eu/supplier_portal_toolbox/esubmissionFileProject/files/BT3/spotsHelpPage_en.html

ANNEX 1 - FINANCIAL OFFER TEMPLATE

FINANCIAL OFFER

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:

- As referred to in part 1.4, the maximum budget EFSA has available for this assignment is 300,000 **€**. 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.**	..... €

Tenderer name: .....

Date: .....

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

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

His/her signature: .....

ANNEX 2 - E-SUBMISSION QUICK REFERENCE GUIDE FOR ECONOMIC OPERATORS

The guide can be viewed here.

ANNEX 3 - DRAFT CONTRACT

Tenderers should note that in the event that their offer is successful, the resulting contract will be based on the model annexed to these tender specifications.

ANNEX 4 - DECLARATION ON HONOUR ON EXCLUSION CRITERIA

ANNEX 5 - DECLARATION ON HONOUR ON SELECTION CRITERIA

ANNEX 6 – ADMINISTRATIVE DATA FORM

ANNEX 7 - INSTITUTIONAL DECLARATION OF INTERESTS

ANNEX 8 – INDIVIDUAL DECLARATION OF INTERESTS

ANNEX 9 – DATA MODEL

The templates are uploaded in e-Tendering with all other procurement documents.

ANNEX 9 - DATA MODEL

Table 1. characterises the relationship between ENDPOINT_STUDY, COMPOSITION, OPINION, GENOTOX, HAZARD AND COMPONENT

FACT_BOTANICAL

Name	Type	Length	Mandatory	Description	Controlled terminology	Enumeration
id_fact	Character	40	Y	Primary key for FACT_BOTANICAL		
id_botanic	Numeric	20	Y	Identifier to group all composition and endpoint records for a botanical		
botanic	Character	255		Name of botanical group with the same id_botanic		
status	Character	20	Y	Enumeration for the status of the various plant species		no info to compendium no alert for tox or adverse effects pending
registration_date	Numeric	8	Y	Complete date of the latest modification for the various plant species in the format yyyymmdd		
identify_source	Character	255		Identifier to be able to trace back where each plant species comes from (e.g. AESGP list, health claims list, exotic country name..)		AESGP Argentina negative list AT (-) tea AT (+) tea BE (-) food BE (list 3) Notif Brasil pharmacopeia Bulgaria (-) Chinese list

					Cyprus (+) CZ (+) tea CZ (5 % restrict) tea CZ (30 % restrict) tea Equator normas pharmacopoeia Greece Indian high traded medical species Italy (-) food suppl La Reunion - potential toxicity La Reunion - preliminary traditional health claims Martin/Guad trad pharmacop Mexico - prohibited or allowed for tea, infusions or vegetal oils NDA Claims UK MHRA list
id_tox	Numeric	20		Unique ID linking to the ENDPOINT_STUDY record	
labSampCode	Character	20		Unique ID linking to the COMPOSITION record	
id_op	Numeric	20		Unique ID linking to the OPINION record	
id_genotox	Numeric	20		Unique ID linking to the GENOTOX record	
id_hazard	Numeric	8	Y	Unique ID linking HAZARD record	
sub_com_id	Numeric	8	Y	Unique ID linking COMPONENT record	
remarks	Character	255		Free text to describe additional plant information on the compendium. e.g. adulteration, contamination	

Table 2. characterises the critical end point study identified

ENDPOINT_STUDY

Name	Type	Length	Mandatory	Description	Controlled terminology	Enumeration
id_tox	Numeric	20	Y	Primary key for ENDPOINT_STUDY. Id for the toxicology study being reported		
study_cat	Character	255	Y	Enumeration of the compartment for which the data is provided		Animal (non-target species) health Animal (target species) health Ecotox (soil compartment) Ecotox (water compartment) Human health
paramCode	Character	255		Code for substance tested from catalogue PARAM	PARAM	
id_plantMat	Character	255		Code for plant tested from catalogue MTX	MTX	
id_plantPart	Character	255		Code for plant part/mix material tested from catalogue MTX	MTX	
id_prepType	Character	255		Code for preparation type from catalogue MTX	MTX	
testsubstance	Character	2000		Description of the test material used in the toxicological study		
id_test_type	Character	255	Y	Code for type of toxicological test from catalogue TEST_TYPE	TEST_TYPE	
limit_test	Character	255		Enumeration of an indicator that the toxicological study was a limit test.		Yes No No data Not applicable
guideline_qualifier	Character	255		Enumeration signifying how strict the guideline given in the subsequent field 'Guideline' was followed or whether no guideline was used or available/required		According to Equivalent or similar to No guideline followed No guideline available No guideline required
id_guideline	Character	255		Code for guideline used in the study design from catalogue GUIDELINE	GUIDELINE	
deviation	Character	255		Enumeration to describe if a critical study contains deviations from the standard test protocol		Yes No

