

TENDER SPECIFICATIONS

Reference: OC/EFSA/PRAS/2016/01

Subject: Evaluation of the applicability of existing (Q)SAR models for predicting the genotoxicity of pesticides and similarity analysis related with genotoxicity of pesticides for facilitating of grouping and read across

Procurement procedure: Open call

Project/Process code: PRAS-07

Activity Code: 2

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 at 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.

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**](mailto: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	20/06/2016	Date of publication being sent to OJ
Deadline for sending a request for clarification to EFSA	18/08/2016	Attention: <i>Requests for clarification may only be submitted through the eTendering website as described in the Invitation Letter.</i>
"Receipt Time Limit" - Closing date and time for offers reception	26/08/2016 at 14:30 (CET)	See details in the Invitation letter. Please also refer to the e-Submission application description attached in annex 2 hereto.
Opening session	29/08/2016	14:30hr, EFSA premises, Parma
Notification of the evaluation results	September 2016	Estimated. <i>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.</i>
Contract signature	October 2016	Estimated

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

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

1.1 BACKGROUND

The use of pesticides on food and feed crops may lead to residues in edible parts of plants or animal products and hence results in exposure of the consumer to a mixture of compounds including the active substance and/or its metabolites, breakdown or reaction products. The terminal residues of pesticide active substances in food and feed commodities should be taken into account for risk assessment and need to be duly identified following the requirements of Commission Regulation (EU) No 283/2013. A practical guidance on the establishment of the residue definition for dietary risk assessment has been developed recently by PPR Panel². This guidance harmonises the process for the establishment of the residue definition for dietary risk assessment by inclusion/exclusion of residues on the basis of their toxicity and potential for dietary exposure. While a comprehensive toxicological dossier is developed for active substances (Commission Regulation (EU) No 283/2013), often none or only limited information about toxicological properties of their metabolites is available. Because of this and following the recommendations of the PPR Panel Scientific opinion, use of (Q)SAR models and read across is proposed for the assessment of genotoxic potential of all metabolites as a first step in the residue definition procedure³.

To facilitate the practical implementation of the guidance on the residue definition for dietary risk assessment, an evaluation of applicability of existing (Q)SAR models for prediction of genotoxicity of pesticides and their metabolites, is needed. It would lead to the compilation of a list of recommended (Q)SAR models with the best performance and with the most reliable predictions of genotoxicity of pesticides active substances and their metabolites. This will be beneficial for the work of the risk assessors when applying the guidance for residue definition as well as in other areas of risk assessment of pesticides.

Read across is widely recognised as an alternative approach for toxicological data gaps filling. In the last years intensive efforts were done for development of different methodology for read across and to overcome the obstacles which are preventing the widespread use of the approach for regulatory purpose. Although some guidance documents have been published, a specific guidance for the application of read across for genotoxicity prediction is missing^{4,5,6}. The molecular initiating events leading to genotoxicity i.e. covalent binding of substances to DNA and/or proteins are well studied and described. Many lists exist with structural alerts (SA) recognised as responsible for interaction of the chemicals with the biological macromolecules. Usually these lists are used for grouping of substances and read across, however it is also known that the remaining part of the molecule could affect the reactivity of these moieties and therefore should be taken into account when the similarity is evaluated as crucial part of the read across approach. Practical guidance on the assessment of the similarity, including (non) common SA, (non)common functional group, "core" structure and their relevance for the

² EFSA PPR Panel, 2015. Guidance on the establishment of the residue definition for dietary risk assessment. EFSA Journal 2016;14(issue):NNNN, 26 pp. doi:10.2903/j.efsa.2016.NNNN

³ EFSA Panel on Plant Protection Products and their Residues (PPR); Scientific Opinion on Evaluation of the Toxicological Relevance of Pesticide Metabolites for Dietary Risk Assessment. EFSA Journal 2012;10(07): 2799. [187 pp.] doi:10.2903/j.efsa.2012.2799

⁴ ECHA (European Chemicals Agency), 2008. Guidance on Information Requirements and Chemical Safety Assessment. Chapter R6. ECHA, Helsinki, Finland. 134pp

⁵ ECHA (European Chemicals Agency), 2015. Read across Assessment Framework, ECHA, Helsinki, Finland

⁶ OECD (Organisation for Economic Co-operation and Development), 2007. Guidance on Grouping of Chemicals. Series on Testing and Assessment Number 80.ENV/JM/MONO(2007)28. OECD Publishing, Paris

purpose of read across for prediction of genotoxicity is needed and would facilitate the systematic, objective and automatic evaluation of the similarity and consequently the justification and acceptability of the read across approach.

The present Call is based on EFSA's 2016 Work Programme for grants and operational procurements as presented in Annex II of the EFSA Programming Document 2016 – 2018, available on the EFSA's website⁷.

