

ECHA/2015/50

**Multiple Framework Contracts with re-opening
of competition for scientific services for ECHA**

2 Lots

Open Procurement Procedure
Specifications and model framework contract

Contract notice: 2015/S 139-255572

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Disclaimer

Whenever the Tender Specifications mention a specific product name or trademark and a sufficiently precise and fully intelligible description is not possible, such mention shall be understood as referring to that product or its equivalent.

1 Summary

Contracting authority	The European Chemicals Agency (ECHA) in Helsinki.
Procedure	Call for Tenders with publication in the Official Journal of the EU. Open procedure.
Purpose	This call for tenders aims for the signature of multiple framework contracts for the provision of scientific services.
Lots	<p>This call for tenders is divided into two lots:</p> <p>Lot 1: Assistance in the processes related to evaluation, restriction, authorisation, harmonised classification and labelling and biocidal products, <u>excluding</u> activities pertaining to substance identification.</p> <p>Lot 2: Assistance in tasks and activities related to substance identification in all relevant REACH, CLP, BPR and PIC processes including training and reviewing of inventories and databases.</p>
Volume (indicative)	<p>The maximum <u>overall</u> value of the multiple framework contracts is estimated between 2.000.000 € and 4.000.000 €, divided by:</p> <ul style="list-style-type: none"> • Lot 1 – 1.600.000 € and 3.400.000 € • Lot 2 – 400.000 € and 600.000 € <p>It should be stressed that framework contracts involve no direct commitment and, in particular, do not constitute orders per se. Instead, they lay down the legal, financial, technical and administrative provisions governing the relationship between the European Chemicals Agency and the tenderer during their period of validity. The indicated budget is a contractual budgetary ceiling. It is the potential maximum overall value of the framework contracts over the whole duration of the contract. The estimate given above is purely indicative and does not bind the Agency in any way. The figure may be subject to revision.</p> <p>ECHA may exercise the option to increase the estimated market amount at a later stage via negotiated procedure with the successful tenderer(s) in accordance with Article 134(1)(f) of the Rules of Application of the Financial Regulation¹.</p>
Contracts	The European Chemicals Agency will sign multiple framework contracts separately for lot 1 and for lot 2 with a maximum of 10 successful tenderers per lot offering best value for money. A Draft framework contract is attached in

¹ COMMISSION DELEGATED REGULATION (EU) No 1268/2012 of 29 October 2012 on the rules of application of Regulation (EU, Euratom) No 966/2012 of the European Parliament and of the Council on the financial rules applicable to the general budget of the Union.

	Annex 6.3.
Submission of offers	Tenderers may submit an offer for one or both lots. In case a tenderer decides to apply for both lots it has to submit separate technical and financial offers for each lot.
Duration of the framework contract	The initial duration of the framework contracts shall be 2 years with 2 possible renewal of 1 year.
Places of delivery	The place of performance of the services shall be the tenderer's premises and ECHA's premises, and any other place as agreed in a specific contract depending on the nature of the specific tasks.
Variants	Not permitted.
Joint offers	Permitted as announced in the Specifications.
Subcontracting	Permitted as announced in the Specifications.

2 Introduction

2.1 About ECHA

The European Chemicals Agency (ECHA) is the driving force in implementing the EU's ground-breaking chemicals legislation for the benefit of human health and the environment. ECHA was founded in 2007 and is based in Helsinki, Finland. We are a modern, science-driven organisation which has grown rapidly to become one of the largest EU agencies.

ECHA has regulatory tasks related to four pieces of EU legislation: Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH); Classification, Labelling and Packaging of substances and mixtures (CLP); Biocidal Products Regulation (BPR); and the Prior Informed Consent (PIC) Regulation.

The purpose of REACH is to ensure a high level of protection of human health and of the environment; to promote alternative methods to animal testing to assess the hazards of chemicals; to facilitate the free circulation of substances within the single market; and to enhance competitiveness and innovation.

The purpose of CLP is to ensure a high level of protection of human health and of the environment, as well as the free movement of substances, mixtures and certain articles, by harmonising the criteria for the classification of substances and mixtures, and the rules on labelling and packaging.

BPR aims to harmonise the European market for biocidal products and their active substances while providing a high level of protection for humans, animals and the environment.

PIC sets requirements for the import and export of certain hazardous chemicals. The regulation implements the Rotterdam Convention at EU level.

ECHA's Mission

ECHA is the driving force among regulatory authorities in implementing the EU's ground-breaking chemicals legislation for the benefit of human health and the environment as well as for innovation and competitiveness. ECHA helps companies to comply with the legislation, advances the safe use of chemicals, provides information on chemicals and addresses chemicals of concern.

ECHA's Vision

ECHA aspires to become the world's leading regulatory authority on the safety of chemicals.

ECHA's Values

Transparent

We actively involve our regulatory partners and stakeholders in our activities and are transparent in our decision-making. We are easy to understand and to approach.

Independent

We are independent from all external interests and impartial in our decision making. We consult members of the public openly before taking many of our decisions.

Trustworthy

Our decisions are science based and consistent. Accountability and the security of confidential information are cornerstones of all our actions.

Efficient

We are goal-oriented, committed and we always seek to use resources wisely. We apply high quality standards and respect deadlines.

Committed to well-being

We stimulate the safe and sustainable use of chemicals to improve the quality of human life in Europe and to protect and improve the quality of the environment.

2.2 Legal framework of ECHA procurement

The present Call for Tenders is governed by the Financial Regulation of the European Chemicals Agency (ECHA), which refers to the Financial Regulation (EU, EURATOM) No 966/2012 of the European Parliament and the Council of 25 October 2012 on the financial rules applicable to the general budget of the Union (hereinafter referred to as the Financial Regulation), and repealing Council Regulation (EC, Euratom) No 1605/2002; as well as to the Commission Delegated Regulation (EU) No 1268/2012 of 29 October 2012 on the Rules of Application of the Financial Regulation No 966/2012 (hereinafter referred to as the Rules of Application), as the regulatory framework for the procurement and contract management of the Agency.

In submitting their tender, the tenderer accepts in full and without restriction the requirements of these tender specifications, and the special and general conditions governing this Framework Contract as the sole basis of this tendering procedure, whatever his own conditions of sale may be, which they hereby waive. Tenderers are expected to examine carefully and comply with all instructions, forms, contract provisions and specifications contained in this tender dossier. Failure to submit a tender containing all the required information and documentation may lead to the rejection of the tender. No account can be taken of any reservation expressed in the tender as regards the tender dossier (if necessary, clarification may be requested by the potential tenderer concerned while the tender submission phase is open – see point 8, first paragraph, of the Invitation to Tender); any reservation may result in the immediate rejection of the tender without further evaluation.

3 The Services Required

3.1 Background

The aim of this call for tenders is the signature of multiple framework contracts for the provision of scientific services for the European Chemicals Agency (ECHA). The call for tenders is divided into two lots:

Lot 1: Assistance in the processes related to evaluation, restriction, authorisation, harmonised classification and labelling, and biocidal products, excluding activities pertaining to substance identification.

Lot 2: Assistance in tasks and activities related to substance identification in all relevant REACH, CLP, BPR and PIC processes including training and reviewing of inventories and databases.

The Framework Contracts are expected to cover the following services:

Lot 1: Assistance in the processes related to evaluation, restriction, authorisation, harmonised classification and labelling, and biocidal products, excluding activities pertaining to substance identification.

- a) Assisting the Agency in the scientific and technical implementation of the REACH, the CLP, the Biocidal Products and the PIC Regulations. Specifically these tasks concern evaluation (testing proposals, compliance checking and substance evaluation), restriction, authorisation, harmonised classification and labelling, and evaluation of biocidal active substances and authorisation applications of biocidal products. This should also include undertaking hazard, exposure, risk and socio-economic assessments.
- b) Evaluating the latest scientific findings related to the health and environmental impacts of chemicals and assessing the possible implications of these findings for implementing the REACH, the CLP, the Biocidal Products and the PIC Regulations.
- c) Developing and improving methodologies supporting the implementation of REACH, the CLP, the Biocidal Products and the PIC Regulations. Tasks include methodologies for hazard, exposure and risk assessment of chemicals, and for testing strategies. Additionally methodologies should also be included for the socio-economic assessment of the impacts of changes in the regulatory management of chemicals, taking due account of the economic cost/benefits as well as the health and environmental benefits of the proposed restriction or authorisation measures.
- d) Monitoring the effectiveness of current Community and Member States' policies to reduce the impacts of chemicals, particularly with respect to achieving the objectives of the REACH, the CLP, the Biocidal Products and the PIC Regulations.

Lot 2: Assistance in tasks and activities related to substance identification in all relevant REACH, CLP, BPR and PIC processes, including training and reviewing of inventories and databases.

Assisting the Agency in the scientific and technical implementation of the REACH, the CLP, the Biocidal Products and the PIC Regulations. Specifically, these tasks concern substance identification in terms of the provision of scientific support and specialist expertise in diverse chemical fields, the provision of training, reviewing available databases and inventories of chemicals, as well as assistance in the regulatory issues related to substance identification. These include the drafting of guides, factsheets and trainings in substance identification related items.

