

ECHA/2013/109

**Framework Service Contract
for the development of Phase 3 of the QSAR
Toolbox**

**Open Procurement Procedure
Specifications**

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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 should be understood as referring to that product or its equivalent.

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 a Framework Contract for the development of Phase 3 of the QSAR Toolbox.
Lots	This call for tenders is not divided into lots.
Volume (indicative)	<p>The overall value of the Framework Contract is estimated between 1 800 000 and 2 400 000 €.</p> <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 value of the Framework Contract 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>
Contracts	The European Chemicals Agency will sign a single framework service contract with the successful tenderer offering best value for money. A Draft Framework Contract is attached as Annex 5.3.
Submission of offers	Each tenderer can only submit <u>one</u> offer.
Duration of Framework Contract	<p>The total maximum duration of the Framework Contract shall be six (6) years for the development plus four (4) years of corrective maintenance. This duration should allow for the implementation of agreed scientific/technical tasks and smooth implementation until the last REACH registration deadline of 2018, and the additional maintenance period will ensure that the system can be maintained throughout its lifetime.</p> <p>The initial contract duration for the development will be 2 years, renewed automatically up to 2 times, each for a period of 2 years. The duration for the maintenance will be 1 year, renewed up to 3 times, each for a period of 1 year. During these additional 4 years, the use of the Framework Contract will be limited to the corrective maintenance; namely no overhaul to the system will take place if the Framework Contract continues in years 7 to 10.</p>

Places of delivery	The place of performance of the services shall be the tenderer's premises and ECHA's\OECD premises, and any other place as agreed in the specific contract or order form 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.

1 Introduction

1.1 About ECHA

The European Chemicals Agency (ECHA) is the driving force in implementing the REACH 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 now regulatory tasks related to four pieces of EU legislation¹: 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).

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. The Regulation will enter into operation in September 2013.

PIC sets requirements for the import and export of certain hazardous chemicals. The regulation implements the Rotterdam Convention at EU level. The Regulation will enter into operation in March 2014.

1.2 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 29.10.2012 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.

¹ On the ECHA web site (<http://echa.europa.eu/>), the REACH, CLP, BPR and PIC Regulations are located in section "Document Library".

In submitting his tender, the tenderer accepts in full and without restriction the requirements of these Tender Specifications, and the Special and General conditions governing this Contract as the sole basis of this tendering procedure, whatever his own conditions of sale may be, which he hereby waives. 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.

2 The Services Required

2.1 Background

The aim of this call for tenders is the selection of a service provider for the development of Phase 3 of the QSAR Toolbox application (or Toolbox in this document).

2.1.1 About the project

In 2003, the OECD launched its QSAR Project, with the aim to improve the acceptance of the use of QSARs in fulfilling data needs in various regulatory settings. The launching of the project is a response both to the increasing attention to avoiding unnecessary use of laboratory animals and to increase the knowledge on chemical substances in an as cost-efficient way as possible. One of the work items of the OECD QSAR Project is the development of a QSAR Toolbox (hereafter referred to as the Toolbox). The Toolbox is a software application intended to be used by OECD member countries, chemical industry and other stakeholders in filling gaps in data needed for assessing the hazards of chemicals. The Toolbox incorporates information and tools from various sources into a logical workflow. Crucial to this workflow is grouping of chemicals into chemical categories.

The Toolbox was being developed in phases. In June 2005 the development of the QSAR Toolbox was endorsed. Phase 1 focused on the technological proof-of-concept. It provided the support for developing chemical categories, for using a number of data gap filling techniques, including a library of QSAR models which OECD member countries use for various regulatory purposes. In 2008, based on the experience from phase 1 of the Toolbox development project, phase 2 was launched with the help and a financial contribution from the European Chemicals Agency (ECHA). Phase 2 work focused on expanding and refining the chemical category approach. Phase 2 followed a 48-month work plan which began in the 4th quarter of 2008. The work plan had five thematic areas namely Information Technology, Chassis Development and Additional Functionalities, Database Compilation, QSAR Library and Expert System Compilation, and Training. The implementation of the features was divided between two versions. Version 2.0 was released in October 2010 and Version 3.0 in October 2012. This last version has been updated in January 2013 with the release of version 3.1. This stand-alone system can be downloaded from the following web site: <http://www.qsartoolbox.org>.

The success of the current version of the Toolbox has led to the formulation of Phase 3 and a chance to further address the long-term issues associated with the prediction of complex hazard endpoints. Specifically, the major areas for Phase 3 development are; (i) usability improvement, (ii) scientific development, including implementation of Adverse Outcome Pathways (AOPs), (iii) development of additional functionalities, (iv) general improvements related to enhancements of IT technology, and (v) corrective system maintenance. While there are five focus areas, many of the proposed Phase 3 projects are interrelated and affect more than one focus area.

2.1.2 QSAR Toolbox application

2.1.2.1 What is the Toolbox

The Toolbox is a software application to identify and fill (eco) toxicological data gaps for chemicals hazard assessment. Grouping chemicals into chemical categories is crucial to the workflow of the Toolbox.

2.1.2.2 What tools are available?

The Toolbox contains:

- Databases with results from experimental studies
- Accumulated knowledge for structural characteristics (alerts) that can indicate the presence of hazards and other properties
- Tools to estimate missing experimental values.

The Toolbox estimates missing values by:

- Read-Across, that extrapolates for an untested chemical from tested chemicals within a category
- Trend Analysis, that estimates for an untested chemical from a "trend" (increasing, decreasing or constant) in effect within a category
- QSAR Models that estimate missing values from a statistical model for a category.

2.1.2.3 Key features of the Toolbox

The Toolbox allows a user to systematically group chemicals into categories according to the presence or potency of a particular effect for all members of the category. It allows a quick evaluation of chemicals for common mechanisms or modes of action as well as for common toxicological behaviour or consistent trends among results related to regulatory endpoints.

2.1.2.4 Typical actions supported by the Toolbox

- Describe the structure of a chemical
- Indicate if a chemical is included in national/regional regulatory inventories or existing chemical categories
- Search for available experimental results for the chemical of interest,
- Explore a chemical list for possible similar chemicals
- Group chemicals based on mechanism of action and/or structural similarity,
- Group chemicals based on a common metabolite
- Enable exclusion of different chemicals from the group
- Extract experimental data for similar chemicals
- Fill data gaps for chemicals using read-across, trend analysis or QSAR models, where applicable
- Design a data matrix of a chemical category for printing/exporting results
- Connect to IUCLID² software for direct data exchange
- Generate reports from prediction.

² www.iuclid.eu

The QSAR Toolbox application as well as user manuals and guidance can be downloaded from www.qsartoolbox.org. Additional information can be found also on the OECD project website: www.oecd.org/env/ehs/risk-assessment/theoecdqsartoolbox.htm.