1.2 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 Pesticides Unit requires the performance of a critical review of existing (Q)SAR models for prediction of genotoxicity (i.e. gene mutations and chromosome aberrations) and evaluation of their predictability for pesticide active substances and their metabolites. The evaluation should also include the assessment of the reliability and uncertainties of the prediction. The models (or combination of models) with the best performance and higher reliability of the prediction should be identified. This would facilitate the application of the guidance for residue definition for dietary risk assessment as well as could be used in other areas of pesticides risk assessment.

In addition, a critical review of the existing methodologies of read across for prediction of genotoxicity is required. Their performance and reliability for prediction of genotoxicity of pesticides active substances and their metabolites should be assessed using selected case studies. In addition, the combination of the resulting best methodologies for read across and (Q)SAR model(s) for the improvement of the overall predictability of genotoxicity should be investigated.

Finally, the impact of structural changes resulting from metabolic or degradation processes on the genotoxic potential of the substances should be performed. Changes leading to activation/deactivation or no impact should be identified and presented in a structural way e.g. as a list of functional groups with explanation of their impact. Such list would facilitate the systematic, objective and automatic evaluation of similarity and consequently the justification and acceptability of the read across in the context of pesticides risk assessment.

Specific objectives:

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

- **objective 1**

To perform a comprehensive and critical review of the state of the art of (Q)SAR models for prediction of *in vitro* and *in vivo* genotoxicity (i.e. gene mutation and structural/clastogenicity and numerical/aneugenicity chromosomal aberrations). The review should cover free available and commercial models as well as literature models for the minimum period starting from 1 January 2009 to 31 December 2016.

The Contractor should intend this review as complementary to the external scientific report done by JRC in 2010⁸ and prepare an interim report listing the existing methods for prediction of genotoxicity and provide detailed information for each of them e.g. their availability, information on predicted endpoints (e.g. Ames and mammalian cell gene

⁷ <http://www.efsa.europa.eu/sites/default/files/mb151203-a2.pdf>

⁸ Worth AP, Fuart-Gatnik M, Lapenna S, Lo Piparo E, Mostrag-Szlichtyng A and Serafimova R, 2010.

Applicability of QSAR analysis to the evaluation of the toxicological relevance of metabolites and degradates of pesticide active substances for dietary risk assessment. Final report of a project carried out by the JRC for the European Food Safety Authority (EFSA). Available from: <http://www.efsa.europa.eu/en/scdocs/scdoc/50e.htm>

mutation, clastogenicity, aneugenicity; in vitro, in vivo) and training set, way of evaluation of the reliability and uncertainties of the prediction, additional information.

The literature search should include publicly available peer reviewed research publications and publicly available "grey literature" (such as government reports and official institutional documents).

A detailed documentation of the search carried out should be provided using an approach similar to the methodology applicable to systematic reviews (see the EFSA 'Guidance on Application of systematic review methodology to food and feed assessments to support decision making⁹), if appropriate. In particular, information regarding the identity of the databases/information sources (e.g. website), criteria for inclusion and exclusion of literature/model, need to be provided. In addition, the retrieved publications should be documented as EndNote database (including the publications).

- **objective 2**

To critically evaluate the performance (e.g. sensitivity, specificity, concordance, positive predictability) of existing (Q)SAR models (identified by carrying out objective 1) for prediction of genotoxicity (gene mutation, aneugenicity and clastogenicity) of pesticide active substances and their metabolites. The evaluation should include as many as possible commercial models; though a minimum of four is required (e.g. MULTICASE, DEREK, TIMES, ACD/Lab Predictors, Topkat) and all freely available models covering aneugenicity, clastogenicity and gene mutation as endpoints. A different combination of models should be also investigated as a possibility for improvement of the prediction performance. Special attention should be given to the evaluation of the reliability and of the uncertainties of the prediction. A list of recommended models (or combination of models) with the best performance and the most reliable predictions for genotoxicity of the pesticide active substances and their metabolites should be reported. The coverage between the pesticide chemical domain and the chemical domain of the training sets used for development of (Q)SAR models should be analysed (if possible). For the purpose of these analyses EFSA will provide to the Contractor a database with experimental data on genotoxic for pesticide active substances and their metabolites. Approximately a complete genotoxicity test battery is available for 400 pesticide active substances. The results of the different (Q)SAR models should be provided in tabulated format (e.g. excel table). The reports as generated by the (Q)SAR models should be also provided.

- **objective 3**

To perform a comprehensive and critical review of the state of the art of the available methodologies and tools for performing read across for the prediction of genotoxicity (i.e. gene mutation and structural and numerical chromosomal aberrations; in vitro and in vivo). The review should cover publicly available as well as "grey" literature (such as government reports and institutional documents) for the minimum period of 10 years starting from 1 January 2006 to 31 December 2016.