3.2 Description of resources

For the implementation of the framework contracts, highly qualified and experienced experts will be needed. The requirements for the profiles indicated below shall be applicable to all resources involved in the implementation of the framework contracts. These requirements will be further defined in the service request for the specific contracts. Justified by the specific nature of the tasks to be performed by the experts, the Agency will stipulate at the level of specific contracts further required knowledge and skills within the relevant areas of expertise for the respective lot.

Lot 1: Assistance in the processes related to evaluation, restriction, authorisation, harmonised classification and labelling, and biocidal products, excluding activities pertaining to substance identification.

Category of expert	1) Educational background	2) Professional experience²	3) Additional requirements
Senior expert	At least, a Master's degree in a subject relevant to the "Areas of expertise" listed below. Alternatively, for lower grade degrees (at least BSci), please see provisions under point 2 (professional experience).	Experience of at least 8 years in at least one of the "Areas of expertise" listed below Alternatively, in the absence of a Master's degree as in point 1 (educational background), experience of 20 years in at least one of the "Areas of expertise" listed below.	Knowledge of written and spoken English at C1 level in the Common European Framework of Reference for languages ³ and Experience in drafting reports and presentations in English.
Expert	At least a Master's degree in a subject relevant to the "Areas of expertise" listed below.	Experience of at least 2 years in at least one of the "Areas of expertise" listed below.	Knowledge of written and spoken English at C1 level in the Common European Framework of Reference for languages ² and Experience in drafting reports and presentations in English

² Only relevant professional experience acquired **after achieving** the minimum qualification stated in point 1 "Educational background" shall be considered

³ See Common European Framework of Reference for Languages - Self Assessment Grid <https://europass.cedefop.europa.eu/en/resources/european-language-levels-cefr>

Areas of expertise:

- 1) Organic chemistry, inorganic chemistry, analytical chemistry, material science, and process engineering.
- 2) Toxicological and eco-toxicological testing methods including alternative testing methods (or other predictive methods).
- 3) Toxicological and eco-toxicological hazard assessment, exposure assessment, risk assessment and risk management related to industrial chemicals or biocidal products.
- 4) Chemical safety assessment (CSA) and its implementation using specific tools such as IUCLID and Chesar, and tools supporting exposure estimation such as ECETOC TRA, Stoffenmanager, ART, Consexpo and EUSES.
- 5) ChemoInformatics including generation and use of different notations for chemical structure, quantitative structure-activity relationships (QSAR) and (eco)toxicological information or fate modelling.
- 6) Environmental and industrial economics and socio-economic assessment relevant for the regulatory management of chemicals.

Lot 2: Assistance in tasks and activities related to substance identification in all relevant REACH, CLP, BPR and PIC processes including training and reviewing of inventories and databases.

Category of expert	1) Educational background	2) Professional experience⁴	3) Additional requirements
Senior expert	<p>At least a Master's degree in a subject relevant to the "Areas of expertise" listed below.</p> <p>Alternatively, for lower grade degrees (at least BSci), please see provisions under point 2 (professional experience).</p>	<p>Experience of at least 8 years in at least one of the "Areas of expertise" listed below</p> <p>Alternatively, in the absence of a Master's degree as in point 1 (educational background), experience of 20 years in at least one of the "Areas of expertise" listed below.</p>	<p>Knowledge of written and spoken English at C1 level in the Common European Framework of Reference for languages⁵ and</p> <p>Experience in drafting reports and presentations in English</p>

⁴ Only relevant professional experience acquired **after achieving** the minimum qualification stated in point 1 "Educational background" shall be considered

⁵ See Common European Framework of Reference for Languages - Self Assessment Grid <https://euopass.cedefop.europa.eu/en/resources/european-language-levels-cefr>

Expert	At least a Master's degree in a subject relevant to the "Areas of expertise" listed below.	Experience of at least 2 years in at least one of the "Areas of expertise" listed below.	Knowledge of written and spoken English at C1 level in the Common European Framework of Reference for languages ² and Experience in drafting reports and presentations in English
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Areas of expertise:

- 1) Organic chemistry, inorganic chemistry, analytical chemistry, biochemistry, material science and industrial chemistry.
- 2) Chemical and process engineering.
- 3) Substance identification under REACH/CLP/BPR/PIC.
- 4) Chemical nomenclature (i.e. IUPAC rules), various conventions and inventories and chemical and scientific literature databases related to substance identity.

Confidentiality and conflict of interest:

Pursuant to Article II.4 of the Framework Contract, the Agency may request a "Declaration absence of conflict of interest" from each member of the team/each expert involved in the implementation of the specific contracts.

Prior to the signature of a specific contract, the contractor may be required to sign a Non-Disclosure Agreement (NDA) with the Agency.

Furthermore, upon signature of a specific contract, all contractor's personnel (including those of partners and subcontractors/freelancers etc.) working under the specific contract may be required to sign a confidentiality declaration (see Article II.5 of the Framework Contract).

3.3 Description of tasks

Different types of tasks need to be performed by the contractors under the Framework Contracts in order to assist the Agency in a range of activities. For information purposes only and in order to aid potential bidders, examples of such tasks are presented below for each of the lots. This description is neither exhaustive nor exclusive nor is the distribution of tasks between the various areas below necessarily an illustration of the final distribution of tasks that will be undertaken via the conclusion of specific contracts.

Lot 1: Assistance in the processes related to evaluation, restriction, authorisation, harmonised classification and labelling, and biocidal products, excluding activities pertaining to substance identification.

1. Market intelligence

The contractor may assist the Agency in setting up (industry) surveys to answer specific questions, such as the expected dossier submissions for REACH deadlines or market surveys for guideline preparations or evidence on how information on safe use of chemicals is being conveyed and implemented in the supply chain. Such surveys can be used to improve ECHA's services, e.g. by analyses of the market. The task will require the contractor to conduct surveys on a large scale and compile and process the results.

2. Assistance in dossier evaluation

The Agency may require assistance in the resolution of issues related to Dossier Evaluation under REACH, in particular in cases where detailed, scientifically reasoned reports are required to facilitate efficient and effective dossier evaluation in the context of compliance checks and testing proposals. The Agency may require assistance in preparations for Seminars/Workshops related to dossier evaluation issues be they internal or with Member State Competent Authorities, Member State Committee of ECHA and/or industry. Assistance in the development/preparation of scientific and administrative reports may be required. Furthermore, assistance may be required in order to build scientific capacity within ECHA in terms of emerging fields of scientific research.

3. Assistance in processes relating to substance evaluation

The Agency may request assistance in developing criteria to prioritise substances for substance evaluation, as well as during the development of the Community Rolling Action Plan. The Agency may require assistance in preparation and reporting on Seminars/Workshops related to substance evaluation issues be they internal or with Member State Competent Authorities, Member State Committee of ECHA and/or industry. Assistance in the development/preparation of regulatory or scientific reports may be required. Furthermore, assistance may be required in order to build scientific capacity within ECHA and Member States in terms of emerging fields of scientific research.

4. Scientific support to Chemical Safety Assessment-related activities, including communication of risk management advice through the supply chain

The Agency supports registrants and downstream users in the development (and application) of tools and communication processes to ensure that meaningful information on uses and conditions on safe use is communicated down the supply chain. The Agency may require assistance in developing examples of good practice and of improvements, and in promoting new tools, e.g. use maps, as well as the results of their implementation for risk management practice on the ground, e.g. through surveys and workshops. The services could also relate to the identification of trends in, and what influences, changes in risk management practices, which stem from the information communicated in the extended safety data sheets (the safety data sheet plus exposure scenarios) between suppliers and their downstream users, in particular for end users of substances and mixtures, and to draw comparisons between which approaches best suit different sectors of industry e.g. construction, engineering, service industries, electronics etc.

5. Service on biocides

ECHA provides technical and scientific support under the Biocidal Products Regulation. Assistance may be needed in these activities. This may vary from contributing to the development of several "submission pipelines" (approval of active substances, national authorisation, Union authorisation, data sharing and technical equivalence for example) to the development of technical guidance. Assistance may also be needed in relation to activities of the Biocidal Products Committee and/or the Coordination Group.

6. Identification of substances for which regulatory actions by the authorities may be required

Assistance in the collation of information (including retrieval from registration dossiers and external databases) relevant for taking decisions as to whether the use(s) of a substance potentially exert risks that would need to be addressed by the authorities and what would be the best regulatory actions for clarifying or controlling the risk. Under this task the Contractor may be requested to collect and analyse use and exposure information for prioritising substances, and identify data gaps and other inappropriate adaptations of the REACH information requirements for registration dossiers. The tasks also covers the development of methodologies for identification of substances for which additional information should be requested under Substance Evaluation and also substances for which the available data are sufficient for SVHC identification or harmonised classification.

With regard to SVHC identification of individual substances, the Contractor may be requested to provide assistance with the collation of relevant information and with the evaluation of data, in particular with regard to assessing PBT, vPvB and endocrine disrupting properties, and with regard to the fulfilment of "equivalent level of concern" definition set out in Article 57(f) of REACH.