2.1.3 Project Context

Based on the benefits that the QSAR Toolbox application can bring to ECHA activities, the Agency has decided to continue co-managing its further development in cooperation with OECD and its financing. As a consequence this call for tenders (aiming to fully cover Phase 3 development) is being launched. Due to the fact that the Toolbox is a very complex software both in terms of IT structure and functionality all tasks foreseen for Phase 3 development shall be performed by one single contractor. The duration of the Framework Contract is up to 6 years with an option of an additional 4 years of corrective maintenance. This duration should allow for the implementation of agreed scientific/technical tasks and smooth implementation until the last REACH registration deadline of 2018, and the additional maintenance period will ensure that the system can be maintained throughout its lifetime.

2.1.4 Project scope

The project will aim to further develop and maintain the QSAR toolbox application in order to address new challenges in the field of regulatory toxicology. The requested services will be categorised as follows:

- Development and implementation of the chemical and toxicological models
- Implementation of the expert knowledge in decision supporting systems and expert systems
- Knowledge extraction from scientific publications
- Software development
- Refactoring of existing code
- Software corrective maintenance
- Provision of the download repository for installation packages and additional documentation
- User support
- Training.

2.2 Description of Resources & Teams

The team(s) that will be deployed for the execution of the tasks under this project shall be composed of qualified and experienced staff, with relevant competences and expertise and, whose availability is guaranteed for the whole duration of the Framework Contract.

ECHA identified the following technical profiles that the contractor will be required to deploy under the Framework Contract:

- Project Manager
- Senior Scientist
- Scientist
- Business analyst
- Senior Analyst/Programmer
- Junior Analyst/Programmer

- Knowledge Analyst
- User Interface Specialist
- Tester

For each of them a set of minimum requirements are defined in Section 4 of Annex 5.1.1 – Technical Specifications. The contractor shall have availability of staff for each of the technical profiles mentioned above and matching the respective minimum requirements. ECHA estimates that during the implementation of the Framework Contract, up to 20 experts might be deployed in parallel on the provision of services related to tasks under one or more specific contracts.

In addition to the above mentioned profiles, it is expected that the tenderer will provide additional resources on the roles of helpdesk support or similar as part of the services to be provided for maintenance and support.

2.3 Description of Tasks

ECHA will procure under the Framework Contract the following types of services:

2.3.1 Inception Phase

The aim of the Inception Phase is that the Contractor takes over the Version 3 of the Toolbox including technical documentation, source code, and methodology to be ready for further development.

The following activities are foreseen during the Inception Phase:

- Project kick-off
- Hand-over from ECHA/OECD of the Version 3 of the Toolbox and related documentation including the source code to the Contractor
- Definition of tools and versions of applications to be used
- Setting up of the development and test environments
- Assessment of general requirements related to scope of the Phase 3 development in order to provide input to the detailed Work Plan for further service requests.

2.3.2 Usability improvements

The Toolbox is a very complex tool and its perceived complexity has been identified as a major impediment to its use. Therefore, one of the priorities in the development Phase 3 is to facilitate its use by making the Toolbox more intuitive. Issues that directly relate to the improvement of the usability of the Toolbox include:

- Streamlining of workflows
- Further improvement of the user interface and addition of new help functions
- Expansion of the repertoire of guidance materials with new examples, and new tutorials
- Enhancement of the documentation describing the various profilers and databases
- Expansion of the repertoire of databases
- Elaboration of a quality assurance protocol for inclusion of databases and applying it to existing and new databases

- Implementation of an ontology to merge databases for the same endpoint
- Improvement of the report documentation
- Possibility for saving the predictions
- Maintenance of the OECD QSAR Toolbox Discussion Forum³
- Capacity building.

2.3.3 Scientific developments

2.3.3.1 Implementation of the Adverse Outcome Pathways (AOPs) into the Toolbox

Activities related to the implementation of AOPs into the Toolbox are

- Software implementation of AOPs
- Review and development of IT functionalities for streamlining AOP implementation
- Further development of available profilers, expanding databases and adding new (AoP specific) profilers and databases.

2.3.3.2 General scientific improvements of the Toolbox

Activities related to the general scientific improvement of the Toolbox are:

- Development of reliability score for alerts and databases
- Improvement of predictions of covalent interactions
- Improvement of predictions of non-covalent interactions, especially interactions with receptor
- Improvement of the ADME predictive capabilities of the Toolbox and integration of PBPK functionalities
- Improvements of the QSAR models.

2.3.4 Development of Additional Functionalities

Issues that directly relate to additional functionalities include:

- Use of the QSAR Toolbox as a prioritisation tool
- Extending the Toolbox capabilities for handling organometallic substances
- Extending the Toolbox capabilities for handling UVCB substances
- Extending the Toolbox capabilities for handling ionisable compounds
- Extending the Toolbox capabilities for handling nanomaterials

2.3.5 General improvements related to enhancements of IT technology

Issues for that directly relate to information technology improvements include:

- Optimisation of the data model and change of the DB engine

³Forum managed by OECD where users can exchange experience and seek guidance with using the QSAR Toolbox (https://community.oecd.org/community/toolbox_forum)

- Refactoring of the calculations and I/O modules to increase the Toolbox performance
- Implementation of the scripting capacity into the Toolbox
- Enhancement of the server component

2.3.6 Corrective maintenance

Issues foreseen for corrective maintenance include:

- Bug fixing
- Assuring compatibility with the new versions of IUCLID
- Update of external modules
- Update of databases
- Provision of the download repository for installation packages and additional documentation
- Direct user's support.

The tenderer must be in a position to provide all services requested under the Framework Contract.

The details for the various types of services to be provided are described in the Technical Specifications in Annex 5.1.1.

2.4 Deliverables and Meetings

2.4.1 Document Deliverables

The format of deliverables can vary considerably and will be specified in the Specific Contracts or Order Forms. Formats for deliverables include (non-exhaustive list):

- Project Reports
- Functional specification documents
- Analysis and design models
- Project plans
- Quality plans
- Testing plans
- Training plans
- Meeting Minutes
- User manuals
- Training materials
- Examples of predictions
- Guidance and support materials
- Documentation of scientific methodology
- Documentation for prototypes
- Scientific publications

During the implementation of the Framework Contract all deliverables shall undergo thorough reviews and/or tests by the contractor before being released to the Agency for acceptance. Each deliverable will be assessed to verify that it conforms to the description of work. Only deliverables that are approved by the

contractor's Project Manager (or equivalent role) will be formally released and then become available for review and acceptance by the Agency.