A detailed documentation of the search carried out should be provided using an approach similar to the methodology applicable to systematic reviews (see the EFSA 'Guidance on Application of systematic review methodology to food and feed assessments to support decision making⁹), if appropriate. In particular, information regarding the identity of the databases/information sources (e.g. website), criteria for inclusion and exclusion of literature/model, need to be provided. In addition, the

⁹ European Food Safety Authority, 2010. Application of systematic review methodology to food and feed safety assessments to support decision making. EFSA Journal 2010; 8(6):1637. [90 pp.].
doi:10.2903/j.efsa.2010.1637.

retrieved publications should be documented as EndNote database (including the publications)

- **objective 4**

To critically evaluate the applicability and reliability of different methodologies (identified by carrying out objective 3) for grouping and read across for prediction of genotoxicity of pesticide active substances and their metabolites. The analysis should be done on a minimum of 20 selected case studies from the pesticide genotoxicity database provided by EFSA; though a higher number would represent a plus. If necessary, toxicokinetic data on pesticide active substance are summarised in the draft assessment reports publicly available on the EFSA's website.¹⁰ The case studies should cover a variety of cases e.g. prediction of *in vitro* and *in vivo* genotoxic and non-genotoxic substances, uses of an active substance as source and its metabolites as target substances. Criteria for selection of the case studies should be duly described. In addition, for the best performing methodologies, the possibility to be used in combination with (Q)SAR models should be investigated in order to get the best overall prediction of genotoxicity.

- **objective 5**

To evaluate the impact of structural changes resulting from metabolic or degradation processes on the genotoxic potential of the substances. The aim of this analysis is to prepare a list of structural moieties, different from the recognised structural alerts for genotoxicity, with a description of their impact (activation or deactivation) on the structural alerts. A theoretical explanation of the observed effects based on the mechanistic/chemical knowledge should be provided where possible. For the purpose of these analyses EFSA will provide the Contractor with a database with the experimental data on genotoxicity for pesticide active substances and their metabolites. If necessary, toxicokinetic data on pesticide active substance are summarised in the draft assessment reports publicly available on the EFSA's website.¹⁰

- **objective 6**

To provide a final report including the results of the critical review of the literature and the evaluation of the applicability of the existing (Q)SAR models and methodologies for grouping and read across carried out by fulfilling the tasks described in objectives 1 to 5. The report should be compliant to the EFSA standard requirements (the EFSA External Scientific Report template that will be provided to the Contractor as soon as Objectives 1 to 5 will be fulfilled). In particular, the minimum content of the report should consist of: a) summary, b) introduction (including a background and Terms of Reference), c) data and methodologies, d) assessment/results, e) conclusions and recommendations. Electronic submission of the report should be performed (no need of hard copy). Electronic copies of relevant publications should be provided (EndNote database). As appendix, the results of the different (Q)SARs models should be provided in tabulated format (e.g. excel table). The reports as generated by the (Q)SARs models should be also provided.

¹⁰ <http://dar.efsa.europa.eu/dar-web/provision>

1.3 TASKS, DELIVERABLES, TIMELINE AND PAYMENTS

No	Deliverables & Tasks	Can be subcontracted?	Deadline for finalisation
1	Provide an Interim Report N.1 , including an EndNote database and an excel table with the different (Q)SAR models, containing the results obtained performing <u>Objectives 1 and 2</u> . EFSA will provide the Contractor with pesticide database containing experimental genotoxicity data	Yes	5 months after the kick off meeting
2	Provide an Interim Report N.2 , including an EndNote database containing the results obtained performing <u>Objectives 3 and 4</u> . EFSA will provide the Contractor with a database with the experimental data on genotoxicity for pesticide active substances and their metabolites	Yes	11 months after the kick off meeting
3	Provide an Interim Report N.3 containing the results obtained performing <u>Objective 5</u> . EFSA will provide the Contractor with a database with the experimental data on genotoxicity for pesticide active substances and their metabolites	Yes	16 months after the kick off meeting
4	Provide a Final Report, including an EndNote database and excel tables with the different (Q)SAR models, as indicated in objective 6 and containing all results and evaluations obtained from Objectives 1, 2, 3, 4, 5	Yes	18 months after the kick off meeting
No	Meetings	Deadline for finalisation	
1	Kick off meeting (physical meeting in Parma - one day), To clarify the objectives and the tasks to be carried out	2 weeks after the entry into force of the contract	
2	Tele/web conference with EFSA to discuss the interim report (task 1) and further tele/web conferences as required to discuss the project implementation.	As required at the request of EFSA or the contractor	
3	Tele/web conference with EFSA to discuss the interim report (task 2) and further tele/web conferences as required to discuss the project implementation.	As required at the request of EFSA or the contractor	
4	Tele/web conference with EFSA to discuss the interim report (task 3) and further tele/web conferences as required to discuss the project implementation.	As required at the request of EFSA or the contractor	
5	Final meeting (physical meeting in Parma-one day) to discuss the draft final report (task 4)	19 months after the kick off meeting	
No	Payments	Linked to approval by EFSA of deliverable No	
1	Interim payment 1 of 40 %	2	
2	Payment of the balance of 60%	4	

The working language for the contract implementation: execution of tasks, meetings and deliverables shall be English. The deliverables shall be delivered to EFSA in electronic format.

1.4 INFORMATION ON THE CONTRACT

Type of contract: direct contract

Nature of expense: services

Duration of tasks in direct contracts: 19 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.