7. Preparation of dossiers of substances of very high concern

The Agency may be asked to prepare Annex XV dossiers under REACH for the identification of substances of very high concern (SVHC). The Agency might consider contracting (parts of) the preparation of such dossiers out.

8. Assessment and prioritisation of substances of very high concern

The Agency needs to submit to the European Commission at least every second year a recommendation of SVHC from the Candidate List to be placed on Annex XIV of the REACH Regulation. Substances included in Annex XIV require authorisation before they can be used. In the context of developing this recommendation, the Agency may request contractors to acquire additional information (including retrieval from registration dossiers) relevant for prioritising substances from the Candidate List and for developing draft Annex XIV entries in accordance with Article 58.

9. Assessment of Annex VI Harmonised Classification and Labelling dossiers (CLH dossiers)

The Agency may need assistance during the assessment of proposals submitted by Member States or Industry for a harmonised classification and labelling of a substance in accordance with Article 37 of Regulation (EC) No 1272/2008 (the CLP Regulation). This would in particular concern analysing the scientific data presented in the CLH dossier to justify a classification of a substance in accordance with the criteria set out in the CLP Regulation as carcinogenic, mutagenic or toxic to reproduction category 1 or 2, or as a respiratory sensitizer. In specific cases, assistance might also be required for the analysis of the scientific data presented in a CLH dossier to justify the classification of a substance for other adverse effects on human health (including the analysis of mode of actions and its relevance to humans), on the environment and for physical hazards.

10. C&L inventory

The Agency may need support for the maintenance and quality assessment as well as for technical and scientific analysis of the content of the inventory. This would require assistance in monitoring compliance with harmonised classification as stipulated in Annex VI of the CLP Regulation. This task can include development of case studies for specific substances and specific groups of substances, or for specific issues to be investigated, particularly focussing on substances classified as carcinogenic, mutagenic or toxic to reproduction category 1 or 2, or as respiratory sensitizers.

11. Preparation of restriction proposals

The European Commission may request the Agency to prepare an Annex XV restriction dossier under REACH for one or more substances. Also the Agency has the responsibility to assess if a restriction is necessary for the use of substances on Annex XIV in articles after the relevant sunset date (under Article 69(2)). In such cases the Agency may require external assistance in the preparation of the Annex XV dossier or parts thereof. The services required comprise potentially any aspect of

dossier preparation, e.g., hazard and exposure assessments and analysis of risks, as well as analyses of technical and economic feasibility of alternatives, substitution costs if the substance is no longer available, compliance costs, human health and environmental impacts of restrictions, and related quantified/monetised benefits.

12. Development of capabilities in health and environmental impact assessment and socio-economic analysis

In order to carry out socio-economic analysis, there may be a need to further develop the methodologies and empirical application of assessing the health and environmental impacts of the regulation of chemicals (including problem assessment, development of risk management options, assessment of economic, social and environmental costs and benefits of alternative options, as well as assessment of costs and benefits related to substitution of hazardous substances with safer alternatives). Specifically, external assistance may be required for revision of relevant guidance documents and for preparation of additional guidance stand-alone documents on specific methodological issues as well as to contribute in possible revisions of SEA guidance documents. Another possible set of task could evolve on the identification of environmental or health related externalities. Further methodological development on possible applications of economic instruments could be requested.

13. Services on the derivation of risk estimates

The Agency may need assistance in the development of reference DNELs, dose-response functions, or other risk estimates in the context of chemical risk management procedures under REACH, e.g. restrictions and authorisations. These risk estimates should reflect all available relevant information on the concerned substances in registration dossiers and the scientific literature. The service requires presentation and dissemination of the findings in the Committee for Risk Assessment especially on the assessment of mode of action and the justifications for selection of critical studies and points of departures for the various endpoints.

14. Training

The Agency may need assistance in the development of training materials and/or training modules in any of the above identified subject areas, as well as in carrying out the training programmes. These training programmes may be directed towards Agency staff, staff from Member States, industry and/or NGOs. Such training courses may be short (e.g. 1 day) and focussed on a specific subject and thus, given to a relatively small group. However, they could also be longer (e.g. 1 week) and more general in scope.

There may also be a need for support to awareness raising activities for industry via webinars, workshops preparation, tutorials, web tutorials and other means on specific topics, e.g. on their obligations related to authorisation or substances in articles, Biocidal Products Regulation, PIC Regulation, C&L of mixtures (CLP 2015), Seveso III Directive etc.

15. Services on other scientific and technical issues

The Agency may need assistance in other scientific and technical questions that have not been mentioned above. These could be of cross-cutting nature, e.g. interlinks between legal and technical issues, ad-hoc needs for organising scientific or technical workshops, assisting in summarising comments received during a consultation, assisting in specific issues in relation to Committees etc. The Agency may also request experts/specialists to work in ad-hoc or other working groups of the Committees or the Forum.

Lot 2: Assistance in tasks and activities related to substance identification in all relevant REACH, CLP, BPR and PIC processes, including training and reviewing of inventories and databases.

1. Assistance in substance identification and review of available databases and inventories

The contractor may be asked to contribute to resolve issues related to substance identification, providing scientific support and specialist expertise in diverse chemical fields and retrieving information from literature and databases. This task can include the preparation of reports relating to substance identification strategies for well-defined substances or complex chemicals where multiple compositional grades are manufactured/imported. It can also include the assessment of the impact a given step in a manufacturing process, on a "substance" under REACH/CLP/BPR/PIC.

In addition, studies and reports may be requested concerning how products on the EU market are manufactured, traded, used and disposed of. This task can include the development of case studies for specific substances and/or specific groups of substances and/or for specific issues relating to any of the above.

The contractor may be required to provide support in the assessment and revision of information from literature or on available databases and inventories etc., and to analyse and propose consistent mapping of those databases and inventories.

The contractor may also be asked to perform analysis, development and implementation, needed for improving searching functionality in intelligent databases. Additionally, support with engine updates and data migration from/to chemical databases might be needed.

2. Assistance in regulatory issues related to substance identification

Scientific support may be requested for tasks relating to the assessment of substance identification information in any relevant REACH, CLP, BPR or PIC process.

Scientific support may be requested for the development and/or verification of Substance Identification strategies taken by stakeholder sectors on how to identify their relevant chemicals under REACH and the Biocidal Products Regulation.

Scientific support may be requested concerning stakeholder queries via ECHA helpdesk, national helpdesk, the Forum, or Committees, if speciality expert knowledge and expertise in substance identification is required.

3. Guides on substance identification related items

The Agency may need assistance in the development of guides, manuals, materials and/or modules on concepts concerning substance identity and some of the subject areas identified in point 1, for internal (ECHA) and external distribution.

4. Training on substance identification related items

The Agency may need assistance in the development of training materials and/or training modules in any of the above subject areas identified in point 1, including the use of specific IT-tools relevant for substance identification, and in carrying out the training programmes. These training programmes may be directed towards the Agency staff, staff from Member States, industry and/or NGOs. Such training courses may be short (e.g. one day) or longer (e.g. two or three days) and they may be more general on the above subject areas identified in point 1 or focussed on a specific subject and, thus, given to a relatively small group.

3.4 Description of deliverables

The Contractor is to provide the required reports, documents and/or other deliverables in accordance with the draft framework service contract (see Annex 6.3). The deliverables will vary in nature from request to request and may, for instance, in terms of the size of the reports range from a few pages on specific questions to a comprehensive analysis on a particular issue or series of issues. Thus, a request for services is likely to vary between few consulting days to several months, depending on the nature of the request.

The deliverables will be established as part of the specific contracts undertaken in the context of the framework contract. As examples, the deliverables could be:

- In the form of a draft report that will be followed by a final report taking into account any comments by the Agency.
- In the form of progress reporting if necessary. The contractor could be asked to provide regular reports to the Contract Manager at the Agency. The frequency of reporting may differ depending on the size and complexity of the services and will be stipulated in the specific contract.
- In the form of workshops or training sessions accompanied by appropriate written material and presentations.
- In the form of technical analysis, evaluation, specifications or other scientific methodology development.

All communication during the execution of the contract will be made in English. Reports have to be provided electronically in appropriate format (e.g. Word, Excel, Oracle, html, pdf etc.) and written in clear manner. The final report shall be provided within the deadline stated in the specific contract.

4 The Contract

4.1 The nature of the contract

Per lot, the contractual relationship between the Agency and the successful tenderers will be governed by a special type of Contract known as a "Framework Contract". It should be stressed that Framework Contracts involve no direct commitment and, in particular, do not constitute orders per se. Instead, they lay down the legal, financial, technical and administrative provisions governing the relationship between the Agency and the Contractor during their period of validity. Actual orders will be placed after the Framework Contract is signed and in force, through "Specific Contracts" concluded in implementation of the Framework Contract. The draft Framework Contract specifies the basic conditions applicable to any assignment placed under its terms. Signature of the Framework Contract does not place the Agency under any obligation to place an assignment. The Framework Contract does not preclude the Agency from assigning tasks in the areas set out above to other Contractors or from having these tasks carried out by the Agency staff.

Per lot, the Agency intends to establish Framework Contracts with a minimum of 3 (three), provided that a sufficient number of admissible tenders meet the award criteria, and a maximum of 10 (ten) contractors.