Contract/Project reports

The contractor shall provide regular reports to the responsible Contract/Project Manager at the Agency in the layout specified in the Specific Contracts or Order Forms. The frequency of reporting (in general monthly) may differ depending on the size and complexity of the service or project and will be stipulated in the Specific Contracts or Order Forms.

The report will include:

- A summary of the activities clearly showing the assignment of tasks to resources over time, including starting and end dates of tasks, task completion percentage, logical relation between the activities, project critical path, milestones, deliverables, delivery dates and budget execution,
- The values of the quality indicators (contractor's service level will be measured by reference to the metrics defined if relevant in the requirements and quality standards as specified in the specific contracts),
- The risks identified, problems encountered and any other issue that may need assessment along with mitigating measures taken/ proposed.

Contract/Project reports, which have been agreed by the Agency's project team, will form part of the deliverables.

2.4.2 IT Deliverables

IT deliverables include (non-exhaustive list):

- Software releases
- Working prototypes
- Development of Proof of Concepts (PoCs)
- Updates of the databases
- Updates of the profilers
- Providing download repository

The IT deliverables shall be related to the scope of the Phase 3 development of the QSAR Toolbox as described in Chapter 2 of Annex 5.1.1 – Technical Specifications. Further definition of the deliverables may be stipulated in the Specific Contracts or Order Forms.

2.4.3 Description of Meetings

Meetings may take place either in the Agency premises in Helsinki or at the headquarters of the OECD in Paris, or by videoconferencing as follows:

- Up to two (2) combined Steering Group / Management Group meetings per year.

- Meetings under Specific Contracts may vary according to the type of project/tasks to be executed. These will be defined in the Specific Contracts and may relate to (non-exhaustive list):
 - Kick-off meeting including project plan review;
 - Project management (from Specific Contract's kick-off to sign off);
 - Training and knowledge build-up during the takeover period.
 - Business analysis and definition of the functionalities to be developed. High interaction with ECHA/OECD is expected during the business analysis activities;
 - System deployment in hosted production environment;
 - Intermediate progress meetings;
 - Final system delivery and acceptance meeting;

The meetings under Specific Contracts may also be through video conference.

The contractor shall provide the necessary videoconferencing equipment and facility at its premises to establish videoconferencing meetings with ECHA and OECD.

The contractor shall prepare the agenda for each meeting, which is subject to approval by ECHA and OECD at least five (5) working days before the meeting takes place. For kick off meetings, the period mentioned above is reduced to two (2) working days.

All meetings shall be conducted in English and the minutes shall be written by the contractor in English and provided in an editable electronic format within 3 working days after the meeting, unless otherwise stipulated in the Specific Contracts or Order Forms.

Meeting minutes, which have been agreed with the joint ECHA/OECD project team will form part of the deliverables. More information about project organisation is in Section 4 of Annex 5.1.1 - Technical Specifications.

2.5 General conditions for the provision of services

2.5.1 Language

The working language of the Agency is English. The English language shall be used throughout the projects duration for all communication (written and oral), reports and other documentation.

2.5.2 Place of performance

The normal place of performance of the services shall be the tenderer's premises, including the premises of partners and/or subcontractors, ECHA's and OECD premises or any other place designated by the tenderer and agreed by ECHA.

As an exception, the Agency may request performance of the services outside the normal place of performance, depending on the nature of the specific project/tasks. In any such case, reimbursement of expenses shall be defined under each Specific Contract or Order Form. The relevant provision of the Framework Contract shall apply (see Article I.3.3 of Annex 5.3.1 for details).

2.5.3 Work time

As a rule, work shall be carried out **within the normal working hours**, from 8 a.m. to 8 p.m., and on normal working days. Normal working days are Monday to Friday, except for ECHA holidays as defined in Annex 5.4 for 2013. Such holidays may differ from national ones, and will be notified every year in advance for the upcoming year.

For Time and Means Specific Contracts, please note that a full time equivalent day (FTE) is 7.5 hours. Deviations of more than 20% per day of service shall be agreed upfront with ECHA. The days and hours worked per resource will – at least on longer-term assignments – be verified by ECHA against the Agency’s electronic time-recording system, which tenderer’s staff shall use regularly and properly to facilitate the verification of service hours in conjunction with invoicing.

In exceptional cases and only on written demand by the Agency, the necessity to deliver services **outside of normal working days and/or hours** may occur.

For these exceptional situations, only the following surcharges may apply:

- On normal working days before 8 a.m. and after 8 p.m.: 50 % of the corresponding person-day price for normal working hours, pro rata.
- On weekends and ECHA holidays: 100 % of the corresponding man/day price for normal working hours, pro rata.
- Surcharges do not apply during travels.

The Agency may exceptionally also request the delivery of **“on-call”** (aka **“stand-by duty”**) intended to ensure the ability of a resource, i.e. to be reachable – typically via mobile phone to be provided by tenderer – during the relevant period of time and to be available to respond to the call within 75 minutes of being alerted. Such “on-call”- services are chargeable by 25% (during normal working days) or 50% (during weekends and ECHA holidays) of the rate applicable for the time-window during which these services are delivered, pro-rata. The service should be delivered by tenderer’s staff with the same profile(s) of the tenderer’s staff providing the service during normal working hours.

2.5.4 Confidentiality

Prior to the signature of the Framework Contract, the tenderer/contractor (including partners and subcontractors) is required to sign a Non-Disclosure Agreement (NDA) with the Agency (see Annex 5.1.1 - Technical Specifications).

Furthermore, upon signature of the Framework Contract, all contractor's staff members (including those of partners and subcontractors/freelancers etc.) working under the Framework Contract shall sign a confidentiality declaration (see Article I.14.1 of the draft FWC - Annex 5.3.1).

3 The Contract

3.1 The nature of the contract

The contractual relationship between the Agency and the successful tenderer will be governed by a special type of contract known as "Framework Contract". The Agency intends to establish a Framework Contract with a single service provider.

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 tenderer during their period of validity. Actual assignments will be placed after the Framework Contract is signed and in force, through specific contracts or order forms concluded in performance of the Framework Contract.

The contracting modes that may be used under the Framework Contract are fixed price, time and means, quoted time and means, as well as order forms. 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.

3.2 Starting date of the contract and duration of the tasks

The Contract shall enter into force on the date on which it is signed by the last contracting party.

The indicative intended date for the signature of the Framework Contract is Q4 2013.

The initial duration of the Framework Contract shall be 2 years with 2 possible renewals for 2 years each. Optionally, the Framework Contract may be renewed annually for up to additional 4 years in order to ensure that the investment in the system can be maintained throughout its lifetime. During these additional 4 years, use of the Framework Contract will be limited to corrective maintenance: no overhaul to the system will take place if the Framework Contract continues in years 7 to 10.