1.5 OWNERSHIP AND INTELLECTUAL PROPERTY RIGHTS

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

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

PARTS OF RESULTS PRE-EXISTING THE CONTRACT

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

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

The draft contract 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.

1.6 ADDITIONAL INFORMATION

Further procedures for the repetition of similar services

By virtue of article 134(1)(e) and article 134(4) of the Rules of Application of the Financial Regulation, EFSA reserves the option to launch further negotiated procedure, with the contractor chosen as a result of the present call for tender, for new services consisting in the repetition of similar services during the three years following the signature of the original contract.

PART 2 EVALUATION - HOW WILL YOUR OFFER BE ASSESSED?

In case you are invited to 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 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: Eligibility of tenderers (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 invited to submit an offer, or in case of subcontracting, such declaration should be submitted for each member of the group and for each identified subcontractor. Evidence may be requested in support of this declaration to the successful tenderer.

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:

- The tenderer must be in a stable financial position;
- The tenderer must have generated an overall annual turnover of at least 350 000 € in each of the 2 closed financial years.

Evidence requested in the offer:

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 framework contract. Such requested evidence will be specified in the award letter and will have to be provided to EFSA before the framework contract is signed.

B) TECHNICAL AND PROFESSIONAL CAPACITY:

The tenderer must have the technical and professional capacity to perform the contract in accordance with the specifications below. In accordance with article 148(6) RAP, 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 must have the following **minimum professional capacity** to perform the contract:

- a) The tenderer must have extensive and demonstrable experience in the area of using of computational methods for chemical risk assessment and in the provision of services described in the technical specifications, and
- b) Ability to provide a team of at least 2 experts in addition to the project leader compliant with these specific expertise requirements (One person can cover more than one type of expertise):
 - with a university degree in the area of toxicology or chemistry or other relevant areas (medicine, pharmacology, biochemistry) and
 - with at least 5 years of experience in the area of the development, application and assessment of (Q)SAR models for prediction of genotoxicity, and
 - with at least 5 years of experience in the area of the development, application and assessment of read across methodologies for prediction of genotoxicity, and
 - with at least 3 years of experience in the area of in vitro genotoxicity testing, and
 - with at least 3 years of experience in information gathering, data collection and management, literature search, and
 - with at least 3 years of experience in preparation of scientific publications or technical reports.
- c) Ability to provide a project leader compliant with these specific expertise requirements:
 - A university degree in toxicology or chemistry or other relevant areas (medicine, pharmacology, biochemistry), and
 - 10 years professional experience in the field of development of computational methods ((Q)SAR models and read across) for chemical risk assessment, and

- 5 years professional experience in field of development, application or assessment of computational methods ((Q)SAR models and read across) for prediction of genotoxicity, and
 - 10 publications in international Journals in the last 10 years in field of (Q)SAR models, and
 - 10 publications in international Journals in the last 10 years in field of read across, and
 - 5 publications in international Journals in the last 10 years in field of using of computational methods ((Q)SAR models and read across) for predicting of genotoxicity of the chemicals.
- d) The team of experts must have, individually, an excellent level of spoken and written standard UK English. For non-native speakers, this should be demonstrated by an Official certificate of English proving a B2 level OR at least 3 years of work in an English-speaking environment etc.

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

- e) The tenderer must have access to the predictions of genotoxicity, as it is specified in the tender specifications, from at least four commercial (Q)SAR models and software tools

Specific Evidence requested for professional and technical capacity:

<u>For requirement a):</u>	A list of 5 major relevant projects related to the subject of this assignment carried out in the course of the past 10 years.
<u>For requirements b and c) and d):</u>	Detailed CVs of all team members proposed for the assignment, taking into account the minimum expertise requirements detailed above, including a list of relevant publications; EFSA strongly recommends submitting the CVs in the EU CV format which can be accessed here .
<u>For requirement e):</u>	A Statement confirming that the tenderer will have access to at least 4 commercial (Q)SAR models and software for prediction of genotoxicity for the contract execution.
	Institutional declaration of interests available here <i>In case of a group of economic operators invited to submit an offer and/or in case of subcontracting, such declaration should be completed separately and submitted for each partner and for each identified subcontractor.</i>
	Individual declarations of interests available here <i>A separate form to be completed by each member of the proposed team.</i>

GENERIC EVIDENCE COMMON FOR ALL SELECTION CRITERIA:

1	Declaration on Honour on selection criteria available in Annex 5
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	<p><i>In case of a joint offer from a group of economic operators invited to submit an offer and/or in case of subcontracting, the declaration must be included for each partner/subcontractor only if the capacity of those partners/subcontractors is necessary to satisfy those minimum capacity requirements.</i></p>
2	<p>Confirmatory statement of resources</p> <p><i>In case of a joint offer from a group of economic operators invited to submit an offer and/or in case of subcontracting, the tenderer must provide a 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 invited partner in a joint offer and/or each subcontractor).</i></p>
3	<p>Allocation of tasks between the partners/subcontractors</p> <p><i>In case of a joint offer from a group of invited economic operators or in case of subcontracting, the tenderer should provide a statement clearly defining the allocation of tasks between the entities.</i></p>

Please note that you do not have to submit any of the above-mentioned evidence if already submitted to EFSA in response to any previous EFSA call, provided the evidence is exactly the same as requested in these tender specifications. If you avail yourself of this possibility, you have to specify the reference of the EFSA call for tenders under which you have already submitted the evidence to EFSA.

