

## Call for tenders' details

Title: Exploring the Use of Artificial Intelligence (AI) for Extracting and Integrating Data obtained through New Approach Methodologies (NAMs) for Chemical Risk Assessment

Start date: 04/06/2021

Time limit for receipt of tenders: 07/09/2021

Contracting authority: European Food Safety Authority (EFSA)

Status: Closed

## Call for tenders question list

#	Submission date	Publication date	Question subject	Question	Answer
1	10/06/2021 17:45	11/06/2021 16:03	Eligibility	Good evening! We would be very interested in this call for tender but have a few doubts. Is this call for tenders only open to the Article 36 organisations? A company not in the list of competent organisations can participate in a consortium with one of these organisations? Or can any company participate even if not in a consortium with one of the competent organisations? Many thanks in advance for your assistance. Kind regards,	<b>11/06/2021</b> This call for tender is open to all economic operators in EU member states: Article 2.3 GROUNDS FOR EXCLUSION Eligibility- Access to EU Market (pag 16). Please refer to the EFSA Guidance for tenderers for further details.

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#	Submission date	Publication date	Question subject	Question	Answer
2	18/06/2021 15:27	21/06/2021 10:36	Technical capacity	Dear madam/sir, I would like to ask if the technical and professional capacity to be demonstrated can be achieved considering both contractors and subcontractors, or it has to be demonstrated only by the contractors. Best regards	<b>21/06/2021</b> Yes, the technical and professional capacity should be demonstrated by the contractor and in case of joint offer/subcontracting a Confirmatory statement of resources (a statement signed by each partner/subcontractor) confirming they will provide the necessary resources for the performance of the contract, should be provided.
3	22/06/2021 11:24	23/06/2021 13:59	Number of expected physical meetings	Dear Sir/Madam, how many physical meetings in EFSA are expected? Regards	<b>23/06/2021</b> In principle two meetings are foreseen in Parma. In practice it may be reduced depending on a possible evolution of the pandemic context.
4	28/06/2021 19:38	01/07/2021 09:53	Subcontractors	Dear EFSA support, Is it possible to have a subcontractor from USA?	<b>01/07/2021</b> The rules on access to the market do not apply to subcontractors, therefore economic operators established in Third Countries (non-EU Countries) can participate as subcontractors.
5	19/07/2021 16:16	29/07/2021 15:21	format preferences	Are there any formal preferences to the submission forms that do not have a template? For example Word or a Power Point presentation?	<b>29/07/2021</b> Preferably for the submission of the forms the tenderer should opt for Word or pdf. files.

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6	19/07/2021 16:24	29/07/2021 15:56	References	Does one need to provide exactly 3 references (major projects or publications) or can we give more than 3 that will be accepted? Do we also need to provide the names of the contractors for the referenced projects?	<b>29/07/2021</b> The list of major projects or publication is 3, but the tenderer can give more references, (no additional score is given for that as it is just a compliance/non-compliance assessment). There is no need to provide the names of the contractors for the referenced projects.

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#	Submission date	Publication date	Question subject	Question	Answer
7	30/07/2021 18:32	03/08/2021 11:50	2nd senior expert Par.2.4 B) b)	- Expertise in computational chemistry, QSAR/QSPR, and molecular modelling are considered chemical risk assessment methodologies and/or NAM methodologies? - The use of methodologies in safety assessment can be demonstrated if an expert worked on chemicals relates to different fields other than food/feed ? (e.g. fine chemicals, pharmaceuticals, detergents ...) - The integration of mechanistic information, development of AOP and AOP network, ITATA and TKTD can be demonstrated by an expert that worked in molecular chemistry, molecular biology and biochemical studies and published in peer-review journals even if not concerning food/feed?	<b>03/08/2021</b> Computational chemistry, QSAR/QSPR, and molecular modelling are considered NAM methodologies. Expertise in these areas may be considered expertise in risk assessment only if these methods were used for risk or safety assessments (comparing the predicted effects with exposure). Regarding the second question, the use of methodologies in safety assessment can be demonstrated for an expert worked on chemical safety assessments other than food/feed, such as the provided examples (e.g. fine chemicals, pharmaceuticals, detergents ...) or others including REACH, biocides, etc. Regarding the third question, the integration of mechanistic information, development of AOP and AOP network, ITATA and TKTD can be demonstrated by an expert that worked in molecular chemistry, molecular biology and biochemical studies and published in peer-review journals in areas not related to food/feed, as long as the work involved the development of AOP and AOP networks, ITATA and TKTD or equivalent activities.

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8	30/07/2021 18:33	03/08/2021 11:57	Objective C-1 and Task 5	It is unclear what is the contents of Deliverables D-7, D-8 and Interim Report 5 since all of them are defined as documents. How software, program codes, search strategies, critical appraisal tools, training datasets ontologies are delivered?	<b>03/08/2021</b> Software, program codes, search strategies, critical appraisal tools, training dataset for machine learning tools, ontology glossaries, etc. will be uploaded into a repository provided by EFSA (through Zenodo <a href="https://zenodo.org/">https://zenodo.org/</a> ) or other platforms if agreed by EFSA. Interim Report 5 (covering Deliverables D-7 and D-8) is a report presenting the compilation of the different elements developed through the full contract, including for each element a description and the link to the repository.