For the development the Framework Contract shall be renewed automatically up to two times, each time for a period of 24 (twenty four) months under the same conditions, unless written notification to the contrary is sent by one of the parties and received by the other three months before expiration.

For the corrective maintenance after development the Framework Contract shall be renewed up to three times upon written request of the Agency, each time for a period of 12 (twelve) months under the same conditions, The execution of the tasks may not start before the first specific contract or order form has been signed.

3.3 Terms of payment

Payments shall be made in accordance with Article I.4 and II. of the draft Framework Contract and of the respective articles in the draft specific contracts and order forms (see Section 5.3 'Contractual documentation'). The terms and schedule of payment will be laid down in the specific contracts or order forms. As a rule, payments for recurring services and Time & Means contracts will be carried out on a monthly or quarterly basis (as specified in each specific contract). 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 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.

3.4 Guarantees

In the context of the implementation of an order form or a Specific Contract a performance guarantee may be required by the Agency (Art. I.4.5 of the draft FWC).

Furthermore, the Agency refers to the requirements for the contractor regarding the insurance of its liability (e.g. professional risk indemnity insurance), as laid down in Article I.15 of the draft FWC. The contractor shall be insured, either through an already existing insurance, or an insurance taken specifically for this Framework Contract, in order to cover liability, which he could incur during the implementation of the Framework Contract.,

3.5 Liability

3.5.1 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 tendering specifications.

3.5.2 Subcontracting

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

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

During execution of the contract, the tenderer will need the Agency's express authorisation 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.

3.6 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 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.

As regards to the processing of personal data entrusted to the tenderer under the Framework Contract, without prejudice to the requirements on security and confidentiality as defined in the tender documentation, Article II.6 of the Framework Contract shall apply.

3.7 Implementation of the contract

The Contract shall be implemented through specific contracts and order forms. Specific contracts can be either on a Fixed Price or a Time and Means or a Quoted

Time and Means basis, in accordance with the provisions related to each order type, as specified hereafter.

3.7.1 Order types

Services shall be provided on the basis of three different kinds of orders:

- Fixed Price orders, which correspond to the order of a defined work;
- Time & Means orders, which correspond to the order of a number of days performed inside or outside the Agency's premises;
- Quoted Time & Means orders which correspond to the order of a number of days for defined subtasks;

3.7.1.1 Fixed Price orders

Fixed Price (FP) orders are 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 expected timeframe.

The following conditions relating to fixed price orders apply:

- The contractor must present proposals meeting the requirements as specified in the Service Requests and associated annexes (specifications, work packages, deliverables, deadlines etc.).
- The offer must include a project plan. It has to indicate the proposed activities, the team structure, profiles, roles, responsibilities and workload (person-days) of the different team members. Based on this, the financial offer must be based on the estimation of the number of days for each profile.
- The offer must include the list of staff members and their CVs proposed for the execution of the order. Contractor's staff must match the profile descriptions as laid down in the Technical Specifications of the Framework Contract.
- The offer must also include the financial bid, which must include the price and the reimbursable, where applicable. The price must be based on the prices indicated in the financial proposal for the Framework Contract. The prices must be all-inclusive. However, travel expenses shall be reimbursed, but only in case of work performed at a location other than the normal place of performance, as indicated in the request for services.
- The work is performed off-site, typically in the contractor's premises. The contractor shall provide all necessary infrastructures on his premises for the successful execution of the work.

- If required by the Agency, meetings and the presentation of the deliverables, and their acceptance process, may take place in the Agency's premises.
- The deliverables must be in line with the delivery schedule, and conform to the specifications as described in the specific contract. A warranty shall apply to the deliverables accepted by the Agency.
- The invoicing is based on the acceptance of the deliverables by the Agency, independently of the real workload.

3.7.1.2 Time & Means orders

Time & Means (TM) orders are executed inside as a rule, or outside, in exceptional cases, the Agency's premises (i.e. on-site or intra-muros or off-site or extra-muros). Work is normally performed in the Agency's premises. In some cases, upon the Agency's request, travels outside the normal location can be required.

The following conditions relating to Time & Means orders apply:

- In a Time & Means order the Agency specifies the workload (e.g. person-day) and its specific needs for requested profiles.
- The contractor must present proposals meeting the requirements as specified in the Service Requests and associated documents. Tenderer's proposed staff must match the requested profile description in the Framework Contract and the specific needs defined in the Service Request.
- The contractor must be able to propose per requested profile at least two qualified persons to choose from. Pre-defined CV forms must be used. All information indicated in the CV has to be correct and validated.
- The financial proposal must include the price and the reimbursable, where applicable. The price must be based on the fixed unit prices per person-day indicated in the financial proposal for the Framework Contract. The prices must be all-inclusive. However, travel expenses shall be reimbursed, but only in case of work performed at a location other than the normal place of performance, as indicated in the request for services.
- Prior to the signature of the specific contract, the Agency will verify that the team of personnel proposed by the contractor meets the requirements of the service request of ECHA and of the profiles in the Framework Contract. Personnel proposed must be available at the start of the assignment. Personnel proposed must be available for interviews.

- When personnel approved by ECHA is no longer available before the start of the implementation of a specific contract, the contractor is obliged to inform the Agency immediately. If the specific contract is not yet signed by both parties, the contractor shall propose as soon as possible, and at the latest within a maximum of 5 working days from the date when the need for replacement is known, new personnel with equivalent qualifications and experience with respect to those of the personnel originally approved by the Agency, and as required for the profile. If the specific contract is signed, but not yet being implemented, the Agency can either ask for a replacement with the performance of 10 working days free of charge or exercise its rights under the Framework Contract.
- During the implementation of a specific contract, in case of replacement at the initiative of the contractor, he must immediately inform the Agency and propose as soon as possible, and at the latest within a maximum of 5 working days from the date when the need for replacement is known, personnel with qualifications and experience equivalent to those of the replaced personnel. Prior agreement of the Agency with the replacement must also be obtained. In case of such a replacement, the handover period must be between 10 and 20 working days (depending on the complexity of the relevant work), free of charge for the Agency. If no handover is possible and additional training is needed for the replacement personnel approved by ECHA, at least 15 working days (free of charge for the Agency) must be performed by the replacement personnel. Any such replacement will be effected at no additional cost to the Agency.
- During the implementation of a specific contract, upon written request from the Agency the contractor must present as soon as possible and within a maximum of 5 working days the CV of personnel with equivalent qualifications and experience to immediately replace the personnel who has proved incapable of carrying out the tasks to the required standards and according to the requirements described in the specific contract. The replacement personnel selected by the Agency will be given sufficient training during an adequate handover period between 10 and 20 working days depending on the complexity of the relevant work (free of charge for ECHA) so that s/he may be immediately operational when the initial personnel is withdrawn. If no handover is possible and additional training is needed for the replacement personnel approved by ECHA, at least 15 working days free of charge for the Agency must be performed by the replacement personnel. Any such replacement will be effected at no additional cost to the Agency.
- In case of force majeure, due to an unforeseeable and exceptional situation or event beyond the control of the contractor, if contractor's personnel is no longer able to carry out the assignment, he is obliged to inform the Agency and immediately provide a competent replacement personnel and arrange sufficient training (during an adequate handover period when possible) to guarantee continuity of the service provided to

the Agency. Any such replacement will be effected at no additional cost to the Agency. This interim replacement may ultimately be replaced by personnel having the same qualifications and experience as the personnel replaced due to force majeure.