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/EU¹¹.

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.

¹¹ OJ L 94 of 28.03.2014, p. 65

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 70%)

- Comprehensive and critical review: detailed description of the searching strategy, proposal for the information sources to be searched and criteria for inclusion/exclusion of information; criteria for critical evaluation of the (Q)SAR models and read across methodology and proposal for presentation of the information; **15 points**
- Evaluation of the applicability of computational methods for predicting of genotoxicity of pesticides and their metabolites:
 - logical and structured step by step explanation of methodology; convincing justification of the choice of proposed methodology; criteria for critical evaluation of the performance, reliability and uncertainty of the predictions and proposal for presentation of the results; **20 points**
 - number of case studies above 20 will be awarded proportionally with additional points up to a maximum **5 points**;
- Evaluation of the impact of the structural changes in the molecule in result of metabolic or degradation processes to the genotoxic potential of the substances: Logical and structured step by step explanation of methodology; convincing justification of the choice of proposed methodology; proposal for presentation of the results; **25 points**
- Risk identification and proposed risk mitigation actions; **5 points**

2. PROJECT ORGANISATION (10 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); **5 points**
- The internal team communication; in case of joint offers & subcontractors also the communication between joint offers partners and subcontractors and communication with EFSA (who, how, when); **5 points**

3. MEASURES TO GUARANTEE QUALITY OF DELIVERABLES (20 points)

This is to assess the quality assurance mechanisms put in place to guarantee the high quality of deliverables and meeting of the agreed deadlines:

- Role of team leader / leading partner in quality assurance; **5 points**
- Special measures for quality assurance proposed for this particular project; **5 points**
- Measures to ensure availability of proposed team members and mitigation strategies to cover absences; **5 points**
- Measures proposed to ensure the meeting of the deadlines; **5 points**

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

Tenderer 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 70 % for the first criterion, and at least 70 % of maximum possible total points against the quality award criteria.

Tenders that do not reach these minimum quality thresholds will be eliminated from 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) =
[CHEAPEST PRICE OFFER/PRICE OF TENDER (X)]*(30)**

+

**TOTAL QUALITY SCORE (OUT OF 100) FOR ALL QUALITY AWARD CRITERIA OF
TENDER (X)/100 *(70)**

PART 3 CONTENT OF THE OFFER – HOW TO SUBMIT YOUR OFFER & WHAT SHOULD YOUR OFFER CONSIST OF?

SUBMISSION GUIDELINES

- You should submit your tender electronically via the e-Submission application in one of the official languages of the European Union through the e-tendering website and before the closing date for offer receipt as described in the Invitation Letter. Please also refer to the e-submission application description attached in **Annex 2**.
- In order to familiarise yourself with the system and to test whether your workstation configuration is working correctly with our environment, you are invited to access the following test environment at:
https://webgate.ec.europa.eu/supplier_portal_toolbox/spots/openSpots.do?CFT_UUID=TEST_CFT_2016-NO_LOTS&VERSION=1&CAID=5790001791483&screenWidth=1000&screenHeight=850

This will enable you to make a test submission well in advance of the time limit for receipt indicated in the Invitation letter.

E-Submission application: The tenderer must provide the following information using the e-Submission application. In the e-submission application, please fill in all mandatory fields (marked with a star *) and other fields as appropriate. All tenders must be clear, complete and consistent with all the requirements laid down in the tender specifications including the below instructions. The documentary evidence/documents required in the tender specifications must be included in section "Qualification" in the e-submission application. Tenders not including the necessary evidence may be rejected.

Step by step guide:

STEP: ACCESS e-submission

In order to access the e-Submission application, the first step is to create a user account in the system (European Commission Authentication System - ECAS):
<https://ecas.ec.europa.eu/cas/eim/external/help.cgi>

A button "Submit your Tender" will then be displayed and you will be able to access the e-Submission application.

Before proceeding to fill in the tender details in the system, you need to accept the Terms & Conditions and acknowledge the Privacy Statement of the e-Submission application.

STEP: Welcome to the tender wizard

Please read the recommendations and instructions.

You can either create a tender for the first time or load a draft tender from your local disk if not created for the first time. In case of doubts refer to user Manual and FAQs:

- https://webgate.ec.europa.eu/supplier_portal_toolbox/spotsHelpPage.jsp

In case of technical problems only, contact DIGIT Helpdesk indicated in the e-submission application at DIGIT-ESUBMISSION-SUPPORT@ec.europa.eu or call +32 2 29 58 181

STEP: e-submission wizard step 2 of 5 - TENDERING DATA

Different ways to submit a tender:

Options 1 to 4 below describe the different ways to submit a tender. Please make sure all required documents and evidence are submitted with your tender.