As described in section 4.7 of these Specifications, per lot, there will be re-opening of competition amongst all contractors for each Specific Contract, which will be a "Fixed-Price".

4.2 Starting date of the contract and duration of the tasks

The Contracts shall enter into force on the date on which it is signed by the last contracting party. The indicative intended date for signing the Framework Contracts for both lots is quarter 4 of 2015.

The Framework Contracts will run for a period of 24 months and will be automatically renewed up to two times by 12 months, unless written notification to the contrary is sent by one of the contracting parties and received by the other 3 months before expiry of the contract.

The execution of the tasks may not start before the specific contract has been signed. The period of execution of the tasks may be extended, only with the written agreement of the contracting parties, before the end of the period originally stated in the contract.

4.3 Place of performance

The place of performance of the tasks shall be either the Contractor's premises or the Agency's premises, as stipulated in the specific contracts. In exceptional cases, travel outside the normal location may be required, at the request of the Agency.

4.4 Terms of payment

Payments shall be made in accordance with Article II.15 of the draft Framework Contract and of the respective articles in the draft specific contracts (see Annex 6.3 'Contractual documentation'). The terms and schedule of payment will be laid down in the specific contracts.

For assignments creating an obligation for the tenderer to provide deliverables, payment will be based on prior acceptance of deliverables by the Agency. Requests for payment of accepted deliverables shall be admissible only where they are based on an

invoice made in good and due form. Each invoice must include the detailed list of services covered.

4.5 Liability

4.5.1 Joint Offers

Partners in a joint offer assume joint and several liabilities towards the Agency for the performance of the contract as a whole.

Statements saying, for instance:

- that one of the partners of the joint offer will be responsible for part of the contract and another one for the rest, or
- that more than one contract should be signed if the joint offer is successful

are thus incompatible with the principle of joint and several liabilities. The Agency will disregard any such statement contained in a joint offer, and reserves the right to reject such offers without further evaluation on the grounds that they do not comply with the tender specifications.

4.5.2 Subcontracting

Certain tasks provided for in the contract may be entrusted to subcontractors, but the main tenderer will retain full liability towards the Agency for performance of the contract as a whole. Accordingly:

- the Agency will treat all contractual matters (e.g. payment) exclusively with the main tenderer, whether or not the tasks are performed by a subcontractor;
- under no circumstances can the main tenderer avoid liability towards the Agency on the grounds that the subcontractor is at fault.

During execution of the Contract, the tenderer will need the Agency's express authorization to replace a subcontractor with another and/or to subcontract tasks for which subcontracting was not envisaged in the original offer.

Tenderers must inform subcontractor(s) and include in their sub-contracting documents that Article II.18 of the Framework Contract may be applied to subcontractors.

Once the contract has been signed, Article II.7 of the Framework Contract shall govern subcontracting.

4.6 Data Protection

Any response to the invitation to tender will require the recording and further processing of personal data (name, address, CV, for example). This data will be processed in accordance with the requirements of Regulation (EC) 45/2001 on the protection of individuals with regard to the processing of personal data by Community institutions and bodies and on the free movement of such data. Except if mentioned otherwise, replies to questions and personal data are necessary for the purpose of assessing a tender according to the specifications of the invitation to tender and will only be processed by the Agency's Data Controller for this purpose. A tenderer may, upon request, obtain the communication of personal data and rectify any inaccurate or incomplete personal data.

Any queries concerning the processing of personal data should be addressed to by the Agency's Data Controller. As regards to the processing of personal data, a tenderer has the right to recourse at any time to the European Data Protection Supervisor.

Where the Contract requires the processing of personal data by ECHA, any personal data shall be processed pursuant to Regulation (EC) 45/2001 of the European Parliament and of the Council of 18 December 2000 on the protection of individuals with regard to the processing of personal data by the EU institutions and bodies and on the free movement of such data. Such data shall be processed by the data controller solely for the purposes of the performance, management and monitoring of the contract without prejudice to its possible transmission to the bodies charged with monitoring or inspection tasks in application of Union law.

The contractor shall have the right to access its personal data and the right to rectify any such data. The contractor should address any queries concerning the processing of its personal data to the data controller.

The contractor shall have right of recourse at any time to the European Data Protection Supervisor.

Where the Contract requires the processing of personal data by the contractor, the contractor may act only under the supervision of the data controller, in particular with regard to the purposes of the processing, the categories of data which may be processed, the recipients of the data, and the means by which the data subject may exercise his/her rights.

The data shall be confidential within the meaning of Regulation (EC) No 45/2001 of the European Parliament and of the Council on the protection of individuals with regard to the processing of personal data by the EU institutions and bodies and on the free movement of such data. The contractor shall limit access to the data to the staff strictly necessary for the performance, management and monitoring of the Contract.

The contractor undertakes to adopt appropriate technical and organisational security measures having regard to the risks inherent in the processing and to the nature of the personal data concerned in order to:

- a) prevent any unauthorised person from having access to computer systems processing personal data, and especially:
- b) unauthorised reading, copying, alteration or removal of storage media;
- c) unauthorised data input as well as any unauthorised disclosure, alteration or erasure of stored personal data;
- d) unauthorised persons from using data-processing systems by means of data transmission facilities;
- e) ensure that authorised users of a data-processing system can access only the personal data to which their access right refers;
- f) record which personal data have been communicated, when and to whom;
- g) ensure that personal data being processed on behalf of third parties can be processed only in the manner prescribed by the Agency;
- h) ensure that, during communication of personal data and transport of storage media, the data cannot be read, copied or erased without authorisation;
- i) design its organisational structure in such a way that it meets data protection requirements.

4.7 Implementation of the contract

Per lot, the Contract shall be implemented through specific contracts that will be awarded, following re-opening of competition amongst all contractors in the given lot, on the basis of the award criteria mentioned below:

4.7.1 Award of specific contracts under the framework contract

The tender is assessed according to the following qualitative award criteria and the weighting applicable to each criterion.

Award of Specific Contracts

No	Qualitative award criteria	Weighting (maximum points)
AW1	Quality and relevance of the methodology This criterion refers to the methodology that the tenderer intends to use to complete the tasks required in the service request for a specific contract.	30
AW2	Composition and organisation of the proposed team This criterion relates to the qualifications and professional experience of the staff proposed for the provision of the services. Organisation of the team facilitating the efficient delivery of the requested services is also covered by this criterion.	30
	Total number of points	60

Assessment basis for award criterion AW1

Criterion 1 - Quality and relevance of the methodology

The assessment basis for this award criterion is the Contractor's offer (30 points).

Assessment basis for award criterion AW2

Criterion 2 – Composition and organisation of the proposed team

The assessment basis for this award criterion is the Contractor's offer (30 points).

Tenders scoring less than 70% in the overall points total or less than 50% in the points awarded for a single criterion will be excluded from the rest of the assessment procedure.

The price criterion (P) is evaluated as follows: a maximum of 40 points is given to the lowest price offer. The other offers are ranked according to the following formula:

$$P = (P_{min}/P_o) \times 40$$

where:

P = Classification of the evaluated offer (points to be awarded)

P_{min} = Minimum price offered among all tenders

P_o = Price of the evaluated offer

40 = Maximum points to be awarded

The specific contract will be awarded to the tender which is the most cost-effective (offering the best value for money) on the basis of the following formula:

Final Evaluation	
Total points	=Total Quality Points +Total Price Points

When tendering for specific contracts, the contractors should compete within the maximum limit of the price offered in their tender for the Framework contract, as specified in Section 5.1.2.3.

The price offer (P_o) shall assume the form of a Fixed-Price for the whole duration of the specific contract (including reimbursable costs, where applicable). Maximum unit prices of the Framework contract will apply, which may be possibly revised when the Framework contract is renewed at the beginning of the third year. The price without VAT is going to be used as the basis for the award of the contract.

4.7.2 Nature of specific contracts under the framework contract

All specific contracts will be on a Fixed-Price basis, as specified hereafter as they will correspond to the order of a defined work.

Fixed-Price (FP) orders are assignments of work executed outside the Agency's premises as a rule (i.e. off-site or *extra-muros*) or exceptionally at the Agency's premises. In a Fixed-Price order the Agency specifies the deliverables corresponding to the work to be delivered with the expected timeframe.

The following conditions relating to fixed-price orders apply:

- In a Fixed-Price service request the Agency specifies the deliverables corresponding to the work to be delivered, as well as the delivery schedule.
- The Contractors must present an offer meeting the requirements as specified in the service requests and associated annexes (specifications, work packages, deliverables, deadlines etc.). The technical offer must include a project plan. It has to indicate the proposed activities, the team structure, where applicable, profiles, roles, responsibilities and workload (person-days) of the consultant(s).
- The technical offer must also contain the CVs of the proposed experts. Pre-defined CV forms must be used. All information indicated in the CV has to be correct and validated. Contractor's staff proposed must match the required profile description mentioned under Section 3.2 and the specific needs indicated in the service request⁶.