- In case of replacement, with the exception of the immediate reaction to a situation of force majeure, the contractor must propose a minimum of two candidates with the equivalent qualifications and experience with respect to those of the replaced personnel and as required for the relevant profile. If the contractor does not propose suitable replacement personnel, the Agency may exercise its rights under the Framework Contract.
- The holidays or other long periods of planned absence of the tenderer's personnel are expected to be agreed in advance with the Agency. On the Agency's demand, during holidays or other periods of planned absence, the contractor may be required to provide an adequate replacement. The replacement personnel will be given sufficient training and provided with all information necessary to guarantee continuity of the service provided to the Agency. All such training and handover work will be carried out at the contractor's expense.
- The invoicing will be based on the number of days performed.

Remarks:

- One full year corresponds normally to an effective workload of 220 days.
- The Service Request can combine different profiles, with the requested quantity for each profile and the individual workload.

3.7.1.3 Quoted Time & Means orders

Quoted Time & Means (QTM) Orders are 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 Quoted Time & Means order the Agency specifies the different tasks to be executed.

The following conditions relating to Quoted Time & Means orders apply:

- In a Quoted Time & Means order the Agency specifies in the service request the different services to be provided, namely the different sub-tasks to be executed in a project, the total number of person-days as well as the duration of the specific contract. The Agency may also specify the required profiles.
- Unless otherwise agreed in the specific contract, the work will be normally performed off site, typically on the tenderer's premises. If required meetings and the physical delivery of a sub-task – including acceptance process –, have to be done at the Agency's

premises. In principle, these activities will not exceed an average of one day per week.

- The contractor must present a proposal meeting the requirements as specified in the service request and associated documents (e.g. technical annex with description of sub-tasks). The offer must include a technical proposal based on the requirements, the profiles and workload (person days). The financial proposal has to be based on the profiles and their workload and be in line with the unit prices of the Framework Contract.
- The offer must include the list of personnel and their CVs proposed for the execution of the order. Contractor's personnel must match the requested profile description as laid down in the Framework Contract.
- The work is divided into various sub-tasks performed during the execution of the specific contract. The Agency will provide the contractor with a detailed description of each sub-task. The contractor will send the Agency a proposal for the execution of each sub-task (including the workload and time schedule) on the basis of a number of person-days with the requested profile(s). When agreement with the Agency has been reached, a Quoted Time and Means form must be signed by both parties. Only agreed costs for the specified sub-tasks are chargeable, after acceptance by the Agency.
- The contractual warranty applies to the sub-tasks accepted by the Agency.
- On the Agency's demand, the contractor must replace personnel who prove incapable of carrying out the specified tasks to the required standards. The replacement personnel will be given sufficient training during an adequate handover period, so that he/she may be immediately operational when the original personnel is withdrawn. Any such replacement and training, if required, will be carried out at no additional cost to the Agency.
- The contractor shall give a month notice to the Agency of any personnel changes in the team. The agreement of ECHA must be obtained prior to any change in the technical team. The contractor shall inform about the departure of the consultant and explain the impact on the project and the preventive measures proposed, which include the submission of CVs of equivalent replacements. Accordingly, the months' notice shall start counting from the moment ECHA has agreed to the replacement of the consultant based on the elements above.
- In case of 'force majeure', due to an unforeseeable and exceptional situation or event beyond the control of the contractor, if the original personnel is no longer able to carry out the work, the contractor is obliged to inform the Agency, immediately provide a competent replacement personnel and

arrange sufficient training (during an adequate handover period where possible) to guarantee continuity of the service provided to the Agency. Any such replacement will be effected at no additional cost to the Agency.

- In case of replacement, the contractor must propose a minimum of two replacement personnel with the equivalent qualifications and experience and as required for the profile. If the contractor does not propose suitable replacement personnel, the Agency may immediately terminate the specific contract.
- On the Agency's demand, during holidays or other periods of planned absence by the personnel employed, the contractor will be required to provide an adequate replacement. The replacement personnel will be given sufficient training and provided with all information necessary to guarantee continuity of the service provided to the Agency. All such training and handover work will be carried out at the contractor's expense.
- When personnel is no more available before the start of a new specific contract, the contractor is obliged to inform the Agency immediately and provide adequate replacement as indicated above.
- The invoicing requires the acceptance of the deliverables by the Agency, and is based on real workload of the profiles used in the specific contract (i.e. QTM assignments). The request for payment of the contractor shall be admissible if accompanied by a report specifying the tasks and deliverables accepted by the Agency.

3.7.2 Acceptance of work

Official acceptance of the work carried out by the contractor will take place at milestones during and at the end of each Order Form or Specific Contract execution, after acceptance of all deliverables forming part of the assignment according to the default procedures described in Annex 5.1.1 – Technical Specifications. Invoices may be issued only for executed tasks that have been completed and duly accepted by the Agency.

3.8 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.11 and I.13 of the Framework Contract;
- (ii) The results of deliverables from services provided will continue to meet the Technical Specifications;

(iii) The software deliverables will be error free for a period of six (6) months after final acceptance and after each installation of an upgrade. The warranty period is extended by the sum of the recovery times for all critical and major issues, where ECHA cannot use the software deliverable during the warranty period. Upon expiration of the warranty period, the Tenderer shall provide software maintenance for the period of execution of tasks under the Framework Contract. Such service shall be subject to one or several Specific Contract(s) under this Framework Contract;

(iv) Tenderer's personnel will continue to meet the agreed qualification with respect to training, expertise and experience for the duration of the Framework Contract;

(v) 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.

3.9 Intellectual Property Rights

Any intellectual property rights, including copyright and industrial property rights in deliverables created or used within the realm of this Framework Contract, shall become a property of ECHA according to Articles I.8 and II.10 of the draft Framework Contract attached (see Section 5.3 'Contractual documentation').

At the end of the Framework Contract, the tenderer shall hand over to the Agency all assets in line with the respective transition procedure as laid down in Annex 5.1.1 – Technical Specifications, and at no additional cost for the Agency.