Option 1: Submission by one tenderer: "single tender" in the e-submission application.

Option 2: Submission by a group of economic operators: "joint tender" in the e-submission application. In case of a (joint tender) one member of the group must be designated as lead partner ("leading partner" in the e-submission application).

Option 3: Submission by one tenderer with subcontractors: "single tender; involving subcontracting" in the e-submission application.

Option 4: Submission by a group of economic operators (joint tender) with subcontractors: "joint tender; involving subcontracting" in the e-submission application.

STEP: e-submission wizard step 3 of 5 - TENDERING DATA

No action for tenderers; text for information only.

STEP: e-submission wizard step 3 of 5 - QUALIFICATION: IDENTIFICATION OF THE TENDERER

1. "Legal Entity Form": In order to prove their legal status, the single tenderer or leading partner in a joint offer must provide a Legal Entity Form (LEF) with its supporting evidence. Subcontractors are not required to provide this document. In case of a joint offer, each partner must fill in and upload a Legal Entity Form (LEF) with its supporting evidence under the section "Qualification" -> "Identification of the tenderer" under "Documents".

Hand written signature of individual forms of the single tenderer or leading partner in a joint offer who submits the tender is not required, since the signature of the Tender Preparation Report implies that all included documents are signed by them.

The standard template of the Legal Entity Form in each EU language is available at:
http://ec.europa.eu/budget/contracts_grants/info_contracts/legal_entities/legal_entities_en.cfm

2. "Administrative Identification Form": This form should be completed by the tenderer using the template available in **Annex 8**, in case of a joint offer, only by the leading partner (see section 2.4A) and needs to be filled in and uploaded under "Qualification" -> "Identification of the tenderer" under "Documents".

3. "Financial identification Form": The tenderer (single tenderer or leading partner in case of joint tender) must provide a Financial Identification Form (FIF) and supporting documents. Only one form per tender should be submitted (no form is needed for subcontractors and other partners in a joint offer). The form is available on:
http://ec.europa.eu/budget/contracts_grants/info_contracts/financial_id/financial_id_en.cfm

The form needs to be printed, filled in and then scanned and uploaded in the section "Qualification" -> "Identification of the tenderer" -> "Documents".

Hand written signature of individual forms of the single tenderer or leading partner in a joint offer who submits the tender is not required, since the signature of the Tender Preparation Report implies that all included documents are signed by them.

STEP: e-submission wizard step 3 of 5 - QUALIFICATION: EXCLUSION CRITERIA

For the exclusion criteria the tenderer is requested to submit the following evidence:

- Declaration on honour on the exclusion criteria by the tenderer using the template available in **Annex 4**, in case of a joint offer by each partner, relating to the exclusion criteria (see section 2.3) needs to be filled in and uploaded under "Qualification" -> "Identification of the tenderer" -> "documents".

The hand written signature of the form is required for the single tenderer or in case of joint offers, by each member of the group, including the leading partner.

STEP: e-submission wizard step 3 of 5 - QUALIFICATION: SELECTION CRITERIA – ECONOMIC AND FINANCIAL CAPACITY

Generic Evidence for selection criteria:

Declaration on honour on the selection criteria by the tenderer using the template available in **Annex 5**, in case of a joint offer, only by the leading partner (see section 2.4A) needs to be filled in and uploaded under "Qualification" -> "Selection Criteria" -> "Financial and Economic Capacity" in the e-Submission application.
<http://www.efsa.europa.eu/en/procurement/toolbox>

The hand written signature of the form is required for the single tenderer or in case of joint offers, by the leading partner.

STEP: e-submission wizard step 3 of 5 - QUALIFICATION: SELECTION CRITERIA – TECHNICAL AND PROFESSIONAL CAPACITY

Specific Evidence for technical and professional capacity:

The tenderer is requested to upload the proof of technical and professional capacity (see 2.4 B) in section "Qualification" -> "Selection Criteria" -> "Technical and Professional

Capacity" in the e-Submission application.

STEP: e-submission wizard step 3 of 5 - QUALIFICATION: tender

Technical offer: The technical tender needs to be uploaded in the section "Tender" in the e-Submission application. The tenderer will need to select the "Technical Tender" document from the dropdown box ("Financial Tender or Technical Tender"). The e-Submission application allows attachment of as many documents as necessary.

This technical section is of great importance in the assessment of the offers, the award of the contract and the future execution of any resulting contract.

The technical offer must cover all aspects required in the technical specifications and provide all the information needed to reply to the quality award criteria (see section 2.6 A).

Offers deviating from the minimum requirements or not covering all minimum requirements will be excluded on the basis of non-conformity with the tender specifications and will not be evaluated (see section 2.5).

In case of subcontracting: please indicate in the technical offer the % proportion of subcontracting.