⁶ See Section 3

- The financial offer must include the price and the reimbursable costs (see Framework contract Art.I.3.3), where applicable. The total price must be based on the estimation of the number of days for each profile and on prices per person-day equal or below the maximum price per person-day indicated in the financial offer for the Framework Contract. The prices must be all-inclusive. However, travel expenses and reimbursable costs shall be reimbursed, but only in case of work performed at a location other than the Contractor’s premises, as indicated in the request for services and in line with the annex to the specific contract.
- Work is performed typically off-site, on the Contractor’s premises. However, some assignments may be for work to be executed on both the Agency’s and the Contractor’s premises. The Contractor shall provide the necessary infrastructure on their premises for the successful execution of the work.
- For activities performed in the Agency, the performance will take place during ECHA working hours, and not during ECHA public holidays.
- The deliverables must be delivered on time, and conform to the specifications, as described in the Specific Contract.
- The invoicing is based on the acceptance of the deliverables by the Agency, independently of the real workload.

4.7.3 Roadmap for specific contracts

Step 1: Need identification



<ul style="list-style-type: none"> • <i>What</i> 	<ul style="list-style-type: none"> • The need for services is identified by the Agency. • The Agency prepares the requirements/specifications. • The Agency specifies how much time it wants to allow the Contractors to prepare their offer. The time allowed to the Contractors must be at least 10 working days as from the Request Date (service request dispatch). "The date, by which the Contractors must submit their offers is referred to as the "submission deadline".
<i>Parties involved</i>	The Agency
<i>Result</i>	<ul style="list-style-type: none"> • Requirements/specifications • "Submission deadline" is fixed

Step 2: Service Request Dispatch



<i>What</i>	<ul style="list-style-type: none"> • The Agency prepares the service request, which indicates the "Submission deadline". • The Agency specifies in the service request the modalities regarding the submission of the offer: in general electronic submission (exceptionally paper submission). • The Agency sends the service request by e-mail to the Contractors, who shall acknowledge receipt. The date on which the Agency sends the service request is referred to as the "Request date".
<i>Parties involved</i>	<ul style="list-style-type: none"> • The Agency • Contractors

<i>Result</i>	<ul style="list-style-type: none"> • "Request date" is fixed. • "Submission deadline" is fixed. • Service request and requirements are dispatched.
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Step 3: Submission of the Offer



<i>What</i>	<ul style="list-style-type: none"> • The Contractors submit an offer, including the technical proposal and the financial offer, by the "submission deadline", according to the modalities mentioned in the service request (electronic submission or paper submission). • The Agency will verify the timely submission of the offers. If the offer has not been submitted by the "submission deadline" it shall be rejected.
<i>Parties involved</i>	<ul style="list-style-type: none"> • Contractors • The Agency
<i>Result</i>	Offers submitted.

Step 4: Evaluation of the Offers



<i>What</i>	<ul style="list-style-type: none"> • The period after the "submission deadline" will be used by the Agency to evaluate the received offers
<i>Parties involved</i>	<ul style="list-style-type: none"> • The Agency
<i>Result</i>	The Agency selects the winning offer and informs by e-mail the Contractors who have submitted an offer.

Step 5: Establishment of the Specific Contract



<i>What</i>	<ul style="list-style-type: none"> • The specific contract is established based on the winning offer. The specific contract will include details of the work to be carried out, the start date, the duration in days and any other relevant information, including the specifications of the Agency and the offer of the Contractor.
<i>Parties involved</i>	<ul style="list-style-type: none"> • Contractors • The Agency
<i>Result</i>	Specific contract is signed.

Step 6: Execution of the Specific Contract



<i>What</i>	<ul style="list-style-type: none"> • The Contractor implements the Contract in line with the requirements set out in the specific contract. • The Agency is informed on a regular basis about the intermediate results achieved. • The final deliverables are provided to the Agency (and if agreed, presented at a deliverables meeting).
<i>Parties involved</i>	<ul style="list-style-type: none"> • Contractor

	<ul style="list-style-type: none"> • The Agency
<i>Result</i>	All tasks outlined in the specific contract are executed.

4.7.4 Acceptance of work

Official acceptance of the work carried out will take place at milestones during and at the end of each specific contract implementation, after acceptance of all deliverables forming part of the assignment. Invoices may be issued only for executed tasks that have been completed and duly accepted by the Agency.

For the specification of deliverables please refer to section 3.4 in this document, and Annex 6.1.1 – Technical Specifications.

4.8 Warranties

The Tenderer shall guarantee:

- (i) To deliver services in a professional way a reasonable person would do in similar circumstances and in accordance with generally accepted standards and practices for similar services, as provided by Articles I.13 and I.19 of the Framework Contract;
- (ii) The results of deliverables from services provided will continue to meet the Technical Specifications for the specific contract;
- (iii) The services and deliverables provided on the basis of this Framework Contract and their use by ECHA shall not infringe the intellectual property rights of others.

4.9 Intellectual Property Rights

Any deliverable, information asset, software asset, etc. created or used within the realm of this Framework Contract, which is not specifically licensed by the Contractor or purchased/licensed from a third party, shall be the intellectual property of ECHA, even when stored on the Contractor’s premises. At the end of the Framework Contract or in case of termination/not renewal, the Contractor shall hand over to the Agency all such assets in line with the “hand-over procedure”, as laid down in Technical Specifications.

4.10 Amendments to the Framework Contract

In exceptional cases duly justified by the applicable public procurement rules, when agreed by the Agency and the Contractor, the Framework Contract may be amended. Such instances may be, e.g. omissions of certain aspects, needs to amend or change technical specifications for particular parts (e.g. due to technological advances not foreseen at the time of writing), and similar well-grounded reasons. An amendment must be duly documented and the associated contract amendment signed by both parties before it becomes effective. The Framework Contract amendments will become an integral part of the original Framework Contract.

5 The procurement procedure

5.1 Preparation of the tender

5.1.1 General

Tenders must be clear and concise, with continuous page numbering, and assembled in a coherent fashion (e.g., bound or stapled, etc.).

Tenders must be written in one of the official languages of the European Union.

Tenders must include the following information:

- all the information and documents requested by the Agency in order to assess the tender;
- the price in euros;
- a statement (e.g. cover letter) signed by a duly authorised representative of the tenderer/s confirming that the tender is valid and its period of validity (six months);
- the name and contact details of a contact person of the tenderer/s in relation to the submission of the bid.

If this is not included, the tender may be excluded from the procedure for the award of the contract.

Since tenderers will be judged on the content of their written bids, these must make it clear that they are able to meet the requirements of the tender specifications.

5.1.2 Content of the tender

Tenders must be presented in three sections:

Section one: Administrative proposal – including documentation regarding eligibility, exclusion and selection criteria (see section 5.1.2.1).

Section two: Technical proposal – including documentation and proposal regarding quality award criteria (see section 5.1.2.2).

Section three: Financial proposal - including documentation and proposal regarding financial award criterion (see section 5.1.2.3).

If a tenderer bids for both lots, one single tender dossier may be submitted. In this case, section one, may be common to both lots (making a clear reference to the respective lot for the evidence to be provided with regard to the selection criteria), whereas sections two and three shall be lot-specific.

5.1.2.1 Section One: Administrative proposal

Eligibility documentation

The competition is open to any physical person or legal entity coming from countries within the EU and any other physical person or legal entity from a third country that has concluded with the European Union a specific agreement in the area of public contracts, under the conditions provided for in that agreement.

In practice, the participation of applicants from third countries that have concluded a bilateral or multilateral agreement with the European Union in the area of public contracts must be allowed, under the conditions provided for in that agreement.

This call for tenders is not covered by the Government Procurement Agreement (GPA).

To identify themselves tenderers must fill in a Legal Entity Form and a Financial Identification Form:

The **Legal Entity Form**⁷ is to be signed by a representative of the tenderer authorised to sign contracts with third parties.

The **Financial identification**⁸ form shall be duly filled in and signed by an authorised representative of the tenderer and its banker.

The above forms must be accompanied by the evidence as indicated in the footnotes at the bottom of each form.

Both joint offers and subcontracting are allowed in response to this call for tenders. Offers may even combine both approaches. In any case, the tender documents must specify very clearly by means of the appropriate forms, detailed hereafter, whether each company involved in the tender is acting as a partner in a joint offer or as a subcontractors (this also applies where the various companies involved belong to the same group, or even where one is the parent company of the others).

All tenderers must provide their legal entity form as well as the evidence indicated at the bottom of that form.

Subcontractors are only obliged to provide the legal entity form without the evidence, and are not required to present the financial identification form.

In case of a joint offer, only the co-ordinator/group leader must return the financial identification form.

In case of a tenderer submitting a joint offer who has already set up a consortium or similar entity for conducting the project in case a contract will be awarded, the tenderer should mention this fact in the tender, together with any other relevant information in this connection.

In case of tenderers submitting a joint offer who have not yet set up a consortium or similar entity, the tenderers should be aware that, in case the tenderers are awarded the contract, the Agency may require the tenderer to give a formal status to this collaboration before the contract is signed. This can take the form of:

- an entity with legal personality recognized by a Member State; or
- an entity without legal personality but offering sufficient protection of the Agency's contractual interests (depending on the Member State concerned, this may be, for example, a consortium or a temporary association).