3.10 Amendments to the Framework Contract

In exceptional instances 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 are an integral part of the original Framework Contract.

4 The procurement procedure

4.1 Preparation of the tender

4.1.1 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, preferably in English, which is the working language of the Agency.

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;
- one specimen signature of an authorised agent (preferably in blue ink) on the legal entity form⁴, and a statement from the same agent confirming the validity of the tender;
- the name and contact details of a contact person 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 specifications.

4.1.2 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 4.1.2.1).

Section two: Technical proposal – including documentation and proposal regarding quality award criteria (see Section 4.1.2.2).

Section three: Financial proposal - including documentation and proposal regarding financial award criterion (see Section 4.1.2.3).

⁴ See section 4.1.2.1

4.1.2.1 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 himself the tenderer must fill in a Legal Entity Form and a Financial Identification Form:

The **Legal Entity Form**⁵ is to be signed by a representative of the tenderer authorised to sign contracts with third parties.

The **Financial identification**⁶ form shall be duly filled in and signed by an authorised representative of the tenderer and his or her 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.

⁵ This form is available at:

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

⁶ The form is available at:

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

In case of a joint offer, only the co-ordinator 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 recognised 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**⁷, depending on the set up that has been chosen by the tenderers.

If the tenderer envisages subcontracting, the tender must include:

- a **document**⁸ clearly stating the roles, activities and responsibilities of the proposed subcontractor(s), and the reasons why subcontracting is envisaged;
- a **letter of intent**⁹ by each proposed subcontractor(s) stating its intention to collaborate with the tender if the tenderer wins the contract and their willingness 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**¹⁰, duly signed and dated in which they:

⁷ Section 5.2.1

⁸ To be provided in free format

⁹ See Section 5.2.2

¹⁰ See Section 5.2.3

- 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 above 30% of the total contract 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 tenders¹¹.

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 Section 4.4

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) will 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 selection 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 Form¹², 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. In the case of joint offer or subcontracting each partner in a joint offer and all subcontractors shall provide the evidence for the economic and financial capacity mentioned above. The assessment of whether the minimum average annual turnover criterion is met will be based on a consolidated assessment (tenderer plus partners/subcontractors).

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 and professional capacities.

¹² See Annex 5.2.4

Evidence of the technical and professional capacity of the providers involved in the tender must be furnished on the basis of the following documents. The Agency reserves the right to request any other documents enabling it to verify the tenderers technical and professional capacity.

a) Evidence for selection criterion 2.1 (Staff Capacity)

Tenderers shall demonstrate ability to provide consistent, skilled scientific, business and technical resources and to ensure that individual resources will be committed throughout the entire duration of the Contract.

(i) The tenderer shall provide a statement on the average number of staff members corresponding to the profiles listed in Section 4.4 of Annex 5.1.1.- Technical Specifications). The statement must be provided by using the attached form (see Annex 5.2.5)

(ii) The tenderer shall provide the CV's (8) of the members of his core team.

The CV's of the key personnel has to be submitted for this tender. All CVs shall be submitted using the Europass CV format:

<http://europass.cedefop.europa.eu/en/documents/curriculum-vitae/templates-instructions>

b) Evidence for selection criterion 2.2 (Project Capacity):

A detailed description of all the contract references must be provided using the attached form (see Annex 5.2.6). The information provided for each of these references shall not exceed **4 pages** (A4) per contract reference.

4.1.2.2 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 for the evaluation of award criteria. Please note also, that proposals deviating from the technical specifications may be rejected for non-conformity.

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. The assessment basis for the AW 1 to 3 (see Section 4.4.3) will be the technical offer of the tenderer.

4.1.2.3 Section Three: Financial proposal

Financial award criteria documentation

Tenderers must use the Pricing sheet in Annex 5.1.2 to submit their financial offer.

It is mandatory that the pricing is fully transparent and contains on-site and off-site daily rates for all profiles foreseen in this FWC.

The tenderers' attention is drawn to the following points:

- 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 Communities are exempt from such charges in the EU under Articles 3 and 4 of the Protocol on the Privileges and Immunities of the European Communities 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 Community is exempt from VAT;
- Prices shall not be conditional and be directly applicable by following the technical specifications.
- Prices shall be fixed and not subject to revision during the first 2 years of duration of the Contract. Price revision shall be done in accordance with Article I.3.2 of the Contract (see Annex 5.3.1).
- Please note that it is not possible to modify the financial proposal after the submission of the tender.

All tenders must contain all the information and all the supporting documents required by these specifications. 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.

4.1.2.4 Form of the tender

The tender must be submitted under double sealed cover.

The outer envelope should bear the address as mentioned below.

The inner envelope should be addressed to the Financial Unit R1 and marked "Invitation to tender No ECHA/2013/109" and "Not to be opened by the internal mail service". If self-adhesive envelopes are used, they must be sealed with adhesive tape and the sender must sign across the tape. The inner envelope must also contain three sealed envelopes, one containing the administrative proposal, the second the technical proposal and the third the financial bid. Each of these envelopes must clearly indicate the content. The administrative proposal, the technical proposal and the financial bid must be submitted, in duplicate (one set of originals and one set of copies) and a third set in electronic format (on CD ROM).

4.1.3 Submission of the tender

4.1.3.1 General terms and conditions for submission

Submission of a tender implies that the tenderer accepts all the terms and conditions set out in these specifications (including the annexes) and waives all other terms of business.

Submission of a tender binds the tenderer to whom the contract is awarded during performance of the contract.

The tenderer's bid, in conjunction with the technical specifications, shall be an integral part of the contract and will constitute annexes to the contract.

Once the Agency has accepted the tender, it shall become the property of the Agency and the Agency shall treat it confidentially.

The Agency shall not reimburse expenses incurred in preparing and submitting tenders.

The Protocol on the Privileges and Immunities or, where appropriate, the Vienna Convention of 24 April 1963 on Consular Relations shall apply to this invitation to tender.

Variants are not allowed.

The offer must remain valid for a period of 6 months following the final date for submitting tenders (see below). During this period, tenderers must maintain all the conditions of their bids.

The tendering procedure shall not involve the Agency in any obligation to award the contract.

Up to the point of signature, the contracting authority may either abandon the procurement or cancel the award procedure. This decision must be substantiated and the tenderers notified.

No compensation may be claimed by tenderers whose tender has not been accepted, including when the Agency decides not to award the contract.