Financial offer: The complete financial offer (according to the form available in **Annex 1**) needs to be uploaded in section "Tender" in the e-Submission application. The tenderer will need to select the "Financial Tender" document from the dropdown box ("Financial Tender or Technical Tender").

Fields: "Tax Exclusive amount", "Tax total", "Total Payable": The total price of the tender needs to be encoded in the e-Submission application. Please indicate the **total price** of the Financial offer template (**Annex 1**) in the fields "Tax exclusive amount" and "Total payable". In the field "Tax total" please indicate "0"/Zero value.

STEP: e-submission wizard step 3 of 5 – validation

To continue to step 4, please click on "**Validate**" button. A **tender preview document** will be generated in your local computer.

STEP: e-submission wizard step 4 of 5 – Consolidate tender docs – finalize package

Once all information and documents have been encoded and uploaded in the e-Submission application and you consider that the tender is complete, the application will require you to consolidate the tender into one consolidated tender package. A Tender Preparation Report will be generated by the e-Submission application. The application will require you to save both files (i.e. the consolidated tender package and the Tender Preparation Report) on your local computer.

The Tender Preparation Report must be signed ONLY in the following way:

Hand signature:

You print out the Tender Preparation Report. The single tenderer's or lead partner's

authorised representative(s) should hand sign the Tender Preparation Report. Upon signature, you will upload the scanned, signed document in the e-Submission application. **The tender (including the scanned copy of the Tender Preparation Report) needs to have been uploaded within the "Receipt Time Limit - Closing date and time for offers reception" indicated in the Invitation letter.**

The signature of the single tenderer's or lead partner's authorised representative(s) on the Tender Preparation Report will be considered as binding with respect to the terms of the tender.

Both (i) the consolidated tender package; and (ii) the scanned hand signed Tender Preparation Report need to be uploaded into the e-Submission application.

STEP: e-submission wizard step 5 of 5 – SUBMITTING YOUR TENDER

The scanned, signed Tender Preparation Report should also be sent immediately after submission, to this **e-mail address:** EFSAProcurement@efsa.europa.eu.

You will receive a tender receipt confirmation in your e-Submission mailbox, including information about the timestamp put on your tender by the e-Submission system. This is considered as the official time of receipt and will constitute proof of compliance with the deadline given in the invitation letter. Late receipt will lead to the exclusion from the evaluation procedure for this contract.

IMPORTANT:

1. Make sure you submit your tender on time: You are strongly advised to start completing your tender early. Do not wait until the last day to upload your offer. To avoid any complications with regard to late receipt/non receipt of tenders within the deadline, please ensure that you submit your tender well in advance of the deadline. In case of any problems with the submission of the electronic tender, you must call the helpdesk a reasonable amount of 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.

Please note that the responsibility rests with you to ensure that your tender is correctly uploaded before the time limit for receipt.

2. After submitting a tender, but within the time limit for receipt, you may still submit a new version of your tender. To do this, you should upload a new consolidated tender package containing corrected tender documents together with formal notification by letter that the previous tender is withdrawn.

3. If, after submission, you wish to withdraw your tender, you must send a duly signed letter to this **e-mail address:** EFSAProcurement@efsa.europa.eu identifying the name and reference of the tender you wish to withdraw. This notification must be signed by the same authorised legal representative(s) who previously signed the tender in question.

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 **300.000,00 €**. 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, cost incurred for allowing full access for EFSA to scientific publications referred to in the final delivery prepared under the contract, etc; should also be factored in to the all inclusive price.

ALL INCLUSIVE TOTAL PRICE to be used for the evaluation and for the contract in the case of award. (Please provide attached to the Financial Offer, for information purposes only, a breakdown of costs using your own template – the submission of this breakdown is not compulsory) €
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Tenderer name:

Date:

Name of person signing the financial offer:

His/her position in the company:

His/her signature:

ANNEX 2 – E-SUBMISSION APPLICATION DESCRIPTION

What is the e-Submission application?

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 TED eTendering is the starting point for launching the e-Submission application.