						No data Not applicable
glp_compl	Character	255		Enumeration describes whether a GLP certificate or compliance statement is available		
id_species	Character	255	Y	Code for test organism used in the study design from catalogue MTX	MTX	
id_strain	Character	255		Code for strain of test organism used in the study design from catalogue STRAIN	STRAIN	
sex	Character	20		Sex of the tested organisms		Female Male Male/Female No data
id_route	Character	255		Code for the route of exposure used in the study design from catalogue ROUTE_EXP	ROUTE_EXP	
exp_duration	Numeric	20,10		Exposure duration		
id_duration_unit	Character	255		Code for units of exposure duration from catalogue UNIT	UNIT	
number_individuals	Numeric			The number of organisms dosed at each dose level of the critical study.		
control	Character	255		Enumeration describes whether and what type of concurrent control groups were used		Yes yes, concurrent no treatment yes, concurrent vehicle yes, plain diet yes, sham-exposed yes, historical no no data
id_endpoint	Character	255	Y	Code for endpoint measured in the study from catalogue ENDPOINT_HGV	ENDPOINT_HGV	
id_qualifier	Character		Y	Code for qualifier used to express effect concentration from catalogue QUALIFIER	QUALIFIER	
value	Numeric	20,10	Y	Effect concentration: numeric field for entering a numeric value		
id_dose_unit	Character	255	Y	Code for units of effect concentration from catalogue UNIT	UNIT	
id_toxicity	Character	255	Y	Code for critical effect at system level from	TOXICITY	

				catalogue TOXICITY	
id_target_tissue	Character	20		Code for target tissue based on OECD Harmonised Template for Gross Necropsy: Repeat dose toxicity: oral (Table 7 from OECD 67) from catalogue TARGET_TISSUE	TARGET_TISSUE
effect_desc	Character	255		Free text to describe effects observed in the critical study	
id_basis	Character	255	Y	Code for effect or parameter linked to the endpoint value from catalogue BASIC_EFFECT	BASIC_EFFECT
remarks	Character	2000		Remarks provide additional information on the study either design or results	

Table 3. characterises where the data was extracted from

OPINION

Name	Type	Length	Mandatory	Description	Controlled terminology	Enumeration
id_op	Numeric		Y	Primary Key for OPINION		
op_type	Character	255	Y	Code to describe the type of reference. Catalogue REF_TYPE	REF_TYPE	
owner	Character	255		Identity of the sponsor company who owns the study report or EFSA panel for EFSA opinions or toxicology committee issuing the report		
author	Character	255		List of authors or EFSA panel for EFSA opinions. $ separator to be used for multiple values		
title	Character	1000	Y	Title of a study report or title of published article of journal or book (e.g. handbook)		
adoption_date	Numeric	8		Complete date of the adoption of the document in the format yyyymmdd		
publication_date	Numeric	8	Y	Complete date of the publication of the document in the format yyyymmdd		
journal_title	Character	255		Title of the journal, or the entity that produce the citation or publisher (e.g. editor)		
id_language	Character	8		Code for language of the intellectual content of the	LANG	

			resource from catalogue LANG
doi	Character	255	Digital Object Identifier is a permanent character string (a "digital identifier") used to uniquely identify an object such as an electronic document, source the study report or publication, URL or EFSA Journal
internation_unique_number	Character	255	International Standard Book Number (ISBN) or International Standard Serial Number (ISSN) is a unique numeric commercial book identifier or periodical publications such as magazines
URL	Character	1000	uniform resource locator, specific character string that constitutes a reference to a resource in internet
citation	Character	1000	Bibliographic citation is a reference to a book, article, web page, or other published item. Citations should supply detail to identify the item uniquely

Table 4. characterises the chemical composition of the botanical extract/material (Other classifications of substances and components may be required in terms of synonyms and trade names, OECD toolbox classification and MESH terminology.)