In case of tenderers submitting a joint offer, the tenderers are asked to fill in and duly sign one of the attached **powers of attorney**⁹, depending on the set up that has been chosen by the tenderers.

If the tenderer envisages subcontracting, the tender must include:

- a **document**¹⁰ clearly stating the roles, activities and responsibilities of the proposed subcontractor(s), and the reasons why subcontracting is envisaged;
- a **letter of intent**¹¹ by each proposed subcontractor(s) stating its intention to collaborate with the tender if the tenderer wins the contract and their willingness

⁷ This form is available at:

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

⁸ The form is available at:

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

⁹ See Annex 6.2.2

¹⁰ To be provided in free format

to accept the tasks and the terms and conditions set out in these Tender Specifications and in the draft Framework Contract attached (in particular article II.18 of the Framework contract).

Exclusion criteria documentation

Tenderers or their representatives shall provide a **declaration on their honour**¹², duly signed and dated in which they:

- state whether or not they are in one or more of the situations referred to in Articles 106 and 107 of the Financial Regulation and detailed in the form;
- undertake to submit to the Agency any additional document relating to the exclusion criteria, that the Agency considers necessary to perform its checks, within seven calendar days following the receipt of the Agency's request.

Where the bid constitutes a joint offer, each entity must provide the form. Where the total amount envisaged for subcontracting is equal to or exceed 30% of the total contract value (independently of the individual subcontractor's contribution to the contract by value), the potential subcontractor(s) must also provide the form (as required from the potential tenderer). The same applies regarding the requirement to present evidence of compliance with the exclusion criteria.

By returning the above-mentioned form, duly signed and dated, tenderers confirm that they have been notified of the following points.

Administrative or financial penalties may be imposed by the Agency on tenderers who are in one of the cases of exclusion provided for in Articles 106 and 107 of the Financial Regulation after they have been given the opportunity to present their observations.

These penalties are detailed in Article 109 of the Financial Regulation and Articles 142 and 145 of the Rules of Application.

Selection criteria documentation

General

This part of the tender concerns the criteria and evidence relating to the technical and professional capacity and economic and financial capacity of the service provider(s) involved in the bid. It should also contain any other document that the tenderer(s) wish(es) to include by way of clarification. The evidence for the selection criteria shall be assessed in the second stage of the evaluation of the tenders¹³.

An economic operator may rely on the capacities of other entities, regardless of the legal nature of the links which it has with them. In that case, evidence must be provided that it will have at its disposal the resources necessary for performance of the contract, for example by producing a clear undertaking on the part of those entities to place those resources at its disposal.

In addition, all tenderers are informed that they may be asked to prove that they are authorised to perform the contract under national law, as evidenced by inclusion in a professional or trade register or a sworn declaration or certificate, membership of a specific organisation, express authorisation, or entry in the VAT register.

¹¹ See Annex 6.2.1

¹² See Annex 6.2.3

¹³ See Section 5.4

In case of joint offer or sub-contracting, the tenderer(s) must stipulate the role, qualifications and experience of each service provider and, where relevant, the monitoring arrangements that exist between them.

In case of sub-contracting for which the total amount envisaged is equal to or exceed 30% of the total contract value (independently of the individual subcontractor's contribution to the contract by value), evidence of the ability of the potential subcontractor(s) to perform the tasks entrusted to him/them shall be included in the offer. Such evidence is the same as that one also required from the tenderer, however, subcontractor(s) have to provide the documents to prove their capacity only for the parts of the contract that are relevant to them. The evidence provided will be checked to ensure that the tenderer with the subcontractor(s) altogether fulfil the criteria.

Selection criterion 1: Evidence of the economic and financial capacity of the service provider(s)

This proof is to be provided by submitting the completed Financial and Economic Capacity Overview Form¹⁴, as well as a full copy of the tenderer's annual accounts (balance sheet, profit and loss account, notes on the accounts and auditors' remarks when applicable) of the last three years, as approved by the general assembly of the company and, where applicable, audited and/or published. These documents must be certified by the tenderer.

If, for some exceptional reason which the Agency considers justified, a tenderer is unable to provide one or other of the above documents, he or she may prove his or her economic and financial capacity by any other document which the Agency considers appropriate. In any case, the Agency must at least be notified of the exceptional reason and its justification in the tender. The Agency reserves the right to request any other document enabling it to verify the tenderer's economic and financial capacity.

All tenderers must provide proof of their economic and financial capacity. The assessment of whether the minimum average annual turnover¹⁵ criterion is met will be based on a consolidated assessment (tenderer plus partners/subcontractors). Therefore, in the case of joint offer or subcontracting each partner in a joint offer and all sub-contractors contributing to the required financial and economic capacity shall provide the evidence mentioned above.

Selection criterion 2: Evidence of the technical and professional capacity of the service provider(s)

The ability of service providers to perform services will be assessed in particular with regard to their know-how, experience and reliability.

By submitting a tender, each legal entity involved therein accepts the possibility of a check being carried out by the Agency on its technical capacities and quality control measures.

Evidence of the technical and professional capacity of the providers involved in the tender must be furnished on the basis of the following documents:

¹⁴ See Annex 6.2.4

¹⁵ In case of tenderers from outside the Eurozone, amounts of turnovers shall be calculated using exchange rates for December of the relevant financial year as published in the Official Journal of the European Union:
http://ec.europa.eu/budget/contracts_grants/info_contracts/infoeuro/infoeuro_en.cfm

Lot 1: Assistance in the processes related to evaluation, restriction, authorisation, harmonised classification and labelling, and biocidal products, excluding activities pertaining to substance identification.

a) Evidence for selection criterion 2.1:

- i. The CV's (in Europass format – see link: <https://europass.cedefop.europa.eu/en/documents/curriculum-vitae>) of 4 experts and 4 senior experts;
- ii. The copy of the relevant University diploma for the above mentioned 4 experts and 4 senior experts;

b) Evidence for selection criterion 2.2:

A list of, at least, four relevant (in terms of subject¹⁶ and value¹⁷) reference projects executed in the last five years, with the values, dates and places. For each reference project it is mandatory to fill in one project reference form¹⁸. The Agency shall be authorised to contact the indicated person to verify the reference.

Lot 2: Assistance in tasks and activities related to substance identification in all relevant REACH, CLP, BPR and PIC processes including training and reviewing of inventories and databases.

a) Evidence for selection criterion 2.1:

- i. The CV's (in Europass format – see link: <https://europass.cedefop.europa.eu/en/documents/curriculum-vitae>) of 3 experts and 2 senior experts;
- ii. The copy of the relevant University diplomas for the above mentioned 3 experts and 2 senior experts;

b) Evidence for selection criterion 2.2:

A list of, at least, three relevant (in terms of subject¹⁹ and value²⁰) reference projects executed in the last five years, with the values, dates and places. For each reference project it is mandatory to fill in one project reference form²¹. The Agency shall be authorised to contact the indicated person to verify the reference.

5.1.2.2 Section Two: Technical proposal

Qualitative award criteria documentation

Please note that, to grant equal treatment of all tenders, it is not possible to modify offers after their submission in relation to the technical and financial proposals. As a consequence, incompleteness in this section can only result in negative impact on the tender evaluation against the award criteria. Please note also, that proposals deviating from the technical specifications may be rejected for non-conformity.

¹⁶ Relevance in terms of subject is coverage of the task(s) mentioned under Section 3.3

¹⁷ Relevance in terms of value is a value of minimum € 30.000 per project

¹⁸ Project reference form to be used (see Section 6.2.5.)

¹⁹ Relevance in terms of subject is coverage of the task(s) mentioned under Section 3.3

²⁰ Relevance in terms of value is a value of minimum € 30.000 per project

²¹ Project reference form to be used (see Section 6.2.5.)

The technical specifications and the tenderer's bid shall be integral parts of the contract and will constitute annexes to the contract.

Tenders should elaborate on all points addressed by these specifications in order to score as many points as possible. The mere repetition of mandatory requirements set out in these specifications, without going into details or without giving any added value, will only result in a very low score. In addition, if certain essential points of these specifications are not expressively covered by the tender, the Agency may decide to give a zero mark for the relevant qualitative award criteria.

The assessment will be performed by applying the award criteria mentioned below. These award criteria will be assessed on the basis of the Questionnaire and the Case study for the respective lot given in Section 6.1 "Documentation for the award criteria".

Assessment of the award criteria under the Framework contract:

Assessment basis for award criterion AW1

Criterion 1 – Understanding of the tasks and quality of the proposed services

The assessment basis for this award criterion is the reply provided to the Questionnaire under Annex 6.1.1 (35 points)

Assessment basis for award criterion AW2

Criterion 2 – Efficiency and project management

The assessment basis for this award criterion is the reply provided to the case study for the respective lot developed under Annex 6.1.2 (25 points)

5.1.2.3 Section Three: Financial proposal

Financial award criteria documentation

Tenderers must use the financial form in Annex 6.1.3 to formulate their financial offer.