4.1.3.2 Requirements for submission

Tenders may be:

a) either sent by registered mail, posted no later than **02/09/2013**, (date as postmark); to the following address:

European Chemicals Agency (ECHA)
Invitation to tender No: ECHA/2013/109
Finance Unit R1
PO Box 400
Annankatu 18
00121 Helsinki
Finland

b) or sent by courier services, no later than **02/09/2013** (date of deposit slip), to the following address:

European Chemicals Agency (ECHA)
Invitation to tender No: ECHA/2013/109
Finance Unit R1
Annankatu 18
00120 Helsinki
Finland

c) or delivered by hand, in person or by an authorised representative no later than **17:00 hours Helsinki time on 02/09/2013**, (date of acknowledgement of receipt by the Agency) to the address mentioned above.

Tenderers shall observe precisely the above indications in order that tenders reach their specified destination in due time.

Evidence of timely submission by post or courier service will be constituted by the date of the postmark or the date of the deposit slip. In the case of hand-delivery, the signed and dated receipt will serve as evidence.

Late 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.

4.2 Contact between the tenderer and the Agency

In principle, no contact is permitted between the Agency and the tenderers during the contract award procedure:

However, in exceptional circumstances contact may be made on the tenderers' initiative before the final date for the receipt of bids, in order (and only for this reason) to clarify the nature of the contract.

Such requests for further information may be made only in writing with the subject indication, «ECHA/2013/109» to the following e-mail address:

procurement@echa.europa.eu

The Agency is not bound to reply to requests for additional information made less than five working days before the deadline for submission of tenders.

Insofar as it has been requested in good time, the questions raised and the additional information provided by the Agency will be published on the website at:

<http://echa.europa.eu/web/guest/about-us/procurement>

All tenderers are advised to take note of the fact that no additional information will be sent (neither by post nor by e-mail) regarding new information that has become available. Therefore, all tenderers are kindly requested to visit the above-mentioned website frequently prior to submitting bids.

Similarly, contact may in exceptional circumstances be made on the Agency's initiative:

- before the final date for the receipt of bids, in order to inform interested parties of an error, a lack of precision, an omission or any other material shortcoming in the drawing up of the documents of the invitation to tender;
- or, after the opening of bids, where a bid requires clarification or in order to correct material errors made in drawing up a bid.

Please note that in any event such contact may not result in a modification of the terms of the bid. In case the Agency deems it appropriate to provide additional information it will be published on the website mentioned above.

4.3 Opening of the tenders

Tenders will be opened at **10:00 hours Helsinki time on 10/09/2013** at the following location:

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

A 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.

4.4 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.

4.4.1 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 form¹³.

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).

4.4.2 Stage 2 - application of selection criteria

These criteria will be assessed on the basis of the documents indicated¹⁴.

¹³ See Section 4.1.2.1

¹⁴ See section 4.1.2.1

SELECTION CRITERIA

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.

1.2 Average annual turnover of the tenderer over the last three financial years must be at least **EUR 1 000 000**

2. TECHNICAL AND PROFESSIONAL CAPACITY

2.1 Staff Capacity: Capability of the tenderer to provide the necessary human resources for the performance of the tasks under the Contract. The tenderer must:

(i) on an average over the last three years, have at least the following number of staff corresponding to the profiles listed in Section 4 of Annex 5.1.1 - Technical Specification:

1 Project Manager; 5 Senior Scientists; 5 Scientists; 1 Business analyst; 2 Senior Analyst/Programmers; 2 Junior Analyst/Programmers; 3 Knowledge Analysts; 1 User Interface Specialist and 1 Tester;;

(ii) have a core team of experts meeting the profile requirements defined in Section 4 of Annex 5.1.1 - Technical Specification, that will be involved in the implementation of the Framework contract consisting of :

1 Project Manager; 2 Senior Scientists; 1 Business analyst; 2 Senior Analyst/Programmers and 2 Knowledge Analysts.

One staff member can be reported only for a single profile.

2.2 Project Capacity:

The tenderer needs to demonstrate in its portfolio a minimum of four (4) contracts for which relevant services were delivered during the period 2008-2013, with a minimum total value per contract of 200.000 EUR.

Contracts presented in tenderer's portfolio **must cover all of the fields of expertise** mentioned below and **each contract must cover at least two of these fields.**

Fields of expertise:

1. Chemical data basing and application of chemical intelligence. Application of chemical data basing means: Database client application which has structural and sub structural database search capacity and user interface allowing user to enter the query criteria using chemical sketcher. In addition such client application should be able to display chemical structures/substructures in the query results.
2. Development of QSAR prediction tools where computational techniques have been applied to predict toxicological profile of the substances in at least one

of the fields: environmental fate, environmental toxicology, human health toxicology, bio-kinetics/toxico-kinetics.

3. Development of the IT tools for predicting biotransformation pathways in environment or for human health.
4. Development of Delphi applications, where Delphi was used as main programming language.
5. Knowledge extraction from scientific publications, where extracted knowledge has been further implemented within the software algorithms.
6. Application of decision trees and building expert systems to support decision making process in the field of regulatory (eco)toxicology.
7. Preparation of guidance and training materials for end-users in the field of QSAR predictions.

4.4.3 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:

- Qualitative award criteria: Tenderers will be assessed on the basis of the submitted offer,
- Financial award criteria: Tenderers will be assessed in relation to price.

4.4.3.1 Qualitative award criteria

No	Qualitative award criteria	Weighting (maximum points)
AW1	Understanding of the services to be performed and appropriateness of the tenderer's overall scientific and technological approach and proposed methodology for conducting the activities described in Section 2 of Annex 5.1.1- Technical Specification.	30
AW2	Quality of the proposal covering specific topics described in section 5 of Annex 5.1.1- Technical Specification:	50
	Quality of the proposal for further improvement of the user interface and addition of new help functionalities. According to description in Section 5.1 of Annex 5.1.1.	12/50
	Quality of the proposal for the development of a reliability score for alerts and databases. According to description in Section 5.2 of Annex 5.1.1.	12/50
	Quality of the proposal for improvement of the ADME predictive capabilities of the QSAR Toolbox and integration of PBPK functionalities. According to description in Section 5.3 of Annex 5.1.1.	10/50
	Quality of the proposal for extending the Toolbox capabilities for handling substances of unknown or variable composition (UVCB). According to description in Section 5.4 of Annex 5.1.1.	8/50
	Quality of the proposal for general enhancements of IT technology (as described in Section 5.5 of Annex 5.1.1).	8/50
AW3	The appropriateness of the organisational set-up of the team proposed for tasks described in Section 5 of Annex 5.1.1- Technical Specification	20
	Total	100

ECHA will evaluate the offers based on the above qualitative award criteria and the suitability of the proposed solutions/approaches to the topics described in section 5 of Annex 5.1.1.

The technical offer should **NOT** exceed 50 pages.

Tenders scoring less than 70% in the overall points resulting from the sum of criteria AW1 to AW3 or less than 50% in the points awarded for each single criterion¹⁵ will be excluded from the rest of the assessment procedure.