COMPOSITION

Name	Type	Length	Mandatory	Description	Controlled terminology	Enumeration
labSampCode	Character	20	Y	Alphanumeric code of the analysed sample.		
lang	Character	2	Y	Language used to fill in the free text fields (ISO-639-1).	LANG	
prodCode	Character	400	Y	Product under analysis	MTX	
prodPart	Character	400		Part plant under analysis from MTX catalogue	MTX	
prodTreat	Character	400		Used to characterise a food product	MTX	

				based on the treatment or processes applied to the product or any indexed ingredient.	
prodCom	Character	250		Additional information on the product, particularly home preparation details if available.	
prodText	Character	250		Free text to describe in detail the product sampled. This element becomes mandatory if “product code” is ’XXXXXXA’ (Not in list).	
resultCode	Character	40	Y	Unique identification number of an analytical result (a row of the data table) in the transmitted file. The result code must be maintained at organisation level and it will be used in further updated/deletion operation from the senders.	
paramCode	Character	20	Y	Parameter/analyte of the analysis described according to the Substance Code of the PARAM catalogue	PARAM
paramText	Character	250		Parameter subject of the analysis described according to the PARAM catalogue	
anMethRefCode	Character	500		Identifier for the method used. When validated methods are used, the official reference code should be provided.	
anMethCode	Character	5		Code describing the instrument used in the method.	ANLYMD

anMethText	Character	250		Free text describing the analytical instrument used, particularly if “other” was reported for “Analytical method code”.	
resUnit	Character	5	Yes/ No accepted only if qualitative results are provided without any other numeric fields (e.g. LOD, LOQ, etc…)	Unit of measurement for the values reported in “Result LOD”, “result LOQ, “CC Alpha”, “CC Beta”, “Result value”, “Result value uncertainty standard deviation, “Result value uncertainty” and “Result legal limit”.	UNIT
resLOD	Numeric	20,10		Limit of detection reported in the unit specified by the variable “Result unit”.	

resLOQ	Numeric	20,10	Limit of quantification reported in the unit specified by the variable “Result unit”	
resMetric	Character	5	Qualifier for result (> for min values < for max values)	QUALIFIER
resVal	Numeric	20,10	The result of the analytical measure reported in the unit specified by the variable “Result unit”,	
moistPerc	Numeric	20,10	Percentage of moisture in the original sample	
fatPerc	Numeric	20,10	Percentage of fat in the original sample	
exprRes	Character	5	Code to describe the how the result has been expressed: Whole weight, fat weight, dry weight, etc…	EXPRRES
resQualValue	Character	3	This field should be completed only if the result value is qualitative e.g. Positive / Negative. In this case the element “Result value” should be left blank	POSNEG
resType	Character	3	Indicate the type of result, whether it could be quantified/determined or not.	VALTYP
resComm	Character	2000	Additional comments for this analytical result	

Table 5. characterises the genotoxicity study

GENOTOX

Name	Type	Length	Mandatory	Description	Controlled terminology	Enumeration
id_genotox	Numeric	20	Y	Primary key and foreign key: This ID is the genotox ID of the gentoxicity study being reported		
study_cat	Character	255	Y	Enumeration of type of genotoxicity data		Genotoxicity Mutagenicity
id_test_type	Character	20		Code for type of toxiciological test from catalogue TEST_TYPE	TEST_TYPE	
method_type	Character	255		Classification of method type either in vivo or in vitro		in vitro in vivo
guideline_qualifier	Character	255		An indicator signifying how strict the guideline given in the subsequent field 'Guideline' was followed or whether no guideline was used or available/required.		According to Equivalent or similar to No guideline followed No guideline available No guideline required
id_genotox_guideline	Character	400		Code for guideline followed from catalogue GUIDELINE	GUIDELINE	
deviation	Character	255		Indication that a genotoxicity study contains deviations from the standard test protocol.		Yes No No data Not applicable
glp_compl	Character	255		Indication whether a GLP certificate or compliance statement is available		Yes No No data Not applicable
id_genotox_spec	Charact	400	Y	Code for species used as the test	MTX	