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9	30/07/2021 18:34	03/08/2021 11:59	Obj B-2 and B-3	Do you confirm that Objective B-3 does not include “integration of the mechanistic knowledge extracted from the validated data through AOP-like knowledge networks for informing the risk assessment” as described in Objective B-2?	<b>03/08/2021</b> Under Objective B-3, the “integration of the mechanistic knowledge extracted from the validated data through AOP-like knowledge networks for informing the risk assessment” described in Objective B-2, will be covered by the “proposal for using the results for improving the mechanistic understanding in regulatory risk assessments” to be prepared by the contractor and discussed at a dedicated workshop. At this level (Objective B-3) results will be available for each case study, and the contractor is expected to do not only the integration, but also to prepare a detailed proposal on the mechanistic understanding linked to the observed effects, considering the current knowledge and the results of the case study, for each chemical or group of chemicals included in each case study.

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10	30/07/2021 18:34	03/08/2021 12:02	Objective B-1	Can you provide a list of NAM-data method/techniques that you would consider acceptable for proposing case-studies? Or, can you provide the precise definition of NAM-data that EFSA considers applicable to this tender?	<p><b>03/08/2021</b></p> <p>NAMs include any new approach methodology non based on in vivo animal testing useful for the hazard assessment and risk characterization of chemicals. In the EFSA NAMs Theme Paper ( available as Annex 4 in this link <a href="https://etendering.ted.europa.eu/cft/cft-documents.html?cftid=7613">https://etendering.ted.europa.eu/cft/cft-documents.html?cftid=7613</a>), NAM-based methods are summarized as:</p> <ul style="list-style-type: none"> <li>• in vitro mechanistic and -omics data, organoids and microfluidic systems, high throughput screening (HTS), high content screening (HCS), for the identification of Mode of Action (MoA) and inform about Adverse Outcome Pathways (AOP);</li> <li>• in-silico tools, enhanced data models, Toxicokinetic and Toxicodynamic (TKTD) modelling and quantitative in vitro in vivo extrapolation (QIVIVE);</li> </ul> <p>In addition, NAMs include the use of epidemiological knowledge for getting mechanistic understanding of the effects of chemicals (e.g. molecular epidemiology and -omics enhanced epidemiological studies) and human data following occupational or environmental exposure, including human inter-individual differences in metabolism and biomonitoring; The tenderer is expected to describe in the offer the approach that will be used for implementing the three objectives</p>

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					for implementing the three objectives under WP-A, including the identification of NAM-data and techniques expected to be suitable for the application of AI.
11	02/08/2021 15:17	03/08/2021 12:03	AI to support TK-plate	<p>ANNEX III mentions the integration of toxikokinetic data and specifies the steps needed to improve TK-plate. In my view, this is not directly related to the use of AI for AOP, but can be seen as additional activity. Citation from ANNEX III - AI tools can be also used to support the development and possible automation of the EFSA physiologically-based kinetic (PBTK) platform. To develop the EFSA PBTK platform a stepwise approach was designed: 1) collection of quantitative parameters, 2) integrate data into algorithm, 3) develop case studies and guidance document, and 4) develop an open-source platform for users which allow us to predict TK and TD properties (e.g. to calculate internal dose). Is it the intention of this tender to include the work on toxikokinetics as described here?</p>	<p><b>03/08/2021</b> Annex 3 is a summary of the workshops. The EFSA PBTK platform is covered by other procurements. The objectives and tasks to be conducted under this call are those described in the Tender Specifications. These tasks do not include the development of the EFSA PBTK platform or the four steps mentioned in your citation. However, as toxicokinetics is an essential part of the risk assessment and needed for getting the mechanistic understanding to be obtained through NAMs, the contractor should include NAM-based toxicokinetic data and studies in the three Workpackages described in the Tender Specifications, and to consider the toxicokinetic aspects in the design and implementation of the case-studies under WP-B.</p>



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#	Submission date	Publication date	Question subject	Question	Answer
12	30/07/2021 18:27	03/08/2021 12:05	1st senior expert Par.2.4 B) b)	Can we provide two senior experts instead of one with complementary expertise? For instance, first expert with expertise in the area of AI, machine learning, deep learning and ANN and, second expert with expertise in data management, bioinformatics, software dev, software adaptation, toxicology and risk assessment. Concerning the sentence "Expertise in the application of this knowledge in toxicology and/or risk assessment will be considered and additional advantage", we do not understand how and where this will be specifically evaluated since Par 2.4 B describe only selection criteria. Can you clarify?	<b>03/08/2021</b> 1. Yes, each profile can be covered by one or several experts. 2. "Expertise in the application of this knowledge in toxicology and/or risk assessment will be considered and additional advantage" for the contractor in the execution of the contract but is indeed not subject to evaluation point / qualitative scoring under the selection criteria when assessing the tenderer.
13	30/07/2021 16:11	03/08/2021 12:07	Submission of paper forms?	Could you please confirm that all relevant submission documents need to be uploaded digitally in the submission portal (properly signed of course), and that no submission document needs to be sent in in paper form? Thank you very much for your clarification!	<b>03/08/2021</b> All relevant documents should be uploaded in e-submission, NO paper forms is requested.