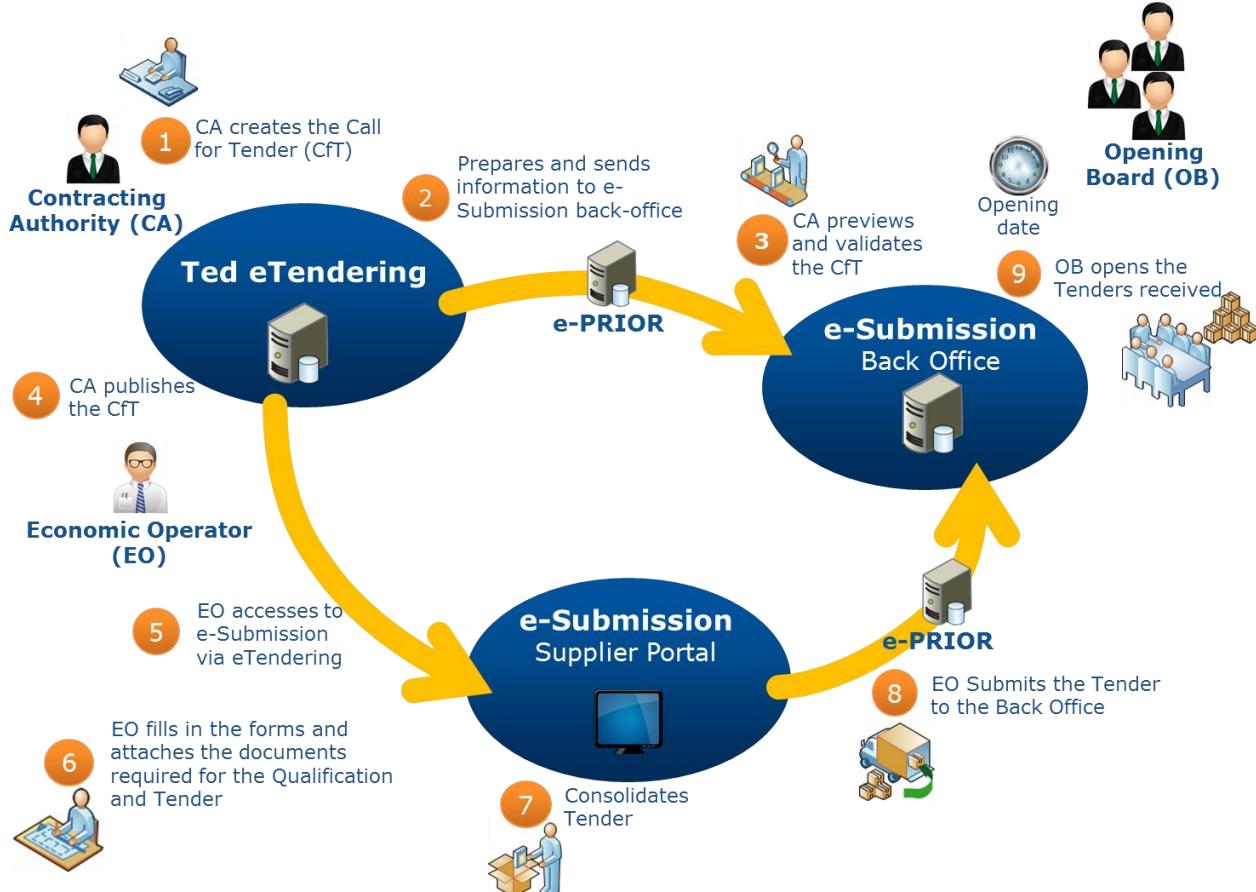
On the Contracting Authority side, this application is responsible for generating the necessary templates and encryption key, and to securely open the received tenders.

As an economic operator you can:

- Prepare, save and load your tender.
- Submit your tender electronically and securely.
- Receive a proof of tender submission
- View the tenders to which you have applied.

Your submitted tender(s) will be received by the corresponding Contracting Authority who will be able to open your electronic tender during the opening session.

How does it work?



1. The Call for Tender (CfT) is first created in TED eTendering by the Contracting Authority (CA).
2. The CA then enables e-Submission. This will allow Economic Operators (EO) to submit tenders via e-Submission once the CfT is published.
3. The CA can preview the CfT as it will be seen by the EO.
4. When the CfT is ready the CA publishes the CfT.
5. When the EO wants to submit a tender, the EO accesses to e-Submission via TED eTendering.
6. Fills in the required information and documents for his Tender.
7. When the Tender is ready the EO creates a "virtual package" (consolidate) of his Tender to prepare it for submission.
8. The EO then submits his Tender to the CA which is received by e-Submission Back Office.
9. On the Opening date, the Opening Board gathers and opens all received e-Tenders on the e-Submission Back Office.

Where to find more information?

https://webgate.ec.europa.eu/supplier_portal_toolbox/spotsHelpPage.jsp

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 – INSTITUTIONAL DECLARATION OF INTERESTS

ANNEX 7 – INDIVIDUAL DECLARATION OF INTERESTS

ANNEX 8 – ADMINISTRATIVE DATA¹²

A) TENDERERS ADMINISTRATIVE DATA:

Name of tenderer	
Address	
Post code	
VAT number	
Tel.	
Fax	
E-mail	
Website (if applicable)	
Legal status	
If private entity number of staff/ Annual turnover	
Contact person for this tender	
Legal representative – who will sign the contract in case of award	
Swift code for the bank account identified in form C) Financial Identification Form	

B) LEGAL ENTITY FORM:

This form is to be downloaded, depending on the nationality of the tenderer, from the following website:

¹² In the case of a consortium submitting an offer all members of the consortium should complete forms A) and B). Form C) should only be completed by the consortium leader.

http://ec.europa.eu/budget/contracts_grants/info_contracts/legal_entities/legal_entities_en.cfm

C) FINANCIAL IDENTIFICATION FORM:

This form is to be downloaded, depending on the nationality of the tenderer, from the following website:

http://ec.europa.eu/budget/contracts_grants/info_contracts/financial_id/financial_id_en.cfm

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