ies	er		organism from catalogue MTX		
id_strain	Character	400	Code for strain used as from catalogue STRAIN published	STRAIN	
sex	Character	255	Sex of the tested animals in vivo genotoxicity study		Female Male Male/Female No data
met_indicator	Character	255	Enumeration specifying whether exogenous metabolic activation was applied or not. (In vitro studies only)		with with and without without not applicable no data
id_route	Character	400	Code for route of exposure from catalogue ROUTE_EXP (when the chemical was administered to the test animals in vivo genotoxicity studies)	ROUTE_EXP	
exp_period	Numeric	20,10	Exposure duration for in vivo genotoxicity studies		
id_exp_period_unit	Character	5	Code for unit of exposure duration from catalogue UNIT	UNIT	
number_individuals	Numeric	20	The number of organisms dosed at each dose level of the in vivo genotoxicty study		
control	Character	255	Indication whether and what type of concurrent control groups were used in in vivo genotoxicity study		yes yes, concurrent no treatment yes, concurrent vehicle yes, plain diet yes, sham-exposed yes, historical no no data

genotox_endpoint	Character	255		Enumeration type of genotoxicity endpoint	gene mutation chromosome aberration DNA damage and/or repair genome mutation
is_genotoxic	Character	255	Y	whether the substance is genotoxic or not according to the study reported in this table	Positive Negative Ambiguous Not determined Not applicable No data Other
remarks	Character	2000		Remarks on genotoxicity study	
acceptability	Character	255		Acceptability of the study according to the RMS' opinion	

Table 6. summaries risk assessment of the substance

HAZARD

Name	Type	Length	Mandatory	Description	Controlled terminology	Enumeration
id_hazard	Numeric	8	Y	Unique ID		
assessment_type	Character	255	Y	Type of HBGV value		
risk_qualifier	Character	255		Qualifier of the HBGV value		
risk_value	Numeric	8		HBGV assessment value		
risk_unit	Character	1024		Unit of HBGV value		
safety_factor	Numeric	8		Safety factor		
population	Character	255		Population applicable for HBGV		
subgroup	Character	255		Subgroup of Population applicable for HBGV		
agegroup	Character	255		Human subgroup to which HBGV is applicable		
assessment	Character	255		Assessment summarised where no health based guideline value is set		
remarks	Character	1024		Remarks		
group_unit	Character	255		Group assessment		
group_com_id	Numeric	8		Components group assessment applies to		

Table 7. characterises the substance and components assessed (Other classifications of substances and components may be required in terms of synonyms and trade names, OECD toolbox classification and MESH terminology.)

COMPONENT

Name	Type	Length	Mandatory	Description
SUB_COM_ID	Numeric	8	Y	Unique ID
SUB_NAME	Character	255	Y	
SUB_TYPE	Character	255		Substance name as defined in the opinions
SUB_ECSUBINVENTENTRYREF	Character	255		The EC reference number as defined by ECHA for substance
SUB_CASNUMBER	Character	255		Chemical Abstracts Service number of substance
SUB_DESCRIPTION	Character	2000		Summary of the substance description as derived from opinions.
SUB_PARAM	Character	50	Y	EFSA PARAM code
COM_QUALIFIER	Character	255	Y	Relationship between substance and components
COMP_VALUE	Numeric	8		Numeric value (in percentage) of the composition
COM_NAME	Character	255	Y	Component name as derived in the opinions
COM_ECSUBINVENTENTRYREF	Character	255		The EC reference number as defined by ECHA for component
COM_CASNUMBER	Character	255		Chemical Abstracts Service number of component
COM_PARAM	Character	50	Y	EFSA PARAM code
COM_IUPACNAME	Character	1000		International Union of Pure and Applied Chemistry name
COM_MOLECULARFORMULA	Character	255		Molecular formula using format specified in the EC reference list
COM_SMILESNOTATION	Character	1000		Simplified molecular input line entry specification
COM_INCHI	Character	2000		International Chemical Identifier
COM_TYPE	Character	255		OEDC substance descriptor
SMILESNOTATIONSOURCE	Character	255		Source of the SMILES notation
COM_STRUCTURESHOWN	Character	255		Type of structure reported