It is mandatory that the pricing is fully transparent and tenderers attention is drawn to the following points:

- The Financial form will be annexed to the Framework Contract and shall constitute an integral part of it. The maximum unit prices of the financial form shall apply to specific contracts signed under the Framework Contract.
- prices must be expressed in euros;
- prices should be quoted free of all duties, taxes and other charges, i.e. also free of VAT, as the European Union is exempt from such charges in the EU under Articles 3 and 4 of the Protocol on the Privileges and Immunities of the European Union of 8 April 1965 (OJEC L 152 of 13 July 1967). Exemption is granted to the Agency by the governments of the Member States, either through refunds upon presentation of documentary evidence or by direct exemption. For those countries where national legislation provides an exemption by means of a reimbursement, the amount of VAT is to be shown separately. In case of doubts about the applicable VAT system, it is the tenderers responsibility to contact his national authorities to clarify the way in which the European Union is exempt from VAT;
- Prices shall not be conditional Prices shall be maximum unit prices within which limit the successful tenderers will compete at the level of the service requests. The maximum prices are fixed and not subject to revision for specific contracts placed during the first two (2) years of duration of the Framework Contract. The maximum prices may be subject to price revision at the beginning of the third year in case the contract is renewed. Price revision shall be done in accordance with Article I.3.2 of the Contract (see Annex 6.3).

At the beginning of the third year of the Contract, 80% of each price may be revised upwards or downwards, if such revision is requested by one of the contracting parties by registered letter no later than three months before the second anniversary of the date on which it was signed. The Agency shall purchase on the basis of the prices in force on the date on which specific contracts are signed. Such prices shall not be subject to revision.

The revision shall be determined by the trend in the harmonised consumer price index (MUICP) published for the first time by the Publications Office of the European Union in the Eurostat monthly 'Data in Focus' publication at <http://www.ec.europa.eu/eurostat/>

Revision shall be calculated in accordance with the following formula:

$$Pr = Po (0,2+0,8 Ir/Io)$$

Pr - revised price

Po - price in the original tender

Io - monthly index of the final date for submitting tenders

Ir - monthly index of the date on which the request for price revision was received

- **The financial proposal for the award of the Framework Contracts** shall be based on the maximum prices for the two categories of experts according to the

weighting mentioned in the price reference table (Annex 6.1.3 Financial Offer) in light of the estimated use of each of the different categories of experts (50% for each category).

- **The financial offer for the award of the specific contracts** shall consist of (i) the total (maximum) amount in payment of the tasks executed and, where applicable, (ii) the amount corresponding to the reimbursable expenses connected with work executed outside the Contractor's premises.

The reimbursable costs, referred to in Article I.3.4 of the Framework Contract, correspond to expenses directly incurred by the Contractor in the execution of the tasks under a given specific contract. Reimbursable expenses are travel, subsistence and shipment expenses in accordance with the rules on reimbursement set out in Article II.16 of the Framework Contract. The daily scales applicable to subsistence expenses are set out in Annex IV of the Framework Contract.

The amount for reimbursable costs estimated on the basis of above articles of the Framework Contract must be indicated in the financial offer separately from the value of the services as in (i), and shall constitute the maximum amount that can be paid for reimbursable expenses incurred in the implementation of the specific contract.

- For work executed at the Contractor's premises no additional reimbursable costs may be charged. Prices for the services as in (i) are all-inclusive.

All tenders must contain all the information and all the supporting documents required by these specifications. Please note that it is not possible to modify the financial proposal after the submission of the tender. In the absence of the required information or documents, the Agency may disqualify the bid. The Agency reserves the right, however, to request additional evidence in relation to the bid submitted for evaluation or verification purposes within a time-limit stipulated in its request.

5.1.3 Submission of the tender

The detailed instructions for the submission of tenders can be found in the Invitation to Tender in the open procurement procedure ECHA/2015/50 for the Multiple Framework Contracts with Re-opening of Competition for Scientific Services (2 lots), signed by the legal representative of the Agency on 10 July 2015.

Tenderers shall precisely and carefully observe the instructions.

- Late submission by post or courier service or late hand-delivery will lead to the exclusion of the tender from the award procedure for this contract.
- Offers sent by e-mail or by fax will also be non-admissible.
- Envelopes found open at the opening session will also lead to non-admissibility of the tender. Consequently, tenderers must ensure that their bids are packed in such a way as to prevent any accidental opening during its mailing.

5.2 Opening of the tenders

Tenders will be opened at 14:00 on 25/09/2015 at the following location:

*Office address:
European Chemicals Agency (ECHA)
Annankatu 18
00120 Helsinki
Finland*

One (1) representative of each tenderer may attend the opening of the bids. Tenderers wishing to attend are requested to notify their intention by sending an e-mail at least 2 working days in advance to the above-mentioned e-mail address. This notification must be signed by an authorised representative of the tenderer and specify the name of the person who will attend the opening of the bids on the tenderer's behalf.

5.3 Evaluation of the tenders

The evaluation will be based on each tenderer's offer. In addition, the Agency reserves the right to use any other information from public or specialist sources.

All the information will be assessed in the light of the criteria set out in these specifications. The procedure for the award of the contract, which will concern only admissible offers, will be carried out in three successive stages.

Only offers meeting the requirements of one stage will be examined in the next stage.

The aim of each of these stages is:

1. to check, in the first stage (exclusion criteria), whether tenderers can take part in the tendering procedure and, where applicable, be awarded the contract;
2. to check, in the second stage (selection criteria), the technical and professional capacity and economic and financial capacity of each tenderer who has passed the exclusion stage;
3. to evaluate on the basis of the award criteria the technical and financial tenders and establish a ranking list, by order of merit, of all tenders having passed the exclusion and selection stages, as well as the quality thresholds set for the evaluation of the award criteria.

5.3.1 Stage 1 – application of exclusion criteria

In accordance with Articles 106 and 107 of the Financial Regulation, tenderers shall be excluded from the selection and award procedures if they do not satisfy criteria a) to f) specified in the exclusion criteria form²².

Furthermore, contracts may not be awarded to tenderers who, during the procurement procedure are subject to a conflict of interest (criteria g) or are guilty of misrepresentation in supplying the information required by the contracting authority as a condition of participation in the contract procedure or fail to supply this information (criteria h) or fall into one of the situations as specified under criteria a) to f).

²² See section 5.1.2.1

5.3.2 Stage 2 - application of selection criteria

These criteria will be assessed on the basis of the documents indicated²³

Lot 1: Assistance in the processes related to evaluation, restriction, authorisation, harmonised classification and labelling, and biocidal products, excluding activities pertaining to substance identification.

<u>SELECTION CRITERIA</u>
1. FINANCIAL AND ECONOMIC CAPACITY
1.1 Sufficient economic and financial capacity to guarantee continuous and satisfactory performance throughout the envisaged lifetime of the contract, in terms of a minimum average annual turnover (or expenditure for public institutions) of at least € 500.000 over the last three years.
2. TECHNICAL AND PROFESSIONAL CAPACITY
2.1 The ability to provide the necessary human resources to carry out the tasks in terms of at least 4 senior experts and 4 experts according to the profiles mentioned under Section 3.2. covering together on the basis of the university degrees the following academic areas: <ul style="list-style-type: none">1) Chemistry2) Toxicology3) Ecotoxicology4) Socio-economic analysis. These experts shall have proven collective work experience in the following areas: <ul style="list-style-type: none">1) Organic chemistry, inorganic chemistry, analytical chemistry, material science, and process engineering (a minimum of four areas to be covered).2) Toxicological and eco-toxicological testing methods including alternative testing methods (or other predictive methods).3) Toxicological and eco-toxicological hazard assessment, exposure assessment, risk assessment and risk management related to industrial chemicals or biocidal products.4) Chemical safety assessment (CSA) and its implementation using specific tools <u>such as</u> IUCLID and Chesar, and tools supporting exposure estimation <u>such as</u> ECETOC TRA, Stoffenmanager, ART, Consexpo and EUSES.5) ChemoInformatics including generation and use of different notations for chemical structure, quantitative structure-activity relationships (QSAR) and (eco)toxicological information or fate modelling.6) Environmental and industrial economics and socio-economic assessment relevant for the regulatory management of chemicals.
2.2. At least four relevant (in terms of subject ²⁴ and value ²⁵) reference projects in the past five years covering all together at least three of the areas of expertise mentioned in Section 3.2.

²³ See section 5.1.2.1

²⁴ Relevance in terms of subject is coverage of the task(s) mentioned under Section 3.3

²⁵ Relevance in terms of value is a value of minimum € 30.000 per project

A consolidated assessment shall be made for joint offers (all members of the consortium together) and in case of subcontracting (tenderer plus subcontractor).

Lot 2: Assistance in tasks and activities related to substance identification in all relevant REACH, CLP, BPR and PIC processes including training and reviewing of inventories and databases.