4.4.3.2 Financial award criteria and Final evaluation

Tenderers shall complete the 'Pricing Sheet' in Annex 5.1.2 in their entirety for the services concerned.

The calculation of the final price is done as follows:

Step 1: the price for each profile is weighted by place of performance.

The onsite price (at ECHA/OECD premises) has a specific weight ([weight for onsite performance]) and its value is defined as listed in column b of the Table 4.1.

The offsite price (at Contractor's premises) has a specific weight ([weight for offsite performance]) and its value is defined as listed in column d of the Table 4.1.

The sum of [weight for onsite performance] and [weight for offsite performance] is 100%

The [price weighted per place of performance] is defined as:
 ([weight for onsite performance] x [price for onsite performance]) + ([weight for offsite performance] x [price for offsite performance]).

Profiles (column a)	Weight for onsite performance (column b)	Price onsite in €/man-day (column c)	Weight for offsite performance (column d)	Price offsite in €/man-day (column e)	Price weighted per place of performance (in €) Result of (b x c) + (d x e) (column f)
Project Manager	15%		85%		0.0
Senior Scientist	15%		85%		0.0
Scientist	10%		90%		0.0
Business analyst	15%		85%		0.0
Senior Analyst/Programmer	10%		90%		0.0
Junior Analyst/Programmer	10%		90%		0.0

¹⁵ For AW 2 the 50% does not apply to the sub-criteria separately, but only to the criterion as a whole.

Knowledge Analyst	5%		95%		0.0
User Interface Specialist	15%		85%		0.0
Tester	5%		95%		0.0

Table 4.1. Calculation of price weighted per place of performance.

Step 2: the overall weighted price is calculated as follow:

Each profile has a specific weight ([weight of profile]) as defined in column i of the Table 4.2.

The sum of the [weight of profile] of all profiles is 100%.

For each profile, the [price weighted per place of performance and profile] is defined as: [price weighted per place of performance] x [weight of profile].

Profiles (column g)	Price weighted per place of performance (in €) (column h) (same as column f)	Weight of profile (column i)	Price weighted per place of performance and profile (in €) Result of (h x i) (column j)
Project Manager	0.0	8.0%	0.0
Senior Scientist	0.0	15.0%	0.0
Scientist	0.0	15.0%	0.0
Business analyst	0.0	10.0%	0.0
Senior Analyst/Programmer	0.0	12.0%	0.0
Junior Analyst/Programmer	0.0	12.0%	0.0
Knowledge Analyst	0.0	15.0%	0.0
User Interface Specialist	0.0	7.0%	0.0
Tester	0.0	6.0%	0.0

Table 4.2. Calculation of price weighted per place of performance and profile.

The **overall weighted price** is calculated by adding the [price weighted per place of performance and profile] of all profiles listed in table 4.2. The overall weighted price will be used as **price of the offer (financial offer)**.

The contract will be awarded to the tenderer which submits the tender offering the best value for money by weighting quality criteria against price on 60 / 40 basis.

Tenderers will be **ranked** based on the **total value of points** allocated to each of them, according to the following formula:

$$\text{score for tender X} = \frac{\text{cheapest price}}{\text{Price of tender X}} \times 40 + \frac{\text{Total quality score (out of 100) for all award criteria of tender X}}{100} \times 60$$

The tenderer with the highest score resulting from this calculation will be awarded with the contract.

4.5 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 of the successful tenderer.

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 procurement procedure may be concluded by a contract signed by the parties. In this case, the General Terms and Conditions applicable to service contracts referred to below shall apply.

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

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

During the standstill period, the Agency will request the tenderer 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 tenderer 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.
- 6 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.

5 Annexes

5.1 Documentation for the award criteria

The technical documentation consists of the following documents:

- Annex 5.1.1 – Technical Specifications (including QSAR Toolbox Technical Documentation and Non-Disclosure Agreement)
- Annex 5.1.2 – Financial offer template

5.2 Administrative documentation

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

- Annex 5.2.1 – Power of Attorney document
- Annex 5.2.2 – Letter of intent
- Annex 5.2.3 – Exclusion criteria form
- Annex 5.2.4 – Financial and Economic Capacity Overview Form
- Annex 5.2.5 – Staff capacity form
- Annex 5.2.6 – Contract Reference Form

5.3 Contractual documentation

The contractual documentation consists of the following documents:

- Annex 5.3.1 – Draft Framework Service Contract
- Annex 5.3.2 – Draft Specific Contract Model – Fixed Price
- Annex 5.3.3 – Draft Specific Contract Model – Quoted Times & Means
- Annex 5.3.4 – Draft Specific Contract Model – Time & Means
- Annex 5.3.5 – Draft Order Form Model
- Annex 5.3.6 – Model Performance Guarantee
- Annex 5.3.7 – Daily subsistence allowances and accommodation flat-rates
- Annex 5.3.8 – Statements from contractor regarding intellectual property rights

5.4 ECHA Public Holidays 2013

1	Tuesday	January 1	New Year's Day
2	Friday	March 29	Good Friday
3	Monday	April 1	Easter Monday
4	Wednesday	May 1	Labour Day
5	Thursday	May 9	Ascension Day
6	Monday	May 20	Whit Monday
7	Friday	June 21	Midsummer's Eve
8.	Friday	November 1	All Saints Day
9.	Friday	December 6	Finnish National Day
10.	Tuesday	December 24	Christmas Eve
11.	Wednesday	December 25	Christmas Day
12.	Thursday	December 26	Boxing Day
13.	Friday	December 27	End-of-Year closure
14.	Monday	December 30	End-of-Year closure
15.	Tuesday	December 31	New Year's Eve

Total: 15 days

5.5 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 section 4.1.2.1)	1		■		
Letter(s) of intent of subcontractor(s) (see section 4.1.2.1)	1				■
Legal Entity Form (see section 4.1.2.1)	1	■	■	■	■
Supporting documents for the Legal Entity Form	1	■	■	■	
Financial Identification Form (see section 4.1.2.1)	1	■		■	
Exclusion Criteria Form (see section 4.1.2.1)	2	■	■	■	(30%) ■
Evidence of Economic and financial capacity (see sections 4.1.2.1 and 4.4)	3	■	■	■	■
Financial and Economic Capacity Overview Form	3	■	■	■	
Evidence of Technical and professional capacity (see sections 4.1.2.2 and 4.4)	3	■	■	■	■
CVs to be filled in based on the template at: http://europass.cedefop.europa.eu/en/documents/curriculum-vitae/templates-instructions (see section 4.1.2.1)	3	■		■	
Staff capacity form (see section 4.1.2.1)	3	■		■	
Contract Reference Form (see section 4.1.2.1)	3	■		■	

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	4	■
Financial offer	5	■