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14	28/07/2021 17:26	03/08/2021 12:09	Submission report	In your linked document “quick guide for economic operators” it is described, that the submission report needs to be signed and uploaded again. However, the quick guide on the webpage of E-Submission says that it is not necessary to sign and upload the submission report. Could be please clarify whether it is necessary or not to sign and upload the submission report? Thank you so much for your clarification!	<b>03/08/2021</b> The economic operator should refer to the following link for the update quick guide: <a href="https://ec.europa.eu/info/funding-tenders/opportunities/docs/esubmission/quickguidepp_en.pdf">https://ec.europa.eu/info/funding-tenders/opportunities/docs/esubmission/quickguidepp_en.pdf</a> The link on EFSA website was obsolete. It was updated accordingly.
15	30/07/2021 16:07	03/08/2021 12:10	Qualification of English Skills	For non-native speakers you request an official certificate or different work or study experiences that verify an excellent level of spoken and written standard UK English. What kinds of official certificates will be accepted? Would a German certificate of general qualification for university entrance combined with several work projects (with meetings and documentation in English) be enough?	<b>03/08/2021</b> The official certificate could be issued by the relevant Country of the tenderer, the demonstration of active participation at Conferences/meetings in English, or the 3 years experience in an English-speaking environment would suffice.

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16	04/08/2021 11:36	04/08/2021 16:10	Question regarding SELECTION CRITERIA: Economic and financial capacity	The section 2.4 in selection criteria under clause A) Economic and financial capacity it is mentioned that, the tenderer must have generated an overall annual turnover of at least 1.500.000 € in each of the last 3 closed financial years (2018, 2019 and 2020). Can a start-up company apply for the tender if its not having proof of three year annual turnover? Is there any provision for young Entrepreneur to be able to participate in submitting the application? Thank you for your kind support. With best regards	<b>04/08/2021</b> The start up company could make a joint offer to reach the annual turnover, the assessment is done on a consolidated basis. It is not possible to apply as sole tenderer if the annual turnover is not met.
17	06/08/2021 16:23	09/08/2021 15:40	Confirmatory statement of resources	Will proper electronic signatures via DocuSign (not advanced, i.e. without a certificate) be accepted as signatures of the Confirmatory statement of resources? If not, will handwritten, printed, and scanned signatures be accepted instead? Thank you for your clarification!	<b>09/08/2021</b> For the confirmatory statement of resources, handwritten scanned and signed document will be accepted.
18	06/08/2021 16:17	09/08/2021 15:41	Financial offer	Does the financial offer need to be signed by all tendering partners? Or is it enough if the leading partner only signs the financial offer?	<b>09/08/2021</b> Only the leading partner has to sign the financial offer.

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19	24/08/2021 09:49	24/08/2021 16:48	Project management on EFSA side	How will the project management level be organized on the EFSA side (e.g. establishment of a steering committee, joint project management team with contractors, etc.)?	<b>24/08/2021</b> EFSA has appointed a coordinator for this project, that will be the contact point for the contractor. Other EFSA staff will participate in the meetings and will be involved in the assessment and approval of the deliverables.
20	24/08/2021 09:49	24/08/2021 16:50	EFSA experts involved in operative project work	To what extent shall the EFSA experts be involved in the operative project work (e.g. participation in status / intermediate meetings solely, co-authoring of deliverables, etc.)?	<b>24/08/2021</b> The execution of the project and drafting the deliverables is the responsibility of the contractor. EFSA staff will provide comments and suggestions on the work plan and the deliverables during the full project. The deliverables are the responsibility of the contractor. In addition, the rights of use of results, including publication in scientific journals, are detailed in the tender specifications (section 1.5) and in the draft contract (Articles I.10 and II.13)

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21	27/08/2021 13:26	30/08/2021 11:42	Economic and financial capacity	In relation to the economic and financial capacity and the expected annual turnover of 1.5 mil Euros for each of the last 3 closed financial years (2018, 2019 and 2020): In case of joint offers you mention in your answer to another question that the assessment will be done on a consolidated basis. Should the leading partner be the one fulfilling the financial capacity of the consortium or is it sufficient that the requirement is simply fulfilled by one of the partners of the consortium?	<b>30/08/2021</b> As stated in section 2.4(A) of the tender specifications, the economic and financial capacity is assessed on a consolidated basis. This means that in case of partners in a joint offer and/or subcontractors, the leading partner is not necessarily the one fulfilling the financial capacity for the whole consortium but the turnover of each partner and/or subcontractors may cumulatively contribute to reaching of the turnover requirement.

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