<u>SELECTION CRITERIA</u>
1. FINANCIAL AND ECONOMIC CAPACITY
1.1 Sufficient economic and financial capacity to guarantee continuous and satisfactory performance throughout the envisaged lifetime of the contract, in terms of a minimum average annual turnover (or expenditure for public institutions) of at least € 200.000 over the last three years.
2. TECHNICAL AND PROFESSIONAL CAPACITY
2.1 The ability to provide the necessary human resources to carry out the tasks in terms of at least 2 senior experts and 3 experts according to the profiles mentioned under Section 3.2. covering together on the basis of the university degrees the following academic areas: <ul style="list-style-type: none">1) Chemistry2) Industrial chemistry3) Chemical and process engineering These experts shall have proven collective work experience in the following areas: <ul style="list-style-type: none">1) Organic chemistry, inorganic chemistry, analytical chemistry, biochemistry, material science and industrial chemistry,2) Chemical and process engineering,3) Substance identification under REACH/CLP/BPR/PIC,4) Chemical nomenclature (i.e. IUPAC rules), various conventions and inventories and chemical and scientific literature databases related to substance identity.
2.2. At least <u>three</u> relevant (in terms of subject ²⁶ and value ²⁷) reference projects in the <u>past five years</u> covering all together at least three of the areas of expertise mentioned in Section 3.2.

A consolidated assessment shall be made for joint offers (all members of the consortium together) and in case of subcontracting (tenderer plus subcontractor).

Stage 3 - application of award criteria

The Framework contract shall be awarded under the best-value-for-money procedure to the most cost-effective tender. The following award criteria will be applied for both lots:

²⁶ Relevance in terms of subject is coverage of the task(s) mentioned under Section 3.3

²⁷ Relevance in terms of value is a value of minimum € 30.000 per project

5.3.3 Stage 3 - application of award criteria

For the award of the framework contracts the following qualitative and price criteria will be applied:

No	Qualitative award criteria	Weighting (maximum points)
AW1	<p>Understanding of the tasks and quality of the proposed services</p> <p>This criterion serves to assess the tenderer's understanding of the tasks (Section 3.3) for the respective lot and the degree to which the tenderer shows how carrying out the tasks of the contract would support ECHA in the implementation of the REACH, the CLP, the Biocidal Products and the PIC Regulations.</p> <p>This criterion also assesses how the tenderer intends to deliver the multidisciplinary services covering the different tasks (in depth²⁸ and breadth²⁹).</p>	35
AW2	<p>Efficiency and project management</p> <p>This criterion relates to the quality of methods and approaches, project planning, team organisation, communication/interaction methods, project management and quality assurance methods with a view to execute multidisciplinary projects effectively.</p>	25
	Total number of points	60

The selected tenders are assessed according to the above qualitative award criteria and the weighting applicable to each criterion.

Tenders scoring less than 60% in the overall points total or less than 50% in the points awarded for a single criterion will be excluded from the rest of the assessment procedure.

²⁸ In terms of specific expertise related to a given task

²⁹ In terms of coverage of different tasks

Price criterion

The price criterion (P) is evaluated as follows: a maximum of 40 points is given to the lowest price offer. The other offers are ranked according to the following formula:

$P = (P_{min}/P_o) \times 40$

where:

P = Classification of the evaluated offer (points to be awarded)

P_{min} = Minimum price offered among all tenders

P_o = Price of the evaluated offer

40 = Maximum points to be awarded

A framework contract will be awarded to tenders (maximum 10 for both lots) which are the most cost-effective (offering the best value for money) on the basis of the following formula:

Final Evaluation	
Total points	= Total Quality Points + Total Price Points

5.4 Award of the contract

The Agency will inform tenderers of decisions reached concerning the award of the contract, including the grounds for any decision not to award a contract or to cancel the procedure.

If a written request is received from any non-successful tenderer, the Agency will inform the tenderer of the reasons for their lack of success and of the name and characteristics and relative advantages of the successful tenderers.

However, certain information may be withheld where its release would impede law enforcement or otherwise be contrary to the public interest, or would prejudice the legitimate commercial interests of economic operators, public or private, or might prejudice fair competition between them.

The Agency shall not sign the framework contract with the successful tenderers until a standstill period of 10 calendar days has elapsed, running from the day after the simultaneous dispatch by electronic means of the notification letters to the tenderers informing them of the award decision.

During the standstill period, the Agency will request the tenderers proposed for award to provide the evidence on exclusion criteria defined in Articles 106 and 107 of the Financial Regulation. If this evidence was not provided or proved to be unsatisfactory, the Agency reserves the right to cancel the award procedure or to change the award decision to the benefit of the next best ranked tenderer on condition that he satisfies with the provision of the evidence on exclusion.

The tenderers to whom the contract is to be awarded shall provide, within the 15 calendar days following the receipt of the letter informing him of the proposed award of the contract and preceding the signature of the contract, the following evidence confirming the declaration of honour:

1. The Agency shall accept as satisfactory evidence that the tenderer to whom the contract is to be awarded is not in one of the situations described in point (a), (b) or (e) of Article 106(1) of the Financial Regulation, a recent extract from the judicial record or, failing that, an equivalent document recently issued by a judicial or administrative authority in the country of origin or provenance showing that those requirements are satisfied;
2. The Agency shall accept, as satisfactory evidence that the tenderer is not in the situation described in point (d) of Article 106(1) of the Financial Regulation, a recent certificate issued by the competent authority of the State.
3. Where the document or certificate referred to in paragraph 1 and 2 is not issued in the country concerned and for the other cases of exclusion referred to in Article 106 of the Financial Regulation, it may be replaced by a sworn or, failing that, a solemn statement made by the interested party before a judicial or administrative authority, a notary or a qualified professional body in his country of origin or provenance.
4. Depending on the national legislation of the country in which the tenderer is established, the documents referred to in paragraphs 1, 2, and 3 shall relate to legal persons and/or natural persons including, where necessary, company directors or any person with power of representation, decision-making or control in relation to the tenderer or tenderer. This would be the case when the national legislation concerned gives juridical responsibility of the acts committed by a legal entity (moral persons) to their legal representatives. The tenderer shall provide information on the ownership or on the management, control and power of representation of the legal entity whenever necessary for the proper understanding of the evidence submitted or whenever the Agency requests it.

5. Where they have doubts as to whether tenderers are in one of the situations of exclusion, the Agency may itself apply to the competent authorities referred to in paragraph 3 to obtain any information they consider necessary about that situation.

The Agency may waive the obligation of a tenderer to submit the documentary evidence referred to in paragraphs 1 and 2 if such evidence has already been submitted to it for the purposes of another procurement procedure and provided that the issuing date of the documents does not exceed one year and that they are still valid. In such a case, the tenderer shall declare on his honour that the documentary evidence has already been provided to the Agency in a previous procurement procedure and confirm that no changes in his situation have occurred. He shall indicate in its tender all the references necessary to allow the Agency services to check this evidence.

After the period of validity of the tender has expired, conclusion of the contract shall be subject to the tenderer's agreement in writing.

6 Annexes

6.1 Documentation for the award criteria

The technical documentation consists of the following documents:

- Annex 6.1.1 – Questionnaire for lot 1 and lot 2
- Annex 6.1.2 – Case studies for lot 1 and lot 2
- Annex 6.1.3 – Financial offer form for lot 1 and lot 2

6.2 Administrative documentation

The administrative documentation includes forms concerning identification and eligibility of tenderers, as well as exclusion and selection criteria.

- Annex 6.2.1 – Letter of intent
- Annex 6.2.2 – Power of Attorney document
- Annex 6.2.3 – Exclusion criteria form
- Annex 6.2.4 – Financial and Economic Capacity Overview Form
- Annex 6.2.5 – Project Reference form

6.3 Contractual documentation

Draft Framework Service Contract.

6.4 Checklist of documents to be submitted

The purpose of the table below is to facilitate the preparation of the tender by providing an overview of the documents that must be included (marked by ■) depending on the role of each economic operator in the tender (coordinator/group leader in joint bid, partner in joint bid, single contractor, main contractor, subcontractor). Some of the documents are only relevant in cases of joint bids or when subcontractors are involved. Additional documents might be necessary depending on the specific characteristics of each tender.

Description	Section	Coordinator or group leader in joint bid	All partners in joint bid	Single or Main contractor	Sub- contractor
Power of attorney of partners in joint bid indicating the group leader (see Annex 6.2.2)	1		■		
Letter(s) of intent of subcontractor(s) (see Annex 6.2.1)	1				■
Legal Entity Form Download the form from:	1	■	■	■	■

http://ec.europa.eu/budget/contracts_grants/info_contracts/legal_entities/legal_entities_en.cfm					
Supporting documents for the Legal Entity Form	1	■	■	■	
Financial Identification Form Download the form from: http://ec.europa.eu/budget/contracts_grants/info_contracts/financial_id/financial_id_en.cfm	1	■		■	
Exclusion Criteria Form (see Annex 6.2.3)	1	■	■	■	■ (30%)
Evidence of Economic and financial capacity (see Annex 6.2.4)	1	■	■	■	■
Financial and Economic Capacity Overview Form	1	■	■	■	■
Evidence of Technical and professional capacity	1	■	■	■	■
CV's and copies of the University diplomas Download the form for the CVs: https://europass.cedefop.europa.eu/en/documents/curriculum-vitae	1	■		■	
Project Reference form (see Annex 6.2.5)	1	■		■	

The following Sections must be provided in the bid, their absence would mean rejection of the bid for incompleteness:

Description	Section	Coordinator or single tenderer
Technical offer	2	■
Financial offer